

SEATTLE GENETICS INC /WA

Form 10-K

March 09, 2007

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, 2006

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.**

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

(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**  
**Common Stock, par value \$0.001**

**Name of each exchange on which registered**  
**The Nasdaq Stock Market LLC**

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

**None**

---

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

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

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

Indicate by check mark 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.

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

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 \$152.0 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 National Market reported for such date. Shares of Common Stock held by each officer and director and by each person who owns 5% or more of the outstanding Common Stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

There were 56,929,336 shares of the registrant's Common Stock issued and outstanding as of March 2, 2007.

### **DOCUMENTS INCORPORATED BY REFERENCE**

Part III incorporates information by reference from the definitive proxy statement for the Annual Meeting of Stockholders to be held on May 25, 2007.

---

**Table of Contents**

**SEATTLE GENETICS, INC.**

**FORM 10-K**

**FOR THE YEAR ENDED DECEMBER 31, 2006**

**TABLE OF CONTENTS**

	<b>Page</b>
<b><u>PART I</u></b>	
Item 1. <u>Business</u>	3
Item 1A. <u>Risk Factors</u>	17
Item 1B. <u>Unresolved Staff Comments</u>	28
Item 2. <u>Properties</u>	28
Item 3. <u>Legal Proceedings</u>	28
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	28
<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>	29
Item 6. <u>Selected Financial Data</u>	31
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	32
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	42
Item 8. <u>Financial Statements and Supplementary Data</u>	43
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	72
Item 9A. <u>Controls and Procedures</u>	72
Item 9B. <u>Other Information</u>	72
<b><u>PART III</u></b>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	73
Item 11. <u>Executive Compensation</u>	73
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	73
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	73
Item 14. <u>Principal Accounting Fees and Services</u>	73
<b><u>PART IV</u></b>	
Item 15. <u>Exhibits, Financial Statement Schedules</u>	74
<u>Signatures</u>	78

## **Table of Contents**

### **PART I**

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

##### **Overview**

Seattle Genetics, Inc. is a biotechnology company developing monoclonal antibody-based therapies for the treatment of cancer and autoimmune diseases. Our strategy is to advance our portfolio of product candidates in diseases with unmet medical need and significant market potential. We have an exclusive, worldwide license agreement with Genentech to develop and commercialize our lead product candidate SGN-40. In addition, we currently have three other proprietary product candidates in ongoing clinical trials, SGN-33, SGN-30 and SGN-35, as well as several lead preclinical product candidates, including SGN-70 and SGN-75. Our pipeline of product candidates is based upon two technologies: engineered monoclonal antibodies and monoclonal antibody-drug conjugates (ADCs). These technologies enable us 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. In addition to our internal pipeline, we have ADC license agreements with a number of leading biotechnology and pharmaceutical companies, including Genentech, Bayer, CuraGen, Progenics, MedImmune and PDL BioPharma, as well as an ADC co-development agreement with Agensys.

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

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 cases to an abnormal autoimmune response. B-cells 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, 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 sales of more than \$6 billion in 2006. 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 550,000 deaths annually. The American Cancer Society estimates that 1.4 million new cases of cancer will be diagnosed in the United States during 2007. The World Health Organization estimates that more than 11 million people worldwide are diagnosed with cancer each year, a rate that is expected to increase to an estimated 16 million people annually by the year 2020. Cancer causes seven million deaths worldwide each year and, according to the National Cancer Institute, approximately 35 percent of people with cancer will die within five years from being diagnosed.

##### **Our Monoclonal Antibody Technologies**

Our pipeline of monoclonal antibody-based product candidates utilizes two approaches to maximize antitumor activity and reduce toxicity. The first technology uses genetic engineering to produce monoclonal antibodies that have intrinsic antitumor activity with lowered risk of adverse events or autoimmune response. The second technology involves attaching a highly potent cytotoxic drug to an antibody, which delivers and releases the drug inside the tumor cell. The resulting hybrid molecule is called an antibody-drug candidate (ADC). We also evaluate the use of our monoclonal antibodies and ADCs in combination with conventional chemotherapy, which can result in increased antitumor activity.

## **Table of Contents**

### *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 antibody and extending the duration of their use in therapy. Our product development pipeline is primarily focused on developing humanized monoclonal antibodies. We have substantial expertise in humanizing antibodies and have non-exclusive licenses to PDL BioPharma's antibody humanization patents. Through our recent 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 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<sup>®</sup>), HER2 (Herceptin<sup>®</sup>), CD52 (Campath<sup>®</sup>), VEGF (Avastin<sup>®</sup>) and EGFR (Erbix<sup>®</sup>) can kill tumor cells in this manner. SGN-40, SGN-33, SGN-30 and SGN-70 also fall into this category of engineered antibodies that have intrinsic antitumor activity without conjugation to a drug.

### *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 upon binding to their cell-surface receptors. The environment inside the cell causes the cell-killing drug to be released from the monoclonal antibody, allowing it to have the desired effect. A key component of our ADC is the linker that attaches the drug to the monoclonal antibody until internalized within the target cell where the drug is released, thereby minimizing toxicity to normal tissues. We use highly potent cell-killing drugs, such as auristatin derivatives, that are synthetically produced and readily scaleable, in contrast to natural product drugs that are often more difficult to produce and link to antibodies. SGN-35 and SGN-75 utilize our proprietary, auristatin-based ADC technology. 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 program.

## **Our Strategy**

Our goal 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 Product Pipeline.* Our primary focus is advancing our pipeline of product candidates: SGN-40, SGN-33, SGN-30 and SGN-35, which are in clinical trials, and SGN-70 and SGN-75, which are in preclinical development. To that end, we have built strong internal expertise in our development, regulatory and clinical groups. We also enter into key relationships with scientific advisors, research organizations and contract manufacturers to supplement our internal efforts. For our clinical trials, we have established relationships with experts in oncology and hematology at leading cancer centers in the United States and Europe.

*Establish Strategic Collaborations to Advance our Product Pipeline.* Our strategy is to enter into collaborations at appropriate stages in our research and development process to accelerate the commercialization of our product candidates. Collaborations can supplement our own internal expertise in key areas such as clinical trials and manufacturing, as well as provide us with access to our collaborators' marketing, sales and distribution capabilities. When establishing strategic collaborations, we endeavor to retain significant product rights. For example, in January 2007, we entered into an exclusive worldwide license agreement with Genentech

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

for the development and commercialization of SGN-40. This collaboration provides us with both significant financial resources and access to Genentech's development and commercialization expertise. Under the terms of this agreement, we received an upfront payment of \$60 million and are entitled to receive potential milestone payments exceeding \$800 million and escalating double-digit royalties starting in the mid-teens on annual net



**Table of Contents**

sales of SGN-40. Genentech will fund future research, development, manufacturing and commercialization costs for SGN-40. We also have an option to co-promote SGN-40 in the United States.

*Develop Industry-Leading Monoclonal Antibody Technologies.* We have developed industry-leading technologies designed to enhance the potency and efficacy of monoclonal antibodies. Our ADC technology enables us to exploit the therapeutic potential of monoclonal antibodies that have target specificity by enhancing their cell-killing capabilities. We are currently developing several product candidates that employ our ADC technology, including SGN-35, which is in phase I clinical development, and SGN-75, which is a future Investigational New Drug (IND) candidate. We also have substantial expertise in antibody engineering to enhance antibody binding and activity, reduce immunogenicity and improve drug linkage sites.

*Selectively License our Technologies.* We have licensed our ADC technology to generate near-term revenue and earn potential future milestones and royalties that can partially offset expenditures on our internal research and development activities. Presently, we have ADC license agreements with Genentech, Bayer, CuraGen, Progenics, MedImmune and PDL BioPharma. Our technology licensing deals have generated more than \$55 million for the company through a combination of upfront and research support fees, milestones and equity purchases. These deals also expand our knowledge base and supplement our internal ADC research and development activities by broadening the use of our ADC technology across multiple targets and antibodies under development by our collaborators. In January 2007, we entered into an ADC collaboration with Agensys, which provides us with the opportunity to supplement our preclinical pipeline through co-development of up to two ADCs targeting solid tumors.

*Identify and Develop Novel Monoclonal Antibody-Based Therapeutics.* We have focused on the research and development of monoclonal antibody-based therapeutics since our inception. We utilize both internal research efforts and collaborations to identify targets that can be used to generate new monoclonal antibodies and ADCs, including our ongoing collaborations with Celera Genomics and Agensys. We believe these programs will enable us to continue to expand our pipeline of therapeutic candidates. In addition, we believe we have created valuable intellectual property by successfully identifying and filing patent applications for novel monoclonal antibodies and ADCs with potential therapeutic uses.

*Acquire or In-license Attractive Product Candidates and Technologies.* In addition to our internal research and development initiatives, we have ongoing efforts to identify 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, Genentech, PDL BioPharma, ICOS Corporation, University of Miami, Arizona State University, Mabtech AB and CLB Research and Development, among others. We plan to continue supplementing our internal research programs through strategic in-licensing transactions.

**Table of Contents****Development Programs**

The following table summarizes the status of our product pipeline:

<b>Product Candidate</b>	<b>Technology</b>	<b>Disease/ Indication</b>	<b>Development Stage</b>	<b>Collaborator</b>
SGN-40	Engineered monoclonal antibody	Non-Hodgkin's lymphoma	Phase II	Genentech
		Multiple myeloma	Phase I	
		Chronic lymphocytic leukemia (CLL)	Phase I	
SGN-33	Engineered monoclonal antibody	Acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS)	Phase I	
SGN-30	Engineered monoclonal antibody	Systemic anaplastic large cell lymphoma (ALCL)	Phase II	National Cancer Institute
		Hodgkin's disease	Phase II	
SGN-35	ADC	CD30-positive hematologic malignancies	Phase I	
SGN-70	Engineered monoclonal antibody	CD70-positive hematologic malignancies and solid tumors; autoimmune diseases	IND planned in 2008	
SGN-75	ADC	CD70-positive hematologic malignancies and solid tumors; autoimmune diseases	Future IND candidate	

**SGN-40**

SGN-40 is a humanized monoclonal antibody that is in phase I and phase II clinical development. We are currently conducting a phase II single agent clinical trial of SGN-40 in patients with diffuse large B-cell lymphoma (DLBCL), as well as single agent phase I dose escalation clinical trials in patients with multiple myeloma or chronic lymphocytic leukemia (CLL). We are also planning to initiate trials of SGN-40 combined with other standard therapies for the treatment of patients with non-Hodgkin's lymphoma or multiple myeloma in collaboration with Genentech. SGN-40 targets the CD40 antigen, which is expressed on many B-cell lineage hematologic malignancies, as well as solid tumors such as bladder, renal and ovarian cancer.

In January 2007, we entered into an exclusive worldwide license agreement with Genentech for the development and commercialization of SGN-40. Under the terms of the agreement, we received an upfront payment of \$60 million, and are entitled to receive potential milestone payments exceeding \$800 million and escalating double-digit royalties starting in the mid-teens on annual net sales of SGN-40. The milestone payments include \$20 million in committed payments during the first two years of the agreement. Genentech will fund future research, development, manufacturing and commercialization costs for SGN-40. We have agreed to continue certain phase I and phase II clinical trials and development activities for SGN-40, the costs of which will be reimbursed by Genentech. We also have an option to co-promote SGN-40 in the United States.



## **Table of Contents**

### *Market Opportunities*

*Non-Hodgkin's Lymphoma.* Non-Hodgkin's lymphoma is the most common form of hematologic malignancy. The American Cancer Society estimates approximately 63,200 cases of non-Hodgkin's lymphoma will be diagnosed in the United States during 2007, the majority of which are of B-cell origin. Approximately 18,700 people are expected to die from the disease in 2007. Advances made with combined chemotherapy and radiotherapy and the use of Rituxan®, a monoclonal antibody, have resulted in durable 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.

*Multiple Myeloma.* The American Cancer Society estimates that approximately 19,900 cases of multiple myeloma will be diagnosed in the United States during 2007, and approximately 10,800 people will die from the disease. Therapeutic advances in recent years, such as the FDA's approval of Velcade® and Revlimid®, have expanded the treatment options for patients with multiple myeloma. However, multiple myeloma remains an incurable disease, and current therapies have limited response duration and significant toxic side effects. Therefore, we believe that targeted therapy using a monoclonal antibody represents a substantial opportunity in this disease either as a single agent or in combination with other treatments.

*Chronic Lymphocytic Leukemia.* CLL is one of the most common types of leukemia. According to the American Cancer Society, approximately 15,300 new cases of CLL will be diagnosed and 4,500 patients will die of CLL in the United States during 2007. In recent years, the combination of chemotherapy agents with Rituxan® has significantly increased the response rate and duration of remission in CLL patients. However, this therapy is not curative, has significant immunosuppression and often results in relapse within several years. Patients frequently cannot tolerate repeated treatments of these combination therapies, and Rituxan® or Campath® both have relatively low efficacy as a single agent for relapsed CLL. Therefore, there is significant need for new therapies that are active in this disease.

### *Clinical Results and Status*

We reported preliminary phase I data from our non-Hodgkin's lymphoma and multiple myeloma studies at the American Society of Hematology (ASH) annual meeting in December 2006. In both studies, patients receive multiple doses of SGN-40 to determine tolerability, safety profile, immunogenicity and pharmacokinetic parameters. In the non-Hodgkin's lymphoma study, we reported data from the first 35 patients enrolled with various subtypes of non-Hodgkin's lymphoma, including diffuse large B-cell, follicular, mantle cell, marginal zone and small lymphocytic lymphomas. Out of 31 evaluable patients, five (16 percent) had measurable objective responses, including one complete response ongoing after 41 weeks. Four patients achieved partial responses, three of which were ongoing with durations of 10, 18 and 31 weeks. Eight additional patients (26 percent) had stable disease at the end of treatment. Notably, of the five objective responses, three were in patients with DLBCL. In the multiple myeloma study, we reported data from the first 32 patients, showing that SGN-40 was well-tolerated with evidence of antitumor activity. Based on the data observed thus far and to explore additional aspects of the dose and schedule, the multiple myeloma protocol has been amended to test higher doses of SGN-40. We have also conducted a phase I single agent clinical trial of SGN-40 in patients with relapsed or refractory CLL to evaluate the safety, pharmacokinetic profile and antitumor activity of escalating doses of SGN-40.

In December 2006, we initiated a phase II single agent study of SGN-40 in patients with relapsed or refractory DLBCL, the most common type of aggressive NHL. This study is designed to assess the antitumor activity, tolerability and pharmacokinetic profile of SGN-40, and is expected to enroll up to 40 patients at multiple centers in the United States.

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

In collaboration with Genentech, we are also exploring potential studies of SGN-40 combined with conventional therapies in multiple myeloma and combined with Rituxan® and standard chemotherapy regimens

## **Table of Contents**

in non-Hodgkin's lymphoma. We have data from preclinical studies of SGN-40 indicating potential synergies with multiple standard therapies in these diseases. We also believe SGN-40 may have applications in autoimmune diseases and CD40-expressing solid tumors such as bladder and renal cancers.

### ***SGN-33 (lintuzumab)***

We are currently conducting a phase I clinical trial of SGN-33, or lintuzumab, in patients with acute myeloid leukemia (AML) or myelodysplastic syndromes (MDS). SGN-33 is a humanized monoclonal antibody that targets the CD33 antigen, which is highly expressed on a number of hematologic malignancies, such as AML, MDS and several myeloproliferative disorders. We have received orphan drug designation from the FDA for SGN-33 in AML.

### ***Market Opportunity***

***Acute Myeloid Leukemia.*** AML, which is 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 leads to a deficiency of red cells (anemia), platelets (thrombocytopenia) and normal white cells (neutropenia) in the blood. According to the American Cancer Society, approximately 13,400 new cases of AML will be diagnosed in the United States during 2007, and 9,000 people will die of the disease. Current therapies for AML include chemotherapy drugs such as cytarabine and daunorubicin or mitoxantrone and an antibody-drug conjugate, Mylotarg®. However, these therapies have low cure rates, lead to relatively short disease remissions, and can have life-threatening side effects. In addition, hematopoietic stem cell transplantation, which may offer a higher probability of cure, is not an option for many patients due to the toxicity, or the absence of an appropriate stem cell donor. Median survival of AML patients older than 65 years of age is less than six months. As such, there is a significant need for well-tolerated, targeted therapies, especially in the relapsed and refractory setting for elderly, untreated patients who cannot tolerate chemotherapy or stem cell transplant.

***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 suppressing normal cell development. According to the American Cancer Society, 10,000 to 15,000 new cases of MDS are diagnosed each year 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 acute leukemia, 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.

### ***Status***

Our ongoing phase I trial of SGN-33 is a single agent, dose escalation study designed to evaluate safety, pharmacokinetic profile and antitumor activity at multiple centers in the United States. The patient population includes individuals with AML or MDS who are not eligible for intensive chemotherapy or stem cell transplantation as well as those who have failed previous therapy. We reported preliminary data from this study during 2006, demonstrating that SGN-33 is well tolerated and has antitumor activity, including blast reductions, improved blood counts and decreased transfusion requirements, in multiple patients. We plan to report additional phase I data from this study at the ASH annual meeting in December 2007.

During 2007, we plan to initiate two additional trials of SGN-33 in combination with standard chemotherapy. The first will be a phase I study evaluating the combination of SGN-33 and Revlimid® for patients with high-risk MDS. We are particularly interested in this combination because preclinical data

## **Table of Contents**

demonstrates that Revlimid® can augment immune effector function, which is a primary mechanism of action for SGN-33. This study will enroll patients with high-risk MDS at escalating doses of SGN-33 to evaluate both tolerability and antitumor activity of the combination.

The second study we plan to initiate in 2007 will be a randomized, double blinded, placebo controlled, phase II study of SGN-33 combined with low-dose chemotherapy in AML patients. This study will accrue older patients with newly diagnosed AML who decline or are ineligible for induction chemotherapy. The primary goal of this study will be to determine whether the addition of SGN-33 prolongs survival of older AML patients for whom aggressive chemotherapy is not indicated. In addition, the trial will evaluate whether patients receiving SGN-33 experience reduced infections, transfusion independence, fewer hospitalizations and improved quality of life. We expect this study will provide sufficient data to direct our next steps towards registration of SGN-33.

### *Anti-CD30 Programs (SGN-30 and SGN-35)*

We are developing two clinical-stage product candidates for the treatment of CD30-positive hematologic malignancies, such as Hodgkin's disease and anaplastic large cell lymphoma (ALCL). SGN-30 is a monoclonal antibody that is currently in multiple phase II clinical trials sponsored by the National Cancer Institute (NCI) in combination with chemotherapy. SGN-35 is an auristatin-based antibody-drug conjugate that is in a phase I clinical trial. The CD30 antigen is an attractive target for cancer therapy because it is expressed on hematologic malignancies including Hodgkin's disease and several types of T-cell non-Hodgkin's lymphomas but has limited expression on normal tissues. We have received orphan drug designation from the FDA for SGN-30 in both Hodgkin's disease and T-cell lymphomas and for SGN-35 in Hodgkin's disease.

### *Market Opportunity*

Lymphoma is the most common type of hematologic malignancy. Of the nearly 500,000 people in the United States with lymphoma, approximately 128,000 have Hodgkin's disease. According to the American Cancer Society, approximately 8,200 cases of Hodgkin's disease will be diagnosed in the United States during 2007, and an estimated 1,100 people will die of the disease. Advances made in the use of combined chemotherapy and radiotherapy for malignant lymphomas have resulted in durable remission rates for front-line therapy in early stage lymphomas. However, the therapeutic options for refractory or relapsed patients are limited, and there are significant opportunities for new treatments in these patient populations.

### *SGN-30*

We presented data from two phase II single agent clinical trials of SGN-30 at the ASH annual meeting in December 2006. In these studies, SGN-30 was well-tolerated and demonstrated objective responses in patients with relapsed or refractory systemic ALCL, as well as a high objective response rate in patients with cutaneous CD30-positive lymphoproliferative disorders. Previously, we reported data from our phase II single agent study of SGN-30 in relapsed or refractory Hodgkin's disease, where we observed patients with reductions in tumor size, but in general the antibody was not sufficiently active as a single agent in this heavily-pretreated patient population to meet the criteria for objective tumor response.

Our current development strategy for SGN-30 is focused on combinations with chemotherapy, and we are collaborating with the National Cancer Institute (NCI) on three phase II combination studies. The first study is a randomized, placebo controlled clinical trial of SGN-30



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

combined with the GVD (gemcitabine, vinorelbine and doxorubicin) chemotherapy regimen. This study was initiated in the third quarter of 2006 and is designed to enroll approximately 140 patients with recurrent Hodgkin's disease. The second study, which combines SGN-30 with the CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone) chemotherapy regimen for patients with front-line ALCL, was initiated in the fourth quarter of 2006 and is expected to enroll approximately 50 patients. A third study of SGN-30 combined with the ICE (ifosfamide, carboplatin and etoposide) chemotherapy regimen in up to 20 pediatric ALCL patients is planned for initiation in the first half of 2007. Through these NCI-sponsored studies, we plan to evaluate the safety and efficacy of SGN-30 as a combination therapy, which will help guide our future development strategy for this program.

## **Table of Contents**

### *SGN-35*

SGN-35 is an ADC composed of an anti-CD30 monoclonal antibody attached by our proprietary, enzyme-cleavable linker to a derivative of the highly potent class of cell-killing drugs called auristatins. In November 2006, we initiated a phase I clinical trial of SGN-35 in patients with relapsed or refractory CD30-positive hematologic malignancies, including Hodgkin's disease. This single-agent, dose-escalation study is designed to evaluate the safety, pharmacokinetic profile and antitumor activity of SGN-35, and is expected to enroll up to approximately 40 patients at multiple centers in the United States. We have previously reported preclinical data demonstrating that SGN-35 effectively targets CD30 and delivers its cytotoxic payload, MMAE, to tumor cells resulting in potent cell-killing and complete regressions of tumors at well-tolerated doses. In addition, preclinical studies indicate that SGN-35 has localized bystander effect within tumors, which may intensify the antitumor activity of the ADC.

### *SGN-70*

SGN-70 is a humanized anti-CD70 monoclonal antibody with potent effector function and intrinsic cell-killing ability. The CD70 antigen is expressed on renal cancer, nasopharyngeal carcinoma and certain hematologic malignancies. We and our collaborators presented preclinical data at the ASH annual meeting in December 2006 demonstrating that SGN-70 has potent antitumor activity in models of hematologic malignancies. During 2007, we are conducting manufacturing activities and toxicology studies to support a planned 2008 IND for this program.

In addition to oncology, we believe that SGN-70 has applications in autoimmune diseases where the body's immune system malfunctions and attacks its own healthy cells. Many therapies for autoimmune disease 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 only on activated T-cells but is absent on these cells when in a resting state. Since resting T-cells make up approximately 95 percent of those types of 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 presented data from preclinical studies at the ASH annual meeting in December 2006, demonstrating that SGN-70 selectively depletes CD70-positive activated T-cells and limits expansion of CD70-positive lymphocytes. Based on our preclinical data, we are positioning SGN-70 for a potential future IND in autoimmune disease.

### *SGN-75*

SGN-75 is an ADC comprised of an anti-CD70 monoclonal antibody linked to an auristatin derivative using our proprietary ADC technology. We presented data at the American Academy of Cancer Research (AACR) annual meeting in April 2006 showing that CD70 has high expression in primary renal cell samples and SGN-75 has potent antitumor activity in preclinical models of renal cell cancer. SGN-75 has also been shown to selectively eliminate activated T-cells without affecting resting T-cells. SGN-75 is a future IND candidate.

## **Research Programs**

In addition to our pipeline of product candidates and antibody-based technologies, we have internal research programs directed towards 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 molecules 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

## **Table of Contents**

Celera Genomics and Agensys. The resulting monoclonal antibodies may represent product candidates on their own or may be utilized as part of our ADC technology.

*Antibody Engineering.* We have substantial internal expertise in antibody engineering, both for antibody humanization and 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 can improve the robustness and cost-effectiveness of our manufacturing processes for conjugation of ADCs.

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

## **Corporate Collaborations**

Part of our business strategy is to establish corporate collaborations with biotechnology and pharmaceutical companies and academic institutions. We license our ADC technology to collaborators to improve the efficacy of their own monoclonal antibodies. These deals benefit us in several ways, including generating revenues that partially offset expenditures on our internal research and development programs, expanding our knowledge base regarding ADCs and leveraging the resources of our collaborators to evaluate our ADC technology across multiple targets and antibodies. We also seek collaborations to advance the development and commercialization of our own product candidates, such as our SGN-40 collaboration with Genentech, or to supplement our internal pipeline, such as our ADC co-development agreement with Agensys. When partnering, we seek to retain significant future participation in product sales through either profit-sharing or product royalties paid on annual net sales. Our principal corporate collaborations are listed below.

### ***Genentech SGN-40 Collaboration***

In January 2007, we entered into an exclusive worldwide license agreement with Genentech for the development and commercialization of SGN-40. Under the terms of the agreement, we received an upfront payment of \$60 million, and are entitled to receive potential milestone payments exceeding \$800 million and escalating double-digit royalties starting in the mid-teens on annual net sales of SGN-40. The milestone payments include \$20 million in committed payments during the first two years of the agreement. Genentech will fund future research, development, manufacturing and commercialization costs for SGN-40. We have agreed to continue certain phase I and phase II clinical trials and development activities for SGN-40, the costs of which will be reimbursed by Genentech. We also have an option to co-promote SGN-40 in the United States.

We initially licensed our anti-CD40 antibody program to Genentech in June 1999. In March 2003, we entered into license agreements with Genentech providing for the return to us of the rights relating to the anti-CD40 antibody program, including an antibody that became our SGN-40 product candidate, as well as a license under Genentech's Cabilly patent covering the recombinant expression of antibodies. As part of that license, we also received material from Genentech for use in our phase I clinical trials of SGN-40.

### ***ADC Collaborations***

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

We have agreements with seven collaborators to allow them to use our proprietary ADC technology with their monoclonal antibodies:

*Progenics.* In June 2005, we entered into an ADC collaboration with PSMA Development Company, which is now a wholly-owned subsidiary of Progenics. Under the terms of the multi-year agreement, we received a \$2 million upfront fee for an exclusive license to our technology for the PSMA antigen, which is highly expressed on prostate cancer as well as tumor vasculature in multiple solid tumor types. 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**

*MedImmune.* In April 2005, we entered into an ADC collaboration with MedImmune, Inc. 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. MedImmune also has an option to take a license to a second antigen by paying an additional fee. 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.

*Bayer.* In September 2004, we entered into an ADC collaboration with Bayer Corporation. 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. 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.

*CuraGen.* In June 2004, we entered into an ADC collaboration with CuraGen Corporation. Under the terms of the multi-year agreement, CuraGen paid us a \$2 million upfront fee for an exclusive license to our technology for a single antigen. In February 2005, CuraGen paid us an additional fee for an exclusive license to a second antigen. CuraGen is also paying service and reagent fees and has agreed to make milestone payments and pay royalties on net sales of any resulting ADC products. CuraGen is responsible for all costs associated with the development, manufacturing and marketing of any ADC products generated as a result of this collaboration. CuraGen initiated a phase I clinical trial of CR011, an ADC for the treatment of metastatic melanoma, in June 2006.

*Genentech.* In April 2002, we entered into an ADC collaboration with Genentech. Upon entering into the multi-year agreement, Genentech paid us a \$2.5 million upfront fee and purchased \$3.5 million of our common stock. We have subsequently expanded this collaboration on several occasions to include additional antigens, including in December 2003 when Genentech paid us a \$3 million fee and purchased an additional \$7.0 million of our common stock and in November 2004 when Genentech paid us a \$1.6 million fee. The total payments we have received from Genentech under this collaboration, including upfront fees, equity investments, technology access and research fees, exceed \$25 million. Genentech has also agreed to pay progress-dependent milestone payments and royalties on net sales of any resulting products. Genentech is responsible for research, product development, manufacturing and commercialization of any products resulting from the collaboration. Over the past several years, Genentech has paid us fees and milestone payments based on achievement of a preclinical milestone and assistance with process development and manufacturing to support potential IND-enabling studies and possible future clinical trials of several ADC product candidates.

*PDL BioPharma.* In June 2001, we entered into an ADC collaboration with Eos Biotechnology. This collaboration was assumed by PDL BioPharma in 2003 upon its acquisition of Eos Biotechnology, and we agreed to expand the collaboration in January 2004. Under the expanded agreement, we agreed to provide additional support to PDL in exchange for PDL paying us increased fees, milestones and royalties on net sales of any ADC products resulting from the collaboration. PDL also granted us a license and options for two additional licenses under their antibody humanization patents. As part of the in-license of our anti-CD33 program from PDL in April 2005, we further amended our ADC collaboration to reduce the royalties payable by PDL to us with respect to ADCs targeting several antigens. In June 2005, PDL sublicensed the rights to develop one of its ADC product candidates to Genentech. PDL or its sublicensee is responsible for all costs associated with the development, manufacturing and marketing of any ADC products generated through this collaboration.

### ***Agensys ADC 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, Seattle Genetics and Agensys will jointly screen and select ADC products to an initial target that has



## **Table of Contents**

already been selected, co-fund all preclinical and clinical development and share equally in any profits. Agensys will also conduct further preclinical studies aimed at identifying ADC products to up to three additional targets. We have the right to exercise a co-development option for one of these additional ADC products at IND filing, and Agensys will have the right to develop and commercialize the other two ADCs product 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.

### ***Celera Genomics Co-Development Agreement***

In July 2004, we formed a collaboration with Celera Genomics Group, an Applera Corporation business, to jointly discover and develop antibody-based therapies for cancer. Products developed under the collaboration may include either genetically engineered monoclonal antibodies or ADCs. Pursuant to the terms of the multi-year agreement, we and Celera jointly designate cell-surface antigens discovered and validated through Celera's proprietary proteomic platform. We are carrying out the initial screening to generate and select the appropriate corresponding antibodies or ADCs for joint development and commercialization, after which preclinical and clinical product development will be co-funded and we will jointly share any profits resulting from collaboration products. Either party may opt out of co-development of a particular product and receive royalties on net sales. Celera will also pay us progress-dependent commercialization milestones for any co-developed ADCs. In August 2005, we announced that we had selected a Celera antigen for further preclinical development.

### ***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 technologies, 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 ADC collaboration, PDL BioPharma granted us one license and options for two additional licenses under PDL's antibody humanization patents. We have used the initial antibody humanization license for our SGN-40 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's technology. In April 2005, we in-licensed an anti-CD33 program from PDL, which is the basis for SGN-33. We paid PDL an upfront fee and have agreed to pay progress-dependent milestones and royalties on net sales of anti-CD33 products incorporating technology in-licensed from PDL, which includes an antibody humanization license for the CD33 antigen. As part of the agreement, we also agreed to reduce the royalties payable by PDL to us with respect to several targets under our ongoing ADC collaboration. We and PDL have also granted each other a co-development option for second generation anti-CD33 antibodies with improved therapeutic characteristics developed by either party.

***ICOS Corporation/Eli Lilly.*** In October 2000, we entered into a license agreement with ICOS Corporation, which was recently acquired by Eli Lilly, for non-exclusive rights to use ICOS' CHEF expression system. We use this system to manufacture the antibody components of SGN-30, SGN-35, 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.

*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 SGN-30 and the

## **Table of Contents**

antibody component of SGN-35. 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.

*Mabtech AB.* In June 1998, we obtained exclusive, worldwide rights to a monoclonal antibody targeting the CD40 antigen, which is the basis for SGN-40, from Mabtech AB, located in Sweden. Under the terms of this license, we are required to make a progress-dependent milestone payment 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, 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 progress-dependent milestone payments or royalties on net sales of products incorporating the auristatin derivatives 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**

We seek appropriate patent protection for our proprietary technologies by filing patent applications in the United States and other countries. As of December 31, 2006, we owned approximately 100 United States and corresponding foreign patents and patent applications and held exclusive or partially exclusive licenses to over 50 United States and corresponding foreign patents and patent applications.

Our patents and patent applications are directed to product candidates, monoclonal antibodies, ADC product candidates, our ADC technology and other antibody-based and/or enabling technologies. Although we believe our 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, or in the event of issuance, may not be sufficient to protect the technology owned by or licensed to us or our corporate 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 corporate collaborators. Our or our corporate collaborators' current patents, or patents that issue on pending applications, may be challenged, invalidated, infringed or circumvented, and the rights granted in those patents may not provide proprietary protection to us. We cannot determine with certainty whether patents or patent applications of other parties may materially affect our or our corporate collaborators' ability to make, use or sell any products.

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

We also rely on trade secrets and proprietary know-how, 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 confidentiality and inventions assignment agreement before beginning their employment,

## **Table of Contents**

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.

## **Government Regulation**

Our product candidates are subject to extensive regulation by numerous governmental authorities, principally the FDA, as well as numerous state and foreign agencies. We need to obtain approval of our potential products 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 potential products will vary, depending on the regulatory categorization of particular products and various other factors.

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

preclinical laboratory and animal tests;

submission to the FDA of an IND which must become effective before clinical trials may commence;

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;

FDA pre-approval inspection of manufacturing facilities for current Good Manufacturing Practices (GMP) compliance; and

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

Clinical trials generally are conducted in three sequential phases that may overlap. 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 determine 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 trials are undertaken to evaluate further clinical efficacy in comparison to standard therapies within a broader patient population, generally at geographically dispersed clinical sites. 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 or efficacy in earlier stage trials do not necessarily predict findings of safety and effectiveness in subsequent trials. Furthermore, the FDA, an institutional review board 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.

The results of preclinical studies, pharmaceutical development and clinical trials are submitted to the FDA in the form of a new drug application (NDA) or a biologics license application (BLA) for approval of the manufacture, marketing and commercial shipment of the pharmaceutical product. 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 if applicable regulatory criteria are not satisfied, require additional testing or information, or require post-market testing and surveillance to monitor the safety or efficacy of the product. In addition, after marketing approval is granted, the FDA may require post-marketing clinical trials, which typically entail extensive patient

## **Table of Contents**

monitoring and may result in restricted marketing of an approved product for an extended period of time. Also, after marketing approval, comprehensive federal and state regulatory compliance obligations exist for the manufacture, labeling, distribution, promotion and pricing of pharmaceutical products. 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 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.

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 corporate partnerships.

We are aware of specific companies that have technologies that may be competitive with ours, including Wyeth, ImmunoGen and Medarex, all of which have antibody-drug conjugate technology. Wyeth markets the antibody-drug conjugate Mylotarg<sup>®</sup> for patients with acute myeloid leukemia, which targets the same antigen as our SGN-33 product candidate. ImmunoGen has several antibody-drug conjugates in development that may compete with our product candidates. ImmunoGen has also established partnerships with other pharmaceutical and biotechnology companies to allow those other companies to utilize ImmunoGen's technology. In addition, Medarex has developed its own technology for

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

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. Novartis and Pfizer are each developing anti-CD40 antibodies that may be competitive with SGN-40, and Medarex has anti-CD30 and anti-CD70 antibody programs that may be competitive with our programs. 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 to treat. These include antibodies such as Genentech's Rituxan®, proteasome inhibitors such as Millennium's Velcade®, 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® or Vion's Cloretazine®.

## **Table of Contents**

### **Manufacturing**

We rely on contract manufacturers to supply drug product for our IND-enabling studies and clinical trials. For SGN-40, Genentech manufactured substantial quantities of clinical grade material that were transferred to us as part of the 2003 license with them, and we have entered into a manufacturing agreement with Abbott to supplement our clinical supplies. Decisions on future SGN-40 drug supply will be made jointly by us and Genentech through our collaboration. For SGN-33, we received material sufficient to supply our ongoing phase I clinical trials as part of our license from PDL BioPharma, and we have contracted with Laureate Pharma for additional clinical drug supply. For the monoclonal antibody used in SGN-30 and SGN-35, we have contracted with Abbott Laboratories for clinical and potential future commercial supplies. We have also contracted with Laureate Pharma to manufacture the antibody component of SGN-70 and SGN-75 to enable future initiation of clinical trials. For our ADC technology, several contract manufacturers, including Albany Molecular, perform drug-linker manufacturing and several other contract manufacturers perform conjugation of the drug-linker to the antibody. In addition, we rely on other third parties to perform additional steps in the manufacturing process, including vialing and storage of our product candidates.

We believe that our existing supplies of drug product and our contract manufacturing relationships with Abbott, Laureate Pharma, Albany Molecular and our other existing and potential contract manufacturers with whom we are in discussions, will be sufficient to accommodate clinical trials through phase II and in some cases phase III of our current product candidates. However, we may need to obtain additional manufacturing arrangements, if available on commercially reasonable terms, or increase our own manufacturing capability to meet our future needs, both of which would require significant capital investment. 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, 2006, we had 151 employees, 49 of whom hold doctoral level degrees. Of these employees, 121 are engaged in or directly support research, development and clinical activities and 30 are 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.

### **Website**

Our website address is [www.seattlegenetics.com](http://www.seattlegenetics.com). We make available, free of charge, through a hyperlink on our website, our annual, quarterly and current reports, and any amendments to those reports, as soon as reasonably practicable after electronically filing such reports with the Securities and Exchange Commission. Information contained on our website is not part of this report.

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



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

You should carefully consider the risks described below, together with all of the other information included in this annual report on Form 10-K and the information incorporated by reference herein. If we do not effectively address the risks we face, our business will suffer and we may never achieve or sustain profitability. See Management's Discussion and Analysis of Financial Condition and Results of Operations.

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.

## **Table of Contents**

*Our product candidates are at early stages of development and, if we are not able to successfully develop and commercialize them, we may not generate sufficient revenues to continue our business operations.*

All of our product candidates are in early stages of development. Significant further research and development, financial resources and personnel will be required to develop commercially viable products and obtain regulatory approvals. Currently, SGN-40, SGN-33, SGN-30 and SGN-35 are in clinical trials and SGN-70 and SGN-75 are in preclinical development. We expect that much of our efforts and expenditures over the next few years will be devoted to these clinical and preclinical product candidates. We have no products that have received regulatory approval for commercial sale.

Our ability to commercialize our product candidates depends on first receiving FDA approval. Thereafter, the commercial success of these product candidates will depend upon their acceptance by physicians, patients, third party payors and other key decision-makers as therapeutic and cost-effective alternatives to currently available products. With respect to SGN-40, commercial success will depend in large part on Genentech's actions to commercialize the product candidate. If we fail to gain approval from the FDA or to produce a commercially successful product, we may not be able to earn sufficient revenues to continue as a going concern.

*Clinical trials for our product candidates are expensive, time consuming and their outcome is uncertain.*

Before we can obtain regulatory approval for the commercial sale of any product candidate that we wish to develop, we are required to complete preclinical development and extensive clinical trials in humans to demonstrate its safety and efficacy. Each of these trials requires the investment of substantial expense and time. We are currently conducting multiple phase I and phase II clinical trials of our clinical product candidates, and we expect to commence additional trials of these and other product candidates in the future. There are numerous factors that could delay each of these clinical trials or prevent us from completing these trials successfully.

Commercialization of our product candidates will ultimately depend upon successful completion of additional research and development and testing in both clinical trials and preclinical models. At the present time, SGN-40, SGN-33, SGN-30 and SGN-35 are our only product candidates in clinical development and SGN-70 and SGN-75 are our lead preclinical product candidates. As a result, any delays or difficulties we encounter with these product candidates may impact our ability to generate revenue and cause our stock price to decline significantly.

Ongoing and future clinical trials of our product candidates may not show sufficient safety or efficacy to obtain requisite regulatory approvals. We still only have limited efficacy data from our phase I and phase II clinical trials of SGN-40, SGN-33 and SGN-30 and we only recently commenced our phase I clinical trial of SGN-35. Phase I and phase II clinical trials are not primarily designed to test the efficacy of a drug candidate but rather to test safety, to study pharmacokinetics and pharmacodynamics and to understand the drug 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. We believe that any clinical trial designed to test the efficacy of SGN-40, SGN-33, SGN-30 or SGN-35, whether phase II or phase III, will likely involve a large number of patients to achieve statistical significance and will be expensive. We may conduct lengthy and expensive clinical trials of SGN-40, SGN-33, SGN-30 or SGN-35, only to learn that the drug candidate is not an effective treatment. We may experience significant setbacks in advanced clinical trials, even after promising results in earlier trials. 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 during a clinical trial could cause it to be redone or terminated. For example, although we generated data showing encouraging results in our single-agent clinical trials of SGN-30, we decided to prioritize our other programs and collaborate with the National Cancer Institute (NCI) to conduct further SGN-30 clinical trials in combination with chemotherapy, which may prolong and delay the results in any of these trials. In addition, failure to construct appropriate clinical trial protocols could result in the test or control group experiencing a disproportionate number of adverse events and could cause a clinical trial to be redone or terminated. The length of time necessary to complete clinical trials



## **Table of Contents**

and to submit an application for marketing approval for a final decision by the FDA or another regulatory authority may also vary significantly based on the type, complexity and novelty of the product involved, as well as other factors.

*Our clinical trials may take longer to complete than we project or they may not be completed at all.*

The timing of the commencement, continuation and completion of 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, and shortages of available drug supply. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments. In addition, future SGN-40 clinical trials will be coordinated with Genentech, which may delay the commencement or affect the continuation or completion of these trials. We have experienced enrollment-related delays in our current and previous clinical trials and may experience similar delays in our future trials. We depend on medical institutions and clinical research organizations to conduct our clinical trials 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 may conduct clinical trials in foreign countries in the future 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 clinical research organizations, as well as expose us to risks associated with 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 institutional review boards 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 the FDA's current Good Manufacturing Practices and other requirements in foreign countries, and may require large numbers of test patients. We, the FDA or other foreign governmental agencies could delay or halt our clinical trials of a product candidate for various reasons, including:

deficiencies in the conduct of the clinical trials;

the product candidate may have unforeseen adverse side effects;

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;

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

we may not be able to produce sufficient quantities of the product candidate to complete the trials.

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 approval, which could reduce or eliminate our revenue by delaying or terminating the potential commercialization of our product candidates.

*In some circumstances we rely on collaborators to assist in the research and development of our product candidates, as well as 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 alliances with third-party collaborators to develop and market some of our current and future product candidates. We entered into a worldwide license agreement in

## **Table of Contents**

January 2007 for the development and commercialization of our SGN-40 product candidate with Genentech. We have also licensed our ADC technology to Genentech, Bayer, CuraGen, Progenics, MedImmune and PDL BioPharma and have an ADC co-development agreement with Agensys. These collaborations provide us with cash and revenues through technology access and license fees, sponsored research fees, equity sales and potential milestone and royalty payments, as well as potential revenues from product sales in the case of Agensys. We use these funds to partially fund the development costs of our internal pipeline of product candidates. Collaborations can also create and strengthen our relationships with leading biotechnology and pharmaceutical companies and may provide synergistic benefits by combining our technologies with the technologies of our collaborators. For example, we have an ongoing collaboration with Celera Genomics to jointly discover and develop antibody-based therapies for cancer.

Under certain conditions, our collaborators may terminate their agreements with us and discontinue use of our technologies. In addition, we cannot control the amount and timing of resources our collaborators may devote to products incorporating our technology. Moreover, our relationships with our collaborators 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, as well as possibly requiring us to devote additional efforts and incur costs associated with pursuing internal development of product candidates. In particular, if Genentech determines to terminate the SGN-40 collaboration, we would not receive milestone payments or royalties for development or sale of SGN-40, which would significantly harm our financial position, adversely affect our stock price and require us to incur all the costs of developing and commercializing SGN-40, which are now being reimbursed by Genentech. Furthermore, if our collaborators do not prioritize and commit substantial resources to programs associated with our product candidates, we may be unable to commercialize our product candidates, which would limit our ability to generate revenue and become profitable. In the future, we may not be able to locate third party collaborators to develop and market our product candidates and we may lack the capital and resources necessary to develop all our product candidates alone.

***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 will continue to come from corporate collaborations until the approval and commercialization of one or more of our product candidates and even then may still be received from Genentech in the case of potential sales of SGN-40. The failure of our collaborators to perform their obligations under their agreements with us, including paying license or technology fees, milestone payments or royalties, could have a material adverse effect on our financial performance. In addition, a significant portion of revenue received from our corporate collaborators is derived from research and material supply fees, and a decision by any of our corporate collaborators to conduct more research and development activities themselves could significantly reduce the revenue received from these collaborations. 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.

## **Table of Contents**

*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 ability to manufacture ourselves the drug products that we need to conduct our clinical trials and rely upon a limited number of manufacturers to supply our drug products. For SGN-40, Genentech manufactured initial quantities of clinical grade material that have been transferred to us, and we have contracted with Abbott Laboratories for later-stage clinical and potential future commercial supplies. Decisions on future SGN-40 drug supply will be made jointly by us and Genentech through our collaboration. For SGN-33, we received clinical-grade material from PDL BioPharma to support ongoing and planned phase I trials and entered into a contract manufacturing arrangement with Laureate Pharma to supplement these supplies and provide later-stage clinical supplies. For the monoclonal antibody used in SGN-30 and SGN-35, we have contracted with Abbott Laboratories for clinical and potential future commercial supplies. We have also contracted with Laureate Pharma to manufacture the antibody component of SGN-70 and SGN-75 to enable future initiation of clinical trials. For our ADC technology, several contract manufacturers, including Albany Molecular, supply us with drug-linker and several other contract manufacturers perform conjugation of the drug-linker to the antibody. In addition, we rely on other third parties to perform additional steps in the manufacturing process, including 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.

Securing phase III and 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 FDA current Good Manufacturing Practices 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. Any difficulties or delays in our contractors' manufacturing and supply of product candidates could increase our costs, cause us to lose revenue or make us postpone or cancel clinical trials.

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. 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

## **Table of Contents**

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.

### ***Our ADC technology is still at an early-stage of development.***

Our ADC technology, utilizing proprietary stable linkers and highly potent cell-killing drugs, is still at a relatively early stage of development. This ADC technology is used in our SGN-35 and SGN-75 product candidates and is the basis of our collaborations with Genentech, Bayer, CuraGen, Progenics, MedImmune, PDL BioPharma, and Agensys. We and our corporate collaborators are conducting toxicology, pharmacology, pharmacokinetics and other preclinical studies and, although both we and CuraGen initiated clinical trials of ADC product candidates during 2006, significant additional studies may be required before other ADC product candidates enter human clinical trials. For example, we have observed evidence of toxicity in some preclinical models with certain drug-linkers and are focusing our efforts on drug-linkers with the best efficacy and lowest toxicity in order to maximize the therapeutic window of our ADC technology. In addition, preclinical models to study 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, 2006, we had an accumulated deficit of approximately \$179.6 million. We expect to make substantial expenditures to further develop and commercialize our product candidates, some of which will be reimbursed by Genentech as part of our SGN-40 collaboration, and 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 potential products. 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. 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.***

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. Some of these expenditures will be reimbursed by Genentech as part of our SGN-40 collaboration; however, we may need to seek additional funding through public or private financings, including equity financings, and through other means, such as collaborations and license agreements. In addition, changes in our business may occur that would consume available capital resources sooner than we expect. 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. We do not know whether additional financing will be available when needed, or that, if available, we will obtain financing on terms favorable to our stockholders or us. Our future capital requirements will depend upon a number of factors, including:



the size, complexity and timing of our clinical programs;

our receipt of milestone-based payments or other revenue from our collaborations or license arrangements, including reimbursements for expenses pursuant to our SGN-40 collaboration with Genentech;

the ability to manufacture sufficient drug supply to complete clinical trials;

**Table of Contents**

progress with clinical trials;

the time and costs involved in obtaining regulatory approvals;

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

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;

competing technological and market developments; and

preparation for product commercialization.

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, CLB Research and Development, Eli Lilly (formerly ICOS), Mabtech AB, 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 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 may require us to secure licenses to additional technologies. We may not be able to secure these licenses on commercially reasonable terms, if at all.

***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.

*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 defending these patents 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,

## **Table of Contents**

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, Genentech and PDL BioPharma, among others. In addition, we have licensed our U.S. and foreign patents and patent applications to third parties.

The standards that the U.S. Patent and Trademark Office and foreign patent offices use to grant patents are not always applied predictably or uniformly and can change. Consequently, our pending patent applications may not be allowed and, if allowed, may not contain the type and extent of patent claims that will be adequate to conduct our business as planned. Additionally, any issued patents 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.***

The defense and enforcement of intellectual property rights in a court of law, U.S. Patent and Trademark Office interference 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 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 several scientific personnel with significant and unique expertise in monoclonal antibodies 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.

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

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 and 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.

## **Table of Contents**

*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. 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, ImmunoGen, Biogen IDEC, Medarex, Novartis and Wyeth are developing and/or marketing products or technologies that may compete with ours. Other potential competitors include large, fully integrated pharmaceutical companies and more established biotechnology companies, which 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;

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 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 sell our product candidates.*

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 our products in the United States, except for SGN-40 for which Genentech will lead the sales and marketing efforts while we retain an ability to co-promote that product. For sales outside the United States, excluding SGN-40, we plan to enter into third-party arrangements. In these foreign markets, if we are unable to establish successful distribution

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

relationships with pharmaceutical companies, we may fail to realize the full sales potential of some of our product candidates.

Additionally, our product candidates may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any approved product candidate will depend on a number of factors, including: establishment and demonstration of clinical efficacy and safety; cost-effectiveness of a product; its potential advantage over alternative treatment methods; and marketing and distribution support for the product.

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. Consequently,

## **Table of Contents**

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 our 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.

***The holders of our Series A convertible preferred stock have voting and other rights that they could exercise against the best interests of our common stockholders.***

The holders of our Series A convertible preferred stock currently have rights to designate two members of our Board of Directors and to vote as a separate class on certain significant corporate transactions, including the issuance of securities that would rank on a par with or senior to the Series A convertible preferred stock or the incurrence of debt in excess of \$20 million. The holders of Series A convertible preferred stock are not entitled to receive any cumulative or non-cumulative dividends, and may only receive a dividend when and as declared by our Board of Directors or if any dividends are paid on any other shares of our capital stock based on the number of shares of common stock into which such holder's shares of Series A convertible preferred stock would then convert. In addition, upon our liquidation or dissolution (including a merger or acquisition), the holders of our Series A convertible preferred stock are entitled to receive a liquidation preference in an amount equal to the greater of the original offering price of \$25.00 per share of Series A convertible preferred stock or the amount that would have been paid had each such share of Series A convertible preferred stock been converted to common stock. The holders of Series A convertible preferred stock also have the right under certain circumstances in the event of our merger or acquisition approved by our Board of Directors to receive their liquidation preference in cash or a combination of cash and new preferred securities of the acquiring or surviving corporation. This requirement to pay cash or issue new preferred securities does not apply if the consideration to be received by the Series A holders has an aggregate value of more than \$6.25 per share (calculated on an as-if-converted to common stock basis) determined on the date definitive documentation for such sale transaction is signed or if holders of 2/3rds of the outstanding shares of Series A convertible preferred stock waive this requirement. The holders of Series A convertible preferred stock may exercise these rights to the detriment of our common stockholders.

The holders of our Series A convertible preferred stock also have the right at any time to request that we register for resale the shares of our common stock that they acquire upon conversion of their Series A convertible preferred stock or upon exercise of their warrants to purchase our common stock, subject to certain limitations. In addition, the holders of our Series A convertible preferred stock may convert their Series A convertible preferred stock into common stock at any time and sell shares of the common stock acquired upon such conversion in the public market in reliance upon Rule 144. Future sales in the public market of such common stock, or the perception that such sales might occur, could adversely affect the prevailing market price of our common stock and could make it more difficult for us to raise funds through a public offering or private placement of our equity securities.

***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 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.





## **Table of Contents**

*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. The cost of compliance with environmental, health and safety regulations is substantial. Our business activities involve the controlled use of hazardous materials and we cannot eliminate the risk of accidental contamination or injury from 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.

*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, for example the recent requirement to expense stock options. 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. For example, we have incurred and expect to continue to incur substantial costs and expend significant resources to comply with the regulations promulgated under Section 404 of the Sarbanes-Oxley Act of 2002.

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

The market prices for securities of biotechnology companies have in the past been, and are likely to continue in the future to be, very volatile. During the fourth quarter of 2006, our stock price fluctuated between \$4.66 and \$6.35 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;

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

termination of or changes in our existing corporate partnerships or licensing arrangements, especially our SGN-40 collaboration with Genentech;

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

our ability to raise capital;

developments or disputes concerning our proprietary rights;

**Table of Contents**

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.

***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 43.2 percent of our voting power as of March 2, 2007. 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.***

In addition to the 928,500 shares of Series A convertible preferred stock that are currently outstanding, as of March 2, 2007, our Board of Directors has the authority to issue up to an additional 3,360,000 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.

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

Not applicable.

**Item 2. Properties.**

Our headquarters are in Bothell, Washington, where we lease approximately 63,900 square feet under a lease expiring May 2011. We may renew the lease, at our option, for two consecutive seven-year periods. We currently occupy and utilize the entire building as laboratory, discovery, research and development and general administration space. We believe that our facilities are sufficient to meet our current and near term requirements. However, additional facilities may be required to meet our future growth.

**Item 3. Legal Proceedings.**

We are not a party to any material legal proceedings.

**Item 4. Submission of Matters to a Vote of Security Holders.**

No matters were submitted to a vote of security holders during the fourth quarter of 2006.

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

Our common stock is traded on the Nasdaq Global Market under the symbol SGEN.

The following table sets forth the high and low sales prices for our common stock, as quoted on the Nasdaq Global Market, for each of the quarters indicated.

	<b>High</b>	<b>Low</b>
<b>2005</b>		
First Quarter	\$ 6.60	\$ 4.59
Second Quarter	5.95	3.52
Third Quarter	6.52	4.86
Fourth Quarter	5.79	4.50
<b>2006</b>		
First Quarter	\$ 5.80	\$ 4.55
Second Quarter	5.20	3.85
Third Quarter	4.94	3.80
Fourth Quarter	6.35	4.66
<b>2007</b>		
First Quarter (as of March 2, 2007)	\$ 9.52	\$ 5.14

As of March 2, 2007, there were 116 holders of record of our common stock. Because many shares of our common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

*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. In addition, for so long as 33 1/3% of the 1,640,000 shares of Series A convertible preferred stock originally issued are outstanding, we need the approval of holders of 66 2/3% of such outstanding shares of Series A convertible preferred stock in order to declare, pay, set aside or reserve amounts for the payment of any dividend on our capital stock, other than the Series A convertible preferred stock. As of March 2, 2007, 928,500 shares of Series A convertible preferred stock were outstanding which are convertible into 9,285,000 shares of common stock.

*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 2006. In addition, we did not repurchase any of our equity securities during the fourth quarter of 2006.

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

We show below the cumulative total return to our stockholders during the period from December 31, 2001 through December 31, 2006 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, 2001 in our common stock and each of the indexes listed above, including reinvestment of dividends, if any.

Company/Index	Base	Years Ending				
	Period	12/01	12/02	12/03	12/04	12/05
<b>Seattle Genetics, Inc.</b>	<b>100.00</b>	<b>54.39</b>	<b>150.53</b>	<b>114.56</b>	<b>82.81</b>	<b>93.51</b>
<b>NASDAQ Composite</b>	<b>100.00</b>	<b>69.66</b>	<b>99.71</b>	<b>113.79</b>	<b>114.47</b>	<b>124.20</b>
<b>NASDAQ Pharmaceutical</b>	<b>100.00</b>	<b>64.40</b>	<b>92.31</b>	<b>100.78</b>	<b>113.36</b>	<b>115.84</b>
<b>NASDAQ Biotechnology</b>	<b>100.00</b>	<b>62.08</b>	<b>90.27</b>	<b>99.08</b>	<b>111.81</b>	<b>110.06</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 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 the financial statements and notes to our financial statements and Management's Discussion and Analysis of Financial Condition and Results of Operations contained elsewhere in this Form 10-K. The selected Statements of Operations data for the years ended December 31, 2006, 2005 and 2004 and Balance Sheet data as of December 31, 2006 and 2005 have been derived from our audited financial statements appearing elsewhere in this Form 10-K. The selected Statements of Operations data for the years ended December 31, 2003 and 2002 and Balance Sheet data as of December 31, 2004, 2003 and 2002 have been derived from our audited financial statements that are not included in this Form 10-K. Historical results are not necessarily indicative of future results.

	2006	Years Ended December 31,			2002
		2005	2004	2003	
		(in thousands, except per share amounts)			
<b>Statements of Operations Data:</b>					
Revenues	\$ 10,005	\$ 9,757	\$ 6,701	\$ 5,070	\$ 1,684
Operating Expenses:					
Research and development	40,136	34,683	37,208	21,928	20,274
General and administrative	10,074	7,145	7,161	6,405	6,605
Loss from operations	(40,205)	(32,071)	(37,668)	(23,263)	(25,195)
Investment income, net	4,190	2,638	2,229	1,177	2,035
Net loss	(36,015)	(29,433)	(35,439)	(22,086)	(23,160)
Non-cash preferred stock deemed dividend			(36,558)	(201)	
Net loss attributable to common stockholders	\$ (36,015)	\$ (29,433)	\$ (71,997)	\$ (22,287)	\$ (23,160)
Basic and diluted net loss per share attributable to common stockholders					
	\$ (0.74)	\$ (0.70)	\$ (1.80)	\$ (0.73)	\$ (0.77)
Weighted-average shares used in computing basic and diluted net loss per share					
	48,659	42,238	39,985	30,722	30,138
	2006	2005	December 31,		2002
			2004	2003	
			(in thousands)		
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and investment securities	\$ 86,573	\$ 79,207	\$ 105,898	\$ 73,682	\$ 44,219
Restricted investments	486	605	977	976	980
Working capital	76,880	33,048	30,233	38,839	23,952
Total assets	97,695	90,019	119,109	81,999	52,536
Stockholders' equity	88,234	75,458	103,833	74,878	46,702

## **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. These statements relate 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 and uncertainties. In evaluating these statements, you should specifically consider various factors, including the risks outlined in Item 1A Risk Factors and those contained from time to time in our other filings with the SEC. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

#### **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 affect the more significant judgments and estimates used in the preparation of our financial statements.

**Revenue Recognition.** Many of our agreements contain multiple revenue elements including upfront payments, license fees, milestone payments, royalties, maintenance fees and payments received for the delivery of supplies or services. Each agreement may contain some or all of these elements and the assessment of multiple element arrangements requires judgment in order to determine the appropriate time, or period of time, that revenue should be recognized. Revenues are recognized when persuasive evidence of an agreement exists, delivery has occurred or services have been rendered, the fees are fixed or determinable and collectibility is reasonably assured. Where activities represent the culmination of a separate earnings process and verifiable evidence of the fair value of each element can be established, revenue is recognized as the activities are completed. When verifiable evidence of fair value cannot be established for each undelivered element, revenue is deferred until all elements have been delivered or until verifiable evidence of the fair value for any undelivered element can be determined. Where activities represent continuing obligations and fair value cannot be determined, revenue is recognized over the service period using either a time-based or an activity-based approach as appropriate in the circumstance. Nonrefundable upfront payments and maintenance and license fees, for which no further performance obligations exist are recognized as revenue on the earlier of when payments are received or when collection is assured. When contracts include nonrefundable upfront payments, maintenance fees or license fees, including any guaranteed time-based payments, that require continuing involvement in the form of development, manufacturing or other efforts by us, we evaluate whether verifiable evidence of fair value of the efforts to be provided exists. If no such evidence exists, we recognize the payments received as revenue over the development period or other period over which services are to be provided. Payments for the achievement of substantive at-risk milestones are generally recognized as revenue when the milestone is achieved. However, payments for milestones which are not the result of the achievement of a substantive at-risk milestone or from an arrangement that contains multiple delivery elements for which verifiable and objective evidence of fair value cannot be established for each element are recognized as revenue over the development period or other periods over which services are provided. 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. We also perform research and development activities on behalf of



## **Table of Contents**

collaborative partners. Revenue from research and development services is generally recognized as the service is provided. However, if the arrangement 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. We generally bill the collaborator monthly, quarterly or upon the completion of the effort, based on the terms of each agreement. Amounts earned, but not billed to the collaborator, if any, are included in accounts receivable in the accompanying balance sheets. Amounts received in excess of amounts recognized as revenue are included in deferred revenue in the accompanying balance sheets.

**Investments.** Our investments are diversified among high-credit quality 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 as a component of 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 determined that unrealized losses are not significant and are temporary as to the extent of the decline in both dollars and percentage of cost, and we have the ability and intent to hold the investments until we recover at least substantially all of the cost of the investment. The fair value of our investments is subject to volatility. To date, the carrying values of our investments have not been written down due to declines in value because such declines are judged to be other than temporary. Declines in the fair value of our investments judged to be other than temporary could adversely affect our future operating results.

**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 make these estimates as of each balance sheet date in our financial statements. Examples of estimated accrued expenses include fees paid to contract research organizations in conjunction with clinical trials, fees paid to contract manufacturers 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 could 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 direct headcount related costs, third-party contract and outside service fees and facilities and overhead expenses for drug discovery and research, preclinical studies and for costs associated with clinical trial activities and are expensed as incurred. Costs, including milestones and maintenance fees, to acquire technologies that are utilized in 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. This estimated cost includes payments to our contract research organizations for trial site and patient-related costs, including laboratory costs related to the conduct of the trial, and other costs.

**Share-based Compensation.** We adopted the provisions of SFAS 123R effective January 1, 2006, which results in the expensing of the fair value of share-based payment transactions to be recognized in the financial statements. We adopted SFAS 123R using the modified prospective application method. 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



## **Table of Contents**

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 Financial Statements included in this Form 10-K.

**Income Taxes.** We have net deferred tax assets which are fully offset by a valuation allowance due to our determination that net deferred assets will not be realized. We believe that a full valuation allowance will be required on losses reported in future periods. 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.

## **Overview**

We are a biotechnology company developing monoclonal antibody-based therapies for the treatment of cancer and autoimmune diseases. Our business strategy is focused on advancing our portfolio of product candidates in diseases with unmet medical need and significant market potential. We currently have four product candidates in ongoing clinical trials, SGN-40, SGN-33, SGN-30 and SGN-35. In addition, we have two other lead preclinical product candidates, SGN-70 and SGN-75. Our pipeline of product candidates is based upon two technologies: genetically engineered monoclonal antibodies and monoclonal antibody-drug conjugates (ADCs). These technologies enable us 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.

In addition to our internal pipeline of product candidates, we have ADC collaborations with leading biotechnology and pharmaceutical companies, including, Genentech, Bayer, CuraGen, Progenics, MedImmune, PDL BioPharma and Agensys. We also have internal research and in-licensing programs for novel antigens and new monoclonal antibodies to provide future opportunities for pipeline growth.

We do not currently have any commercial products for sale. All of our product candidates are in relatively early stages of development and 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, 2006, we had an accumulated deficit of approximately \$179.6 million. Over the next several years, we expect to incur substantial expenses as we continue to invest in research, development and manufacturing and move towards commercialization of our product candidates. Our commitment of resources to research and the continued development and potential commercialization of our product candidates will require substantial additional funds and resources. Our operating expenses will likely increase as we invest in research or acquire additional technologies, as additional product candidates are selected for clinical development and as some of our earlier stage product candidates move into later stage clinical development. In addition, we may incur significant milestone payment obligations as our product candidates progress through clinical trials towards commercialization. Because a substantial portion of our revenues for the foreseeable future will depend on achieving development and clinical milestones under our existing collaboration and license agreements, particularly our SGN-40 collaboration with Genentech, as well as entering into new collaboration and license agreements, our results of operations may vary substantially from year to year and quarter to quarter. 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.



**Table of Contents****Results of Operations****Years Ended December 31, 2006, 2005 and 2004****Revenues**

Total revenues in 2006 increased by 3% to \$10.0 million from 2005 and increased in 2005 by 46% to \$9.8 million from 2004. These increases primarily reflect the earned portion of technology access fees and milestone payments received under our ADC collaborations as well as funded research and material supply fees. Revenues are summarized by collaborators as follows:

Collaboration and license agreement revenues (\$ in thousands)	Annual percentage change				
	2006	2005	2004	2006/2005	2005/2004
Genentech	\$ 4,117	\$ 4,926	\$ 2,901	-16%	70%
CuraGen	1,760	2,001	888	-12%	125%
Progenics	1,621	401		304%	
MedImmune	932	573	80	63%	616%
Bayer	929	805	188	15%	328%
PDL Biopharma	163	123	1,265	33%	-90%
Genencor		535	782	-100%	-32%
Other collaborations	483	393	597	23%	-34%
<b>Total</b>	<b>\$ 10,005</b>	<b>\$ 9,757</b>	<b>\$ 6,701</b>	<b>3%</b>	<b>46%</b>

Revenues in 2006 consist primarily of amounts earned under our Genentech, CuraGen and Progenics collaborations, which represent approximately \$7.5 million, or 75%, of total collaboration and license agreement revenues. Similarly, revenues in 2005 consist primarily of amounts earned under our Genentech and CuraGen collaborations, which represent approximately \$6.9 million, or 71%, of total collaboration and license agreement revenues. Revenues in 2004 consist primarily of amounts earned under our Genentech, PDL BioPharma, CuraGen and Genencor collaborations, which represent approximately \$5.8 million, or 87%, of total collaboration and license agreement revenues. These revenues will vary from year to year and from quarter to quarter depending on the development progress made by our collaborators with their product candidates.

**Genentech**

We entered into an ADC collaboration with Genentech in April 2002, pursuant to which we have received technology access fees totaling \$7.7 million. These fees are being recognized as revenue over the five year research period of the collaboration. Revenues in 2006 decreased by \$809,000, or 16%, from 2005 reflecting lower milestone payments and funded research and supply fees earned during the year. Revenues in 2005 increased by approximately \$2.0 million, or 70%, compared to 2004 due primarily to higher technology access fees earned during the year.



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

In January 2007, we entered into an exclusive worldwide license agreement with Genentech for the development and commercialization of SGN-40. Under the terms of the agreement, we received an upfront payment of \$60 million in February 2007 and are entitled to receive research and development funding, potential future milestone payments and royalties on product sales. Payments to be received from Genentech during the six year development period will be recognized as revenue over the development period using a time-based method. We expect revenues earned from Genentech to increase in 2007 as a result of this collaboration.

### *CuraGen*

We entered into a collaboration agreement with CuraGen in June 2004 which included an upfront technology access fee of \$2.0 million. This fee, along with additional access fees received, was recognized as revenue over the two year research period of the collaboration. Revenues in 2006 decreased by \$241,000, or

## **Table of Contents**

12%, from 2005 reflecting the partial year amortization of the upfront technology access fee and included a milestone payment resulting from CuraGen's initiation of clinical testing of its lead ADC product candidate utilizing our technology. Revenues in 2005 increased by \$1.1 million, or 125%, from 2004 reflecting the full year amortization of the upfront technology access fee in 2005. We may receive additional progress-dependent milestones, annual maintenance fees and support fees as CuraGen's ADC product candidates progress through development and royalties on product sales.

### ***Progenics***

We entered into a collaboration agreement with PSMA Development Company LLC, now a wholly-owned subsidiary of Progenics, in June 2005 which included an upfront technology access fee of \$2.0 million. This fee is being recognized as revenue over the three year research period of the collaboration. Revenues increased by \$1.2 million, or 304%, in 2006 and totaled \$401,000 in 2005 reflecting the earned portion of the upfront technology access fee in each year. The increased revenues in 2006 also include funded research and material supply fees and milestone payments earned. We anticipate receiving additional progress-dependent milestones, annual maintenance fees and support fees as Progenics' ADC product candidate progresses through development and royalties on product sales.

### ***MedImmune***

We entered into a collaboration agreement with MedImmune in April 2005 which included an upfront technology access fee of \$2.0 million. This fee is being recognized as revenue over the two year research period of the collaboration. Revenues increased by \$359,000, or 63%, in 2006, and increased by \$493,000, or 616%, in 2005 primarily attributable to the earned portion of the upfront technology access fee. We anticipate receiving additional progress-dependent milestones, annual maintenance fees and support fees as MedImmune's ADC product candidate progresses through development and royalties on product sales.

### ***Bayer***

We entered into a collaboration agreement with Bayer in September 2004 which included an upfront technology access fee of \$2.0 million. This fee is being recognized as revenue over the three year research period of the collaboration. Revenues increased by \$124,000, or 15%, in 2006 primarily reflecting a full year of amortization of the upfront technology access fee as well as increased funded research and material supply fees. Revenues increased by \$617,000, or 328%, in 2005 reflecting a partial year's recognition of the upfront technology access fee. We anticipate receiving additional progress-dependent milestones, annual maintenance fees and support fees as Bayer's ADC product candidate progresses through development and royalties on product sales.

### ***PDL BioPharma***

We entered into a collaboration agreement with Eos Biotechnology in June 2001, which was assumed by PDL BioPharma in 2003 upon its acquisition of Eos Biotechnology. We amended the collaboration agreement in January 2004. Technology access fees are being recognized as revenue over the four year research period beginning January 2004. Revenues decreased approximately \$1.1 million, or 90%, in 2005 due to lower research and material supply fees and milestone payments earned in 2005 compared to 2004. We anticipate receiving additional progress-dependent milestones, annual maintenance fees and support fees as PDL BioPharma's ADC product candidates progress through development and royalties on product sales.

*Genencor*

We entered into a collaboration with Genencor in 2002 and in January 2006 the research period of the agreement expired. Revenues decreased by \$247,000, or 32%, in 2005 primarily due to lower funded research and material supply fees received in 2005 compared to 2004.

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

Research and development expenses increased 16% to \$40.1 million in 2006 from 2005 and decreased 7% to \$34.7 million in 2005 from 2004. Our research and development expenses are summarized as follows:

Research & development (\$ in thousands)	2006	2005	2004	Annual percentage change	
				2006/2005	2005/2004
Research	\$ 12,608	\$ 12,527	\$ 11,017	1%	14%
Development and contract manufacturing	16,885	15,686	19,664	8%	-20%
Clinical	7,586	6,458	6,321	17%	2%
Share-based compensation expense	3,057	12	206	25,375%	-94%
<b>Total</b>	<b>\$ 40,136</b>	<b>\$ 34,683</b>	<b>\$ 37,208</b>	<b>16%</b>	<b>-7%</b>

Research expenses include, among other things, personnel, occupancy and laboratory expenses associated with the discovery and identification of new monoclonal antibodies and the development of novel classes of stable linkers and potent cell-killing drugs. 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 of \$12.6 million in 2006 increased less than 1% from 2005, primarily due to slightly higher personnel expenses. The increase in research expenses in 2006 is net of lower in-license fees paid to gain access to new technologies. Research expenses increased 14% to \$12.5 million in 2005 from 2004 primarily due to higher personnel expenses, related general lab supplies, in-license fees and depreciation related to new lab equipment purchases.

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, including IND-enabling pharmacology and toxicology studies. Development and contract manufacturing expenses also include quality control and assurance activities, including storage and shipment services of our drug product candidates. Development and contract manufacturing costs increased 8% to \$16.9 million in 2006 from 2005 primarily due to the timing of manufacturing campaigns. Manufacturing costs decreased by \$3.5 million for SGN-40 and decreased \$1.3 million for SGN-35 in 2006 from 2005, reflecting the substantial completion of related activities for those programs with Abbott Laboratories for SGN-40 and Albany Molecular for SGN-35 during 2005. Contract manufacturing costs increased \$2.6 million for SGN-70 and increased \$1.2 million for SGN-33 in 2006 from 2005 primarily reflecting new activities with Laureate Pharma. Development and contract manufacturing expenses in 2006 also include increases in personnel expenses, lab supplies associated with higher staffing levels and depreciation expenses. Development and contract manufacturing costs decreased 20% to \$15.7 million in 2005 from 2004. Manufacturing costs decreased by \$9.9 million for SGN-30 in 2005 from 2004, reflecting the substantial completion of manufacturing activities during 2004 with Abbott Laboratories. Manufacturing costs increased by \$3.6 million in 2005 from 2004 for SGN-40. Contract manufacturing expenses in 2005 also reflect increases in staffing costs and quality control and assurance activities, including storage and shipment services of our drug product candidates.

Clinical expenses include personnel expenses, travel, occupancy costs and external clinical trial costs including principal investigator fees, clinical site expenses, clinical research organization charges and regulatory activities associated with conducting human clinical trials. Clinical costs increased 17% to \$7.6 million in 2006 from 2005 and increased 2% to \$6.5 million in 2005 from 2004. In 2006, clinical expenses increased due to higher personnel expenses and third party costs associated with SGN-40 and SGN-33, which were partially offset by decreased third party costs due to the discontinuation of our SGN-15 program. In 2005, clinical expenses increased due to higher personnel costs and expanded third-party costs for our SGN-40 phase I trials.

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

Share-based compensation expenses reflect the non-cash charge relating to the adoption of FAS 123R on January 1, 2006, which requires us to measure the fair value of all employee share-based payments and recognize that value as an operating expense over the vesting period of the stock option. Approximately \$3.1 million was attributable to research and development expenses during 2006.

**Table of Contents**

We utilize our employee and infrastructure resources across multiple projects, including our discovery and research programs directed towards identifying monoclonal antibodies and new classes of stable linkers and cell-killing drugs. Many of our costs are not directly attributable to a specific project and we have not historically allocated our infrastructure costs or accounted for internal research and development costs on a project-by-project basis. As a result, we do not report actual total costs incurred for each of our clinical and preclinical projects on a project-by-project basis. We do, however, separately account for significant third-party costs of development programs identified as product candidates for further preclinical and clinical development. The following table shows expenses incurred for preclinical study support, contract manufacturing for clinical supplies and clinical trial services provided by third parties as well as milestone payments for in-licensed technology for each of our product candidates and the remaining unallocated costs for such periods:

Product candidates (\$ in thousands)				Annual Percentage Change		(5 years)
	2006	2005	2004	2006/2005	2005/2004	January 1, 2002 to December 31, 2006
SGN-70	\$ 2,881	\$ 286	\$	907%		\$ 3,207
SGN-33	1,764	742		138%		2,506
SGN-35	1,737	2,844	2,532	-39%	12%	8,650
SGN-40	1,705	4,400	835	-61%	427%	7,266
SGN-30	1,545	1,749	12,183	-12%	-86%	19,439
SGN-15	161	1,067	1,529	-85%	-30%	9,708
Total third party costs	9,793	11,088	17,079	-12%	-35%	50,776
Unallocated costs and overhead	27,286	23,583	19,923	16%	18%	98,728
Share-based compensation expense	3,057	12	206	25,375%	-94%	4,725
Total research and development	\$ 40,136	\$ 34,683	\$ 37,208	16%	-7%	\$ 154,229

Our third party costs for SGN-70 and SGN-33 in 2006 included activities conducted by Laureate Pharma to perform scale-up and GMP manufacturing to support clinical trials. We expect third party costs for SGN-70 and SGN-33 to increase from amounts incurred in 2006 as pharmacology/toxicology activities increase and clinical and manufacturing activities expand. SGN-35 third party costs in 2006 and 2005 are primarily attributable to contract manufacturing and preclinical studies necessary to initiate a phase I clinical trial in 2006. We expect third party costs for SGN-35 to increase as we expand our clinical trials. SGN-40 costs primarily reflect third party clinical costs in 2006 and contract manufacturing costs incurred at Abbott Laboratories in 2005. We expect third party costs associated with clinical trials of SGN-40 to increase as we continue to enroll patients and expand our SGN-40 phase I and II clinical trials and initiate additional trials. Such third party costs will be reimbursed by Genentech under our new license agreement entered into in January 2007 for the worldwide development and commercialization of SGN-40. SGN-30 third party costs in 2006 are attributable to patient enrollments in our phase II clinical trials in the United States and Europe. 2005 costs attributable to SGN-30 were lower than costs in 2004 due to manufacturing activities for SGN-30 at Abbott Laboratories that occurred in 2004. We have initiated clinical trials of SGN-30 in cooperation with the National Cancer Institute (NCI), the costs of which will be incurred by the NCI and not reflected in our future financial results. As a result, we expect third party costs for SGN-30 to decrease from the amounts incurred in 2006 as we conclude our company-sponsored phase II clinical trials.

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 may 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;



**Table of Contents**

The length of time required to enroll trial participants;

The number 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 may include 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 research, development, contract manufacturing and clinical expenses will continue to grow in the foreseeable future as we expand our discovery and preclinical activities, as new product candidates enter clinical trials and as we advance our product candidates already in clinical trials to new clinical sites in North America and Europe. These expenses will fluctuate based upon many factors including the degree of collaborative activities, timing of manufacturing campaigns, numbers of patients enrolled in our clinical trials and the outcome of each clinical trial event.

The risks and uncertainties associated with our research and development projects are discussed more fully in Item 1A Risk Factors. As a result of the uncertainties discussed above, we are unable to determine with any 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 & Administrative (\$ in thousands)	Annual percentage change				
	2006	2005	2004	2006/2005	2005/2004
General and administrative	\$ 8,397	\$ 7,145	\$ 6,498	18%	10%
Share-based compensation expense	1,677		663	NA%	-100%
<b>Total</b>	<b>\$ 10,074</b>	<b>\$ 7,145</b>	<b>\$ 7,161</b>	<b>41%</b>	<b>0%</b>



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

General and administrative expenses increased to approximately \$10.1 million in 2006, or 41%, compared to approximately \$7.1 million in 2005 and \$7.2 million in 2004. General and administrative expenses, excluding share-based compensation expense, increased 18% in 2006 from 2005 and increased 10% in 2005 from 2004. In 2006, the increase was primarily attributable to consulting fees, administrative personnel costs, and professional service fees. In 2005, the increase was primarily attributable to additional administrative personnel and recruiting fees. Share-based compensation expense in 2006 reflect non-cash charges relating to the adoption of FAS 123R, which requires us to measure the fair value of all employee share-based payments and recognize that value as an operating expense over the vesting period of the stock option. Share-based compensation expense in 2004 is attributable to scheduled amortization of deferred share-based compensation and accelerated vesting of stock options related to employee severance pay. We anticipate that general and administrative expenses will increase in 2007 as a result of costs related to adding personnel in support of our operations.

**Table of Contents****Investment income, net**

Investment income, net (\$ in thousands)	Annual percentage change				
	2006	2005	2004	2006/2005	2005/2004
Total	\$ 4,190	\$ 2,638	\$ 2,229	59%	18%

Investment income increased 59% to \$4.2 million in 2006 from 2005 and increased 18% to \$2.6 million in 2005 from 2004. In 2006, the increase was primarily due to increasing average interest yields and additional interest income received from investing the net proceeds of approximately \$43.1 million from our follow-on public offerings of common stock that were completed in April and May 2006. Investment income during 2006 reflects realized losses of \$289,000 following an investment decision made during the second quarter of 2006 to rebalance the portfolio away from mortgage-backed securities in an effort to improve the overall yield of the portfolio. In 2005, the increase was primarily due to increasing average interest yields. We expect investment income to increase in 2007 reflecting the higher level of invested funds resulting from payments received from Genentech pursuant to the SGN-40 collaboration.

**Non-cash accretion of preferred stock deemed dividend**

Non-cash accretion of preferred stock deemed dividend (\$ in thousands)	2006	2005	2004
Total	\$	\$	\$ 36,558

Non-cash accretion of preferred stock deemed dividend was \$36.6 million in 2004. In connection with our Series A convertible preferred stock financing in July 2003, we recorded a beneficial conversion feature on the preferred stock. The beneficial conversion feature has been treated as a preferred stock deemed dividend, which resulted in an increase to reported net loss in arriving at net loss attributable to common stockholders. The non-cash accretion of the preferred stock deemed dividend was recorded using the effective interest method through the date of earliest conversion in July 2004 and therefore affected only 2004 and 2003. Non-cash accretion charges did not have an effect on net loss or cash flows for the applicable reporting periods or have an impact on total stockholders' equity as of the applicable reporting dates.

**Liquidity and Capital Resources**

Liquidity and Capital Resources	December 31,		
	2006	2005	2004
Cash, cash equivalents and short-term and long-term investment securities	\$ 86,573	\$ 79,207	\$ 105,898
Working capital	76,880	33,048	30,233
Stockholders' equity	88,234	75,458	103,833

  

	Year ended December 31,		
	2006	2005	2004
Cash provided by (used in):			
Operating activities	\$ (35,181)	\$ (25,472)	\$ (23,279)
Investing activities	(10,761)	25,831	(40,330)
Financing activities	43,923	1,152	63,629
Capital expenditures (included in Investing Activities)	(1,680)	(1,402)	(5,723)

We have financed the substantial majority of our operations through the public and private sale of equity securities, which is supplemented by funding received from our collaboration and license agreements. During 2006 we received approximately \$43.1 million through the sale of our common stock and approximately \$4.3 million in fees and milestone payments under our collaboration and license agreements. To a lesser degree,

## Table of Contents

we have also financed our operations through interest earned on cash and cash equivalents. These financing sources have historically allowed us to maintain adequate levels of cash and investments.

Our combined cash, cash equivalents and investment securities were \$86.6 million at December 31, 2006, compared to \$79.2 million at December 31, 2005 and \$105.9 million at December 31, 2004. The increase in 2006 was primarily the result of net proceeds of \$43.1 million from our common stock financings in the second quarter, offset by \$35.2 million used to finance our operations. Our working capital was \$76.9 million at December 31, 2006, compared to \$33.0 million at December 31, 2005 and \$30.2 million at December 31, 2004. The increase in working capital during 2006 reflects the proceeds from our common stock financings as well as changes in the composition of our investment portfolio. We have structured our investment portfolio so that scheduled maturities of investment securities can be used to fund our working capital needs. As of December 31, 2006, most of our investment portfolio was invested in short-term securities in recognition of market yields. Our cash, cash equivalents, short-term and long-term investments are held in a variety of interest-bearing instruments, consisting of U.S. government and agency securities, high-grade U.S. corporate bonds, taxable municipal bonds, commercial paper and money market accounts.

Capital expenditures of \$1.7 million in 2006 and \$1.4 million in 2005 consisted primarily of lab equipment and computers and related information systems in support of our research and development activities and in support of employee growth. Capital expenditures of \$5.7 million in 2004 consisted of leasehold improvements, lab equipment, furniture and fixtures, primarily in connection with the expansion of our existing headquarters and operations facility for lab and office expansion which was completed during August 2004. We expect that our 2007 capital expenditures will increase compared to 2006 reflecting higher capital purchases and facilities improvements.

At our currently planned spending rate, we believe our remaining financial resources in addition to the expected fees and milestone payments earned under new and existing collaboration and license agreements will be sufficient to fund our operations for at least the next several years. We expect that our operating activities will generate \$35 to \$45 million of cash in 2007. However, changes in our spending rate may occur that would consume available capital resources sooner, such as increased manufacturing and clinical trial expenses preceding commercialization of a product candidate. Further, this estimate is based on the assumption that successful progress is made pursuant to our collaboration with Genentech resulting in the receipt of payments and milestones. While we do not foresee the need to raise additional capital in the short-term, our long-term needs may cause us to seek additional funding through some or all of the following methods: corporate collaborations, licensing arrangements, or public or private equity financings. We do not know whether additional capital will be available when needed, or that, if available, we will obtain financing on terms favorable to our stockholders or us. If we are unable to raise additional funds should we need them, we may be required to delay, reduce or eliminate some of our development programs, which may adversely affect our business and operations.

We expect to incur substantial costs as we continue to develop and commercialize our product candidates. We anticipate that our rate of overall spending will accelerate as a result of the increased costs and expenses associated with adding personnel, clinical trials, regulatory filings, manufacturing, and research and development activities. However, we may experience fluctuations in incurring these costs from quarter to quarter based on the timing of manufacturing campaigns, accrual of patients to clinical trials and collaborative activities. 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.

In 2007, we expect our revenues to range from \$17 million to \$19 million, which reflects the earned portion of the upfront payment and estimated milestones and funded research payments expected to be received from Genentech, as well as revenues earned under our existing ADC collaborations. In total, across all of our collaborations, we expect to receive between \$80 and \$90 million in cash during 2007; the majority of which will be under our SGN-40 license agreement. In 2007, we expect our operating expenses to range from \$55 million to \$65 million with increases over 2006 levels driven primarily by:

Manufacturing campaigns for SGN-33 in preparation for phase II clinical trials;



**Table of Contents**

Costs associated with continued expansion and acceleration of our clinical programs particularly SGN-40 and SGN-33; and

Increases in headcount and employee costs, led by growth in our clinical development team.

We expect that 2007 expenses will include our non-cash expenses projected to be in the \$7 to \$9 million range. Of this amount, stock-based compensation expense is expected to be in the range of \$5 to \$7 million. This estimate is based on a number of assumptions, including future stock prices and the number and timing of option grants, and is therefore subject to change. We expect operating expenses to be relatively consistent quarter-over-quarter, although the timing of certain activities, such as manufacturing campaigns, the rate of clinical trial accruals and the speed at which we can hire new employees is variable and subject to change. We expect that research and development expenses will continue to comprise approximately 80 percent of our total expenses.

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 for at least the next several years. The amounts set forth below could be substantially higher if we are required to make milestone payments or if we receive regulatory approvals or achieve commercial sales and are required to pay royalties earlier than anticipated.

The following are our future minimum contractual commitments for the periods subsequent to December 31, 2006 (in thousands):

	<b>Total</b>	<b>2007</b>	<b>2008</b>	<b>2009</b>	<b>2010</b>	<b>Thereafter</b>
Operating leases	\$ 9,934	\$ 2,197	\$ 2,231	\$ 2,253	\$ 2,291	\$ 962
Manufacturing, license and collaboration agreements	4,528	3,778	335	205	210	
Lab Equipment	381	381				
<b>Total</b>	<b>\$ 14,843</b>	<b>\$ 6,356</b>	<b>\$ 2,566</b>	<b>\$ 2,458</b>	<b>\$ 2,501</b>	<b>\$ 962</b>

The minimum payments under manufacturing, license and collaboration agreements in 2006 primarily represent contractual obligations related to manufacturing campaigns to perform scale-up and cGMP manufacturing for monoclonal antibody and ADC product candidates for use in our clinical trials, including our contract manufacturing agreement with Laureate Pharma. The above table excludes royalties and up to approximately \$10.0 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, regulatory and/or commercial milestones. Because the achievement of these milestones is neither probable nor reasonably estimable, such contingent payments have not been included in the above table.

As part of the terms of our office and laboratory lease, we have collateralized certain obligations under the lease with approximately \$486,000 of our investments and the majority of our property and equipment. These investment securities are restricted as to withdrawal and are managed by a third party. In the event that we fail to meet specific thresholds of market capitalization, stockholders' equity or cash and investment balances, we are obligated to increase our restricted investment balance to approximately \$3.4 million. At December 31, 2006, we were in compliance with these thresholds.

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

In accordance with our 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, high-grade U.S. corporate bonds, taxable municipal bonds, adjustable mortgage-backed securities, commercial paper and money market accounts. Such securities are subject to interest rate risk and will rise and fall in value if market interest rates change; however, we do not expect any material loss from such interest rate changes.

**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>	44
<u>Balance Sheets</u>	46
<u>Statements of Operations</u>	47
<u>Statements of Stockholders' Equity</u>	48
<u>Statements of Cash Flows</u>	49
<u>Notes to Financial Statements</u>	50



**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Shareholders

of Seattle Genetics, Inc.:

We have completed integrated audits of Seattle Genetics, Inc.'s financial statements and of its internal control over financial reporting as of December 31, 2006 in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

*Financial statements*

In our opinion, the financial statements listed in the accompanying index present fairly, in all material respects, the financial position of Seattle Genetics, Inc. at December 31, 2006 and 2005, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2006 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit of financial statements includes 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. We believe that our audits provide a reasonable basis for our opinion.

As discussed in Note 1 to the financial statements, the Company changed the manner in which it accounts for share-based compensation in 2006.

*Internal control over financial reporting*

Also, in our opinion, management's assessment, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A, that the Company maintained effective internal control over financial reporting as of December 31, 2006 based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, based on criteria established in *Internal Control - Integrated Framework* issued by the COSO. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management's assessment and on the effectiveness of the Company's internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

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

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

**Table of Contents**

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 8, 2007

**Table of Contents****Seattle Genetics, Inc.****Balance Sheets****(In thousands)**

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 9,137	\$ 11,156
Short-term investments	73,450	31,315
Interest receivable	539	678
Accounts receivable	898	683
Prepaid expenses and other	1,405	314
Total current assets	85,429	44,146
Property and equipment, net	7,794	8,532
Restricted investments	486	605
Long-term investments	3,986	36,736
Total assets	\$ 97,695	\$ 90,019
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities		
Accounts payable and accrued liabilities	\$ 5,389	\$ 5,045
Current portion of deferred revenue	3,160	6,053
Total current liabilities	8,549	11,098
Long-term liabilities		
Deferred rent	513	513
Deferred revenue, less current portion	399	2,950
Total long-term liabilities	912	3,463
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized: Series A convertible preferred stock, 1,500,000 shares issued and outstanding at December 31, 2006 and 2005	2	2
Common stock, \$0.001 par value, 100,000,000 shares authorized; 51,029,542 shares issued and outstanding at December 31, 2006 and 42,379,895 shares issued and outstanding at December 31, 2005	51	42
Additional paid-in capital	267,807	219,159
Accumulated other comprehensive loss	(37)	(171)
Accumulated deficit	(179,589)	(143,574)
Total stockholders' equity	88,234	75,458
Total liabilities and stockholders' equity	\$ 97,695	\$ 90,019

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

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

	Years Ended December 31,		
	2006	2005	2004
Revenues from collaboration and license agreements	\$ 10,005	\$ 9,757	\$ 6,701
Operating expenses			
Research and development	40,136	34,683	37,208
General and administrative	10,074	7,145	7,161
Total operating expenses	50,210	41,828	44,369
Loss from operations	(40,205)	(32,071)	(37,668)
Investment income, net	4,190	2,638	2,229
Net loss	(36,015)	(29,433)	(35,439)
Non-cash accretion of preferred stock deemed dividend			(36,558)
Net loss attributable to common stockholders	\$ (36,015)	\$ (29,433)	\$ (71,997)
Net loss per share attributable to common stockholders basic and diluted	\$ (0.74)	\$ (0.70)	\$ (1.80)
Shares used in computation of net loss per share attributable to common stockholders basic and diluted	48,659	42,238	39,985

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

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

	Preferred Stock		Common Stock			Additional paid-in capital	Deferred stock compensation	Accumulated Comprehensive deficit	Accumulated Other Comprehensive Income	Total Stockholders Equity
	Shares	Amount	Shares	Amount	Amount					
Balances at December 31, 2003	1,640	\$ 2	32,031	\$ 32	\$ 154,497	\$ (990)	\$ (78,702)	\$ 39	\$ 74,878	
Net loss							(35,439)		(35,439)	
Unrealized loss, net of reclassification adjustment								(104)	(104)	
Total comprehensive loss									(35,543)	
Issuance of common stock for employee stock purchase plan			78	1	235				236	
Stock option exercises			425		1,290				1,290	
Public offering (net of issuance costs of \$4,310)			8,050	8	62,094				62,102	
Conversion of preferred series A stock into common stock	(140)		1,400	1					1	
Deferred share-based compensation					(605)	605				
Amortization of deferred share-based compensation						385			385	
Accelerated vesting of stock options for employee severance					348				348	
Remeasurement and issuance of stock options in exchange for consulting services					136				136	
Balances at December 31, 2004	1,500	2	41,984	42	217,995		(114,141)	(65)	103,833	
Net loss							(29,433)		(29,433)	
Unrealized loss, net of reclassification adjustment								(106)	(106)	
Total comprehensive loss									(29,539)	
Issuance of common stock for employee stock purchase plan			98		400				400	
Stock option exercises			298		752				752	
Remeasurement and issuance of stock options in exchange for consulting services					12				12	
Balances at December 31, 2005	1,500	2	42,380	42	219,159		(143,574)	(171)	75,458	
Net loss							(36,015)		(36,015)	
Unrealized gain, net of reclassification adjustment								134	134	
Comprehensive loss									(35,881)	
Public offering (net of issuance costs of \$229)			7,300	7	37,212				37,219	

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

Issuance of common stock to entities affiliated with Baker Brothers Investments	1,129	1	5,926	5,927							
Issuance of common stock for employee stock purchase plan	97		391	391							
Stock option exercises	124	1	385	386							
Stock based compensation			4,640	4,640							
Remeasurement and issuance of stock options in exchange for consulting services			94	94							
Balances at December 31, 2006	1,500	\$ 2	51,030	\$ 51	\$ 267,807	\$	\$ (179,589)	\$	(37)	\$	88,234

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



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

	Years Ended December 31,		
	2006	2005	2004
<b>Operating activities</b>			
Net loss	\$ (36,015)	\$ (29,433)	\$ (35,439)
Adjustments to reconcile net loss to net cash used in operating activities			
Stock-based compensation expense	4,734	12	869
Depreciation and amortization	2,418	2,333	1,760
Amortization on investments	(51)	1,235	2,306
Deferred rent		41	82
Changes in operating assets and liabilities			
Interest receivable	139	140	(148)
Accounts receivable	(215)	794	(651)
Prepaid expenses and other	(1,091)	162	(131)
Accounts payable and accrued liabilities	344	230	3,089
Deferred revenue	(5,444)	(986)	4,984
Net cash used in operating activities	(35,181)	(25,472)	(23,279)
<b>Investing activities</b>			
Purchases of securities available for sale	(118,171)	(38,025)	(125,817)
Proceeds from maturities of securities available for sale	78,196	64,980	84,921
Proceeds from sales of securities available for sale	30,894	278	6,289
Purchases of property and equipment	(1,680)	(1,402)	(5,723)
Net cash (used in) provided by investing activities	(10,761)	25,831	(40,330)
<b>Financing activities</b>			
Net proceeds from issuance of common stock	43,146		62,103
Proceeds from exercise of stock options and employee stock purchase plan	777	1,152	1,526
Net cash provided by financing activities	43,923	1,152	63,629
Net (decrease) increase in cash and cash equivalents	(2,019)	1,511	20
Cash and cash equivalents, at beginning of period	11,156	9,645	9,625
Cash and cash equivalents, at end of period	\$ 9,137	\$ 11,156	\$ 9,645

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



**Table of Contents**

**Seattle Genetics, Inc.**

**Notes to Financial Statements**

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

*Nature of business*

Seattle Genetics, Inc., the Company, was incorporated in the State of Delaware on July 15, 1997 for the purpose of discovering and developing monoclonal antibody-based drugs to treat cancer and autoimmune diseases. The Company's product candidates are based primarily on two technologies: genetically engineered monoclonal antibodies and antibody-drug conjugates (ADCs). These technologies enable the Company to develop monoclonal antibodies that are intended to kill target cells on their own, as well as increase the potency of monoclonal antibodies by linking them to other cell-killing agents. The Company operates in a single reporting segment; the development of pharmaceutical products on its own behalf, or in collaboration with others.

*Capital Requirements*

Over the next several years, the Company may seek additional funding through public or private financings, including equity financings, and through other means, including collaborations and license agreements. If the Company can not 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 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. The Company invests its cash and cash equivalents with major financial institutions, which, at times, exceed federally insured limits. The Company has not experienced any significant losses on its cash and cash equivalents.

*Investments*

Investments in securities with maturities of less than one year at the date of acquisition, 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. Management's classification of its marketable securities is in accordance with the provisions of Statement of Financial Accounting Standards No. 115, Accounting for Certain Investments in Debt and Equity Securities. The Company classifies its securities as available-for-sale, which are reported at fair value with related unrealized gains and losses included as a component of stockholders' equity. Realized gains and losses, and declines in value of securities judged to be other than temporary, are included in investment income. The Company has determined that unrealized losses are temporary as the extent of the decline, in both dollars and percentage of cost is not significant, and the Company has the ability and intent to hold the investments until it recovers at least substantially all of the cost of the investment. 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. Interest and dividends on all securities are included in investment income.

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

Restricted investments consist of a money market account and government bonds backed by U.S. government agencies. These investments are carried at fair value, and are restricted as to withdrawal in accordance with the lease of the Company's office and laboratory facility. Restricted investments are held in the Company's name with a major financial institution.

*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 and office equipment	3
Vehicles	5

Leasehold improvements are amortized over the shorter of the term of the applicable lease or the estimated useful life of the asset. Gains and losses from the disposal of property and equipment are reflected in the statement of operations at the time of disposition and have not been significant. Expenditures for additions and improvements to the Company's facility are capitalized and expenditures for maintenance and repairs are charged to expense as incurred.

*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 by comparing the anticipated undiscounted net cash flows to the related asset's carrying value. The amount of a recognized impairment loss is the excess of an asset's carrying value over its fair value. If an impairment exists, the asset is written down to its estimated fair value. The Company has not recognized any impairment losses through December 31, 2006.

*Revenue recognition*

The Company recognizes revenue in accordance with Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements (SAB No. 101), as amended by Staff Accounting Bulletin No. 104, Revenue Recognition (SAB No. 104), and Emerging Issues Task Force Issue No. 00-21, Revenue Agreements with Multiple Deliverables (EITF No. 00-21). Many of the Company's agreements contain multiple revenue elements including upfront payments, license fees, milestone payments, royalties, maintenance fees and payments received for the delivery of supplies or services. Each agreement may contain some or all these elements and the assessment of multiple element arrangements requires judgment in order to determine the appropriate time, or period of time, that revenue should be recognized. Revenues are recognized when persuasive evidence of an agreement exists, delivery has occurred or services have been rendered, the fees are fixed or determinable and collectibility is reasonably assured. Where activities represent the culmination of a separate earnings process and verifiable evidence of the fair value of each element can be established, revenue is recognized as the activities are completed. When verifiable evidence of fair value cannot be established for each undelivered element, revenue is deferred until all elements have been delivered or until verifiable evidence of the fair value for any undelivered element can be determined. Where activities represent continuing obligations and fair value cannot be determined, revenue is recognized over the service period using either a time-based or an activity-based approach as appropriate in the circumstance.

**Table of Contents**

**Seattle Genetics, Inc.**

**Notes to Financial Statements (Continued)**

Nonrefundable upfront payments and maintenance and license fees, for which no further performance obligations exist are recognized as revenue on the earlier of when payments are received or when collection is assured. When contracts include nonrefundable upfront payments, maintenance fees or license fees, including any guaranteed time-based payments, that require continuing involvement in the form of development, manufacturing or other efforts by the Company, the Company evaluates whether verifiable evidence of fair value of the efforts to be provided exists. If no such evidence exists, the Company recognizes the payments received as revenue over the development period or other period over which services are to be provided.

Payments for the achievement of substantive at-risk milestones are generally recognized as revenue when the milestone is achieved. However, payments for milestones which are not the result of the achievement of a substantive at-risk milestone or from an arrangement that contains multiple delivery elements for which verifiable and objective evidence of fair value cannot be established for each element are recognized as revenue over the research period. 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.

The Company also performs research and development activities on behalf of collaborative partners. Revenue from research and development services is generally recognized as the service is provided. However, if the arrangement 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. The Company generally bills the collaborator monthly, quarterly or upon the completion of the effort, based on the terms of each agreement. Amounts earned, but not paid by the collaborator, if any, are included in accounts receivable in the accompanying balance sheets. Deferred revenue arises from payments received in advance of the culmination of the earnings process. Deferred revenue expected to be recognized within the next twelve months is classified as a current liability. Deferred revenue will be recognized as revenue in future periods when the applicable revenue recognition criteria have been met.

*Research and development expenses*

Research and development expenses consist of salaries, benefits and other related costs, third-party contract and outside service fees and facilities and overhead expenses for drug discovery and research, development activities, preclinical studies and clinical trial activities. Research and development activities are expensed as incurred. In-licensing fees and other costs to acquire technologies that are utilized in research and development and that are not expected to have alternative future use are expensed when incurred.

*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 are classified as available for sale and recorded at fair value. Fair value is generally determined by quoted market prices.

*Concentration of credit risk*

Cash, cash equivalents and investments are invested in deposits with major banking and brokerage firms. The Company has not experienced any significant losses on its deposits of cash, cash equivalents and investments as a result of credit risk concentration. The Company invests its excess cash in accordance with its investment policy, which has been approved by the Board of Directors and is reviewed periodically by management and with the Company's Audit Committee to minimize credit risk.



**Table of Contents**

**Seattle Genetics, Inc.**

**Notes to Financial Statements (Continued)**

*Major customers*

Three customers under the Company's collaboration and related agreements accounted for 75% of total revenues in 2006, two customers accounted for 71% of total revenues in 2005 and four customers accounted for 87% of total revenues in 2004. Two customers accounted for 96% of accounts receivable at December 31, 2006 and three customers accounted for 95% of accounts receivable at December 31, 2005.

*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.

*Stock-based compensation*

On January 1, 2006, the Company adopted the fair value recognition provisions of Financial Accounting Standards Board (FASB) Statement No. 123(R), Share-Based Payment (FAS 123R). Prior to January 1, 2006, the Company accounted for share-based payments under the recognition and measurement provisions of APB Opinion No. 25, Accounting for Stock Issued to Employees (APB 25), and related Interpretations, as permitted by FASB Statement No. 123, Accounting for Stock-Based Compensation (FAS 123). In accordance with APB 25, no compensation expense was recognized for options granted to employees that had an exercise price equal to or greater than the market value of the underlying common stock on the date of grant.

The Company adopted FAS 123R using the modified prospective method. Under this transition method, compensation expense recognized in the year 2006 includes: (a) compensation related to stock options granted prior to, but not yet vested as of January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of FAS 123; (b) compensation related to stock options granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of FAS 123R; and (c) compensation related to the Company's employee stock purchase plan. In accordance with the modified prospective method, the results for the prior periods have not been restated.

The Company uses the straight-line attribution method for recognizing compensation expense under FAS 123R. Prior to the adoption of FAS 123R, the Company used the accelerated method of expense recognition pursuant to FASB Interpretation No. 28, Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans (FIN 28) under the disclosure-only provisions of FAS 123. For all unvested options outstanding as of January 1, 2006, the previously measured but unrecognized compensation expense, based on the fair value at

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

the original grant date, is recognized on an accelerated basis over the remaining vesting period. For share-based payments granted subsequent to January 1, 2006, compensation expense, based on the fair value on the date of grant, is recognized on a straight-line basis over the vesting period. 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's adoption of FAS 123R requires the Company to determine the amount of eligible windfall tax benefits (the pool of windfall tax benefits) that are available on the adoption date to offset future shortfalls. The Company has elected to calculate its historical pool of windfall tax benefits (i.e., the amount that would have accumulated as of the adoption date of FAS 123R) using the short-cut method. Subsequent to the adoption of FAS 123R, the Company will continue to track the balance of the pool of windfall tax benefits based on windfalls or shortfalls incurred after the adoption date.

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

The Company accounts for options issued to non-employees under FAS 123 and EITF Issue No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. As such, the value of such options is periodically re-measured and adjusted as necessary during their vesting terms.

The impact on the Company's results of operations due to the adoption of recording share-based payment awards under FAS 123R is as follows (in thousands):

	<b>Year Ended</b>
	<b>December 31, 2006</b>
Research and development	\$ 2,963
General and administrative	1,677
<b>Total</b>	<b>\$ 4,640</b>

Due to the adoption of FAS 123R, the Company's basic and diluted net loss increased by \$0.10 in 2006. The Company granted options to purchase a total of 15,000 shares to certain members of its scientific advisory board during the year ended December 31, 2006. The Company has accounted for these non-employee options in accordance with EITF 96-18 and recorded non-cash stock-based compensation expense of \$94,000 for the year ended December 31, 2006. Such amounts have been excluded from the table above which summarizes the effects of adopting FAS 123R.

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 calculated 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:

<b>Option Plan and Directors Plan</b>	<b>Employee Stock Purchase Plan</b>
<b>Years ended December 31,</b>	<b>Years ended December 31,</b>

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

	2006	2005	2004	2006	2005	2004
Risk-free interest rate	4.7%	4.0%	3.7%	4.7%	4.0%	1.5%
Expected lives in years	5.4	5.0	4.3	1.6	1.3	1.2
Expected dividends	0%	0%	0%	0%	0%	0%
Expected volatility	70%	74%	78%	71%	74%	79%

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 historical experience of similar awards, giving consideration to the contractual terms of the stock-based awards, vesting schedules and expectations of future employee behavior. The application of FAS 123(R) assumes a forfeiture rate to reflect the amount of options that are granted, but are 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 that 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 Financial Statements (Continued)****Pro forma information for periods prior to the adoption of FAS 123R**

Results for periods prior to January 1, 2006 have not been restated to reflect the effects of implementing FAS 123R. The following table illustrates the pro forma effect on net loss and net loss per share if a fair value method had been applied for each respective period (in thousands, except per share amounts):

	<b>Years ended December 31,</b>	
	<b>2005</b>	<b>2004</b>
Net loss attributable to common stockholders as reported	\$ (29,433)	\$ (71,997)
Add: stock-based compensation for employees under APB No. 25 included in reported net loss		733
Deduct: total stock-based compensation expense for employees determined under the fair value method	(3,751)	(5,218)
Pro forma net loss attributable to common stockholders	\$ (33,184)	\$ (76,482)
Basic and diluted net loss per share attributable to common stockholders		
As reported	\$ (0.70)	\$ (1.80)
Pro forma	\$ (0.79)	\$ (1.91)

In the pro forma information required under FAS 123 for the periods prior to 2006, the Company accounted for forfeitures as they occurred.

*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 other 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 other parties, including certain employees, collaboration partners, lessors and parties to other transactions with the Company, with respect to certain matters. The Company has agreed to hold the other parties harmless against losses arising from a breach of representations or covenants, or out of intellectual property infringement or other claims made against certain parties. These agreements may limit the time within which an indemnification claim can be made and the amount of the claim. It is not possible to determine the maximum potential amount under these indemnification agreements since the Company has not had any prior indemnification claims to base a maximum amount. 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 Financial Statements (Continued)**

*Recent accounting pronouncements*

*SFAS No. 157, Fair Value Measurements.* SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 is effective for the Company on January 1, 2008 and is not expected to have a material impact on the Company's financial statements.

*FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement 109.* Interpretation 48 prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Benefits from tax positions should be recognized in the financial statements only when it is more likely than not that the tax position will be sustained upon examination by the appropriate taxing authority that would have full knowledge of all relevant information. A tax position that meets the more-likely-than-not recognition threshold is measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. Tax positions that previously failed to meet the more-likely-than-not recognition threshold should be recognized in the first subsequent financial reporting period in which that threshold is met. Previously recognized tax positions that no longer meet the more-likely-than-not recognition threshold should be derecognized in the first subsequent financial reporting period in which that threshold is no longer met. Interpretation 48 also provides guidance on the accounting for and disclosure of unrecognized tax benefits, interest and penalties. Interpretation 48 is effective for the Company on January 1, 2007. The Company is currently evaluating the impact that FIN 48 will have on its financial condition or results of operations; however, the Company does not believe that the adoption of FIN 48 will have a material impact given its net operating losses.

*Staff Accounting Bulletin (SAB) No. 108, Considering the Effects of a Prior Year Misstatements When Quantifying Misstatements in Current Year Financial Statements.* SAB 108 addresses how the effects of prior year uncorrected errors must be considered in quantifying misstatements in the current year financial statements. The effects of prior year uncorrected errors include the potential accumulation of improper amounts that may result in a material misstatement on the balance sheet or the reversal of prior period errors in the current period that result in a material misstatement of the current period income statement amounts. Adjustments to current or prior period financial statements would be required in the event that after application of various approaches for assessing materiality of a misstatement in current period financial statements and consideration of all relevant quantitative and qualitative factors, a misstatement is determined to be material. SAB 108 is applicable to all financial statements issued by the Company after November 15, 2006 and has had no impact on the accompanying financial statements as of December 31, 2006.

*Net loss per share attributable to common stockholders*

Basic and diluted net loss per share attributable to common stockholders 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, and shares of common stock subject to repurchase from the calculation of diluted net loss per share attributable to common stockholders, as such securities are antidilutive for all periods presented.





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

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 attributable to common stockholders (in thousands):

	<b>Years Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
Convertible preferred stock	15,000	15,000	15,811
Warrants to purchase common stock	2,050	2,050	2,050
Options to purchase common stock	5,922	4,977	5,089
Shares of common stock subject to repurchase			23
<b>Total</b>	<b>22,972</b>	<b>22,027</b>	<b>22,973</b>

**2. Investments**

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

	<b>Amortized cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
<b>December 31, 2006</b>				
U.S. corporate obligations	\$ 68,917	\$ 8	\$ (44)	\$ 68,881
U.S. government and agencies	6,337		(3)	6,334
U.S. municipal bonds	2,706	1		2,707
<b>Total</b>	<b>\$ 77,960</b>	<b>\$ 9</b>	<b>\$ (47)</b>	<b>\$ 77,922</b>
<b>Contractual Maturities</b>				
Due in one year or less	\$ 73,960			\$ 73,936
Due in one to three years	4,000			3,986
<b>Total</b>	<b>\$ 77,960</b>			<b>\$ 77,922</b>
<b>Reported as:</b>				
Short-term investments				\$ 73,450
Long-term investments				3,986
Restricted investments				486
<b>Total</b>				<b>\$ 77,922</b>

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

December 31, 2005				
Mortgage-backed securities	\$ 36,793	\$ 85	\$ (142)	\$ 36,736
U.S. corporate obligations	28,321		(94)	28,227
U.S. government and agencies	3,713		(20)	3,693
<b>Total</b>	<b>\$ 68,827</b>	<b>\$ 85</b>	<b>\$ (256)</b>	<b>\$ 68,656</b>
 Contractual Maturities				
Due in one year or less	\$ 32,034			\$ 31,920
Mortgage-backed securities	36,793			36,736
<b>Total</b>	<b>\$ 68,827</b>			<b>\$ 68,656</b>
 Reported as:				
Short-term investments				\$ 31,315
Long-term investments				36,736
Restricted investments				605
<b>Total</b>				<b>\$ 68,656</b>

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

During the second quarter of 2006, an investment decision was made to rebalance the portfolio away from mortgage-backed securities in an effort to improve the overall yield in the portfolio. As a result, certain available-for-sale securities were sold for total proceeds of \$28,607,000 with an aggregate realized loss of \$289,000. The aggregate realized losses on sales of available-for-sale securities for all other periods presented are not significant. The basis on which the cost of a security sold or the amount reclassified out of accumulated other comprehensive income into earnings was determined by the specific identification method.

The Company has determined that unrealized losses are temporary and insignificant as the extent of the decline, in both dollars and percentage of cost, and the Company has the ability and intent to hold the investment until it recovers at least substantially all of the cost of the investment. As of December 31, 2006, the period of continuous unrealized losses is less than 12 months.

**3. Property and equipment**

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

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
Leasehold improvements	\$ 7,640	\$ 7,489
Laboratory equipment	6,627	5,628
Computers and office equipment	1,636	1,250
Furniture and fixtures	1,265	1,229
	17,168	15,596
Less: accumulated depreciation and amortization	(9,374)	(7,064)
<b>Total</b>	<b>\$ 7,794</b>	<b>\$ 8,532</b>

The Company has pledged substantially all of its property and equipment as collateral against certain obligations under its office and laboratory lease agreement.

**4. Accounts payable and accrued liabilities**

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

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
Compensation and benefits	\$ 2,054	\$ 1,560
Trade accounts payable	1,329	1,791
Clinical trial costs	995	948
Contract manufacturing	807	558
Franchise and local taxes	204	188
 Total	 \$ 5,389	 \$ 5,045

## 5. Income taxes

At December 31, 2006, the Company had net operating loss carryforwards of approximately \$93.1 million, which may be used to offset future taxable income. These carryforwards expire from 2018 to 2026 if not utilized. Utilization of net operating loss and tax credit carryforwards are subject to certain limitations under Section 382 of the Internal Revenue Code of 1986, as amended, in the event of a change in the Company's ownership, as

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

defined. The Company has not performed this ownership analysis due to its full valuation allowance; however, it is possible that there has been a change in ownership, which would limit the amount of net operating loss available to be used in future years.

At December 31, 2006 the Company had research and experimentation credit carryforwards of approximately \$6.4 million, which will expire from 2019 to 2026 and which are also subject to Section 382 limitations.

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

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
Deferred tax assets		
Net operating loss carryforwards	\$ 31,650	\$ 24,225
Capitalized research and development	21,356	17,471
Research and development credit carryforwards	6,411	5,109
Deferred revenue	1,004	2,642
Stock-based compensation	2,057	740
Depreciation and amortization	720	509
Other	665	575
<b>Total deferred tax assets</b>	<b>63,863</b>	<b>51,271</b>
Less: Valuation allowance	(63,863)	(51,271)
<b>Net deferred tax assets</b>	<b>\$</b>	<b>\$</b>

Increases in the valuation allowance were \$12.6 million in 2006, \$11.3 million in 2005 and \$13.6 million in 2004.

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

	<b>Year ended</b>		
	<b>December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
Statutory federal income tax rate	(34)%	(34)%	(34)%
Research and development tax credits	(4)	(4)	(4)
Valuation allowance	35	38	38
Share-based compensation	3		

Effective tax rate	0%	0%	0%
--------------------	----	----	----

**Table of Contents****Seattle Genetics, Inc.****Notes to Financial Statements (Continued)****6. Collaboration, license, manufacturing and other agreements***ADC collaboration agreements*

The Company has entered into various collaboration agreements relating to the use of its antibody-drug conjugate (ADC) technology. Under the ADC agreements, the collaboration partner performs research and development activities during the research term of the agreement and has the right to obtain exclusive commercialization rights to the Company's technology for antigen targets identified during the research term. The Company receives upfront technology access payments and is reimbursed for support that it provides during the term of the agreement. The Company is also entitled to receive fees, progress dependent milestone payments and royalties on any commercialized products covered by the agreements. Revenues recognized under these agreements were as follows.

	Year ended December 31,		
	2006	2005	2004
Genentech	\$ 4,117	\$ 4,926	\$ 2,901
CuraGen	1,760	2,001	888
Progenics	1,621	401	
MedImmune	932	573	80
Bayer	929	805	188
PDL Biopharma	163	123	1,265
Genencor		535	782
Other collaborations	483	393	597
Collaborations and license agreements	\$ 10,005	\$ 9,757	\$ 6,701

*Genentech*

In April 2002, the Company entered into an ADC collaboration with Genentech. Upon entering into the multi-year agreement, Genentech paid a \$2.5 million upfront fee to the Company and purchased \$3.5 million of the Company's common stock in a private placement. The \$2.5 million fee has been deferred and is being recognized over the research term of 60 months pursuant to the ADC collaboration agreement. Under the collaboration, Genentech pays the Company research fees for assistance with development of ADCs. Genentech also pays technology access fees and has agreed to pay progress-dependent milestone payments and royalties on net sales of any resulting products. Genentech is responsible for research, product development, manufacturing and commercialization of any products resulting from the collaboration.

In December 2003, Genentech designated additional targets under the ADC collaboration agreement, triggering the payment of an additional \$3.0 million fee and the purchase of \$7.0 million of the Company's common stock in a private placement. The \$3.0 million fee has been deferred and is being recognized over the then remaining research term of 40 months pursuant to the ADC collaboration agreement. The private

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

placement transaction closed on December 18, 2003. Due to an increase in the price of the Company's common stock between the designation date and the closing date, the excess of the fair value of the shares of common stock issued to Genentech over the purchase price, which excess totaled to \$669,000, was recorded as a discount to deferred revenue. This discount is also being recognized over the then remaining 40 month term of the Genentech agreement and is recorded as a reduction in revenue being recorded under the collaboration agreement. The Company anticipates that it will record the remaining non-cash contra revenue of approximately \$59,000 in 2007.

In November 2004, Genentech designated additional targets under the ADC collaboration agreement, triggering the payment of an additional \$1.6 million fee. This fee has been deferred and is being recognized over 30 months, which represented the then remaining term of the research period under the original collaboration agreement.



**Table of Contents**

**Seattle Genetics, Inc.**

**Notes to Financial Statements (Continued)**

During 2004, 2005 and 2006, the Company also received fees and milestone payments under development agreements with Genentech related to process development and manufacturing of ADC product candidates. Revenues in 2004, 2005 and 2006 reflect the earned portion of upfront payments, milestones, and material supply and service fees under these agreements, including certain at-risk milestones that were recognized as incurred.

*CuraGen*

In June 2004, the Company entered into an ADC collaboration with CuraGen Corporation which paid the Company an upfront fee of \$2.0 million for an exclusive license to the Company's ADC technology for a single antigen. In February 2005, CuraGen paid the Company an additional fee to exercise an option for an exclusive license to the Company's ADC technology for a second antigen under the parties' existing collaboration agreement. These fees were recognized as revenue over the two year research period of the agreement. CuraGen also paid material supply and research support fees for any assistance provided by the Company in developing ADC products, as well as annual maintenance fees. The material supply and research support fees were recognized as the activities were performed and maintenance fees received are recognized as revenue over the maintenance period. CuraGen is responsible for research, product development, manufacturing and commercialization of all products under the collaboration and may make progress-dependent milestone payments and pay royalties on net sales of resulting ADC products. Progress dependent milestones are recognized to revenue as the milestones are achieved.

In June 2006, CuraGen initiated a phase I clinical trial of CR011, an ADC for the treatment of metastatic melanoma, triggering a milestone payment to the Company.

*Progenics*

In June 2005, the Company entered into an ADC collaboration with PSMA Development Company LLC, formerly a joint venture between Progenics Pharmaceuticals, Inc. and Cytogen Corporation which is now a wholly-owned subsidiary of Progenics. The license provides Progenics with rights to utilize the Company's ADC technology with Progenics' fully human monoclonal antibodies that target prostate-specific membrane antigen (PSMA). Under the terms of the collaboration, Progenics paid the Company a \$2.0 million upfront fee which is being recognized as revenue over the three year research period of the collaboration. Progenics has also agreed to make progress-dependent milestone payments and pay royalties on net sales of resulting ADC products. Progenics is responsible for research, product development, manufacturing and commercialization of all products under the collaboration. The Company will receive material supply and annual maintenance fees as well as research support payments for any assistance provided to Progenics in developing ADC products.

*MedImmune*

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

In April 2005, the Company entered into an ADC collaboration with MedImmune, Inc. MedImmune paid an upfront fee of \$2.0 million for rights to utilize the Company's ADC technology against a single tumor target under this agreement. The upfront fee is being recognized as revenue over the two year research period of the collaboration. MedImmune also has an option to access the ADC technology for a second proprietary antibody program upon payment of an additional fee. Under the terms of the collaboration, MedImmune has agreed to make progress-dependent milestone payments and pay royalties on net sales of any resulting ADC products. MedImmune is responsible for research, product development, manufacturing and commercialization of all products under the collaboration. The Company will receive material supply and annual maintenance fees as well as research support payments for any assistance provided to MedImmune in developing ADC products.

### *Bayer*

In September 2004, the Company entered into an ADC collaboration with Bayer Pharmaceuticals Corporation. Under the terms of the multi-year agreement, Bayer paid the Company an upfront fee of \$2.0

**Table of Contents**

**Seattle Genetics, Inc.**

**Notes to Financial Statements (Continued)**

million for an exclusive license to the Company's ADC technology for a single antigen. The upfront fee is being recognized as revenue over the three year research period of the agreement. Bayer pays material supply and research support fees for any assistance provided by the Company in developing ADC products, as well as annual maintenance fees. The material supply and research support fees are recognized as the activities are performed and the maintenance fees are recognized over the applicable maintenance period. Bayer is responsible for research, product development, manufacturing and commercialization of all products under the collaboration and may make progress-dependent milestone payments and pay royalties on net sales of resulting ADC products. Progress dependent milestones will be recognized to revenue as the milestones are achieved.

*PDL BioPharma*

In June 2001, the Company entered into an ADC collaboration with Eos Biotechnology, which was assumed by PDL BioPharma in 2003 upon its acquisition of Eos Biotechnology. In January 2004, the Company and PDL BioPharma, agreed to expand the ADC collaboration. The Company agreed to provide additional support to PDL BioPharma in its development of ADC product candidates in exchange for receipt of increased fees, milestones and royalties on net sales of any ADC products resulting from the collaboration. PDL BioPharma also granted the Company a license and options for two additional licenses under their antibody humanization patents. Under this collaboration, the Company received technology access fees, which are being recognized as revenue over the relevant option periods for each designated antigen.

In April 2005, as part of the Company's in-license of an anti-CD33 program from PDL BioPharma, the ADC collaboration was amended to reduce the royalties payable by PDL BioPharma to the Company with respect to ADCs targeting several antigens. PDL BioPharma is responsible for all costs associated with the development, manufacturing and marketing of any ADC products generated as a result of this collaboration.

*Co-development Agreements*

*Genencor International*

In January 2002, the Company formed a strategic alliance with Genencor International to discover and develop a class of cancer therapeutics based on tumor-targeted enzymes that activate prodrugs. As part of the collaboration, Genencor purchased \$3.0 million of the Company's common stock in a private placement. In July 2003, the Company and Genencor agreed to amend and extend the collaboration for an additional two years in exchange for an additional payment from Genencor, recognized as revenue over the remaining research period of the agreement. The research period of the agreement expired on January 4, 2006.

*Celera Genomics Group*

In July 2004, the Company and Celera Genomics Group, an Applera Corporation business, entered into a co-development agreement to jointly discover and develop antibody-based therapies for cancer. Products developed under the co-development agreement may include either monoclonal antibodies or ADCs. Under the terms of the multi-year agreement, Celera Genomics and the Company will jointly designate a number of cell-surface proteins discovered and validated through Celera Genomics' proprietary proteomic platform as antigen targets. The Company will carry out initial screening to generate and select the appropriate corresponding antibodies or ADCs for joint development and commercialization, after which Celera Genomics and the Company will co-fund preclinical and clinical product development and will share any profits resulting from co-developed products. Either party may opt out of co-development of a particular product and receive royalties on net sales. Celera Genomics will also pay progress-dependent commercialization milestones to the Company for any co-developed ADCs.

**Table of Contents**

**Seattle Genetics, Inc.**

**Notes to 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 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 SGN-40 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.

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 SGN-33 product candidate, for both unconjugated antibody and ADC applications. Under the license agreement, the Company received rights to patents and patent applications, as well as supplies of clinical-grade materials and a nonexclusive CD33 license under PDL BioPharma's antibody humanization patents. The Company paid an upfront fee and has agreed to pay progress-dependent payments totaling up to \$6.5 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 the royalties payable by PDL BioPharma with respect to a limited number of products that PDL BioPharma might develop under the existing 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. The upfront fee paid to PDL BioPharma has been recorded as an offset to deferred revenue and will be recognized as contra-revenue over the remaining research period of the existing ADC collaboration. Future progress dependent milestone payments and royalties paid to PDL BioPharma will be expensed as research and development expense when incurred.

*Eli-Lilly and Company (ICOS Corporation)*

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

In October 2000, the Company entered into a license agreement with ICOS Corporation, recently acquired by Eli-Lilly and Company, for nonexclusive rights to use ICOS' CHEF expression system. The Company has used this system to manufacture the antibody components of SGN-30, SGN-35, SGN-70 and SGN-75. Under the terms of this agreement, the Company is required to make progress-dependent milestone payments of up to \$650,000 in the aggregate per product candidate and pay royalties on net sales of products manufactured using the CHEF expression system.

### *University of Miami*

In September 1999, the Company entered into an exclusive license agreement with the University of Miami, Florida, covering an anti-CD30 monoclonal antibody that is the basis of SGN-30 and the antibody component of SGN-35. Under the terms of this license, the Company made an upfront payment and is required to pay annual

**Table of Contents**

**Seattle Genetics, Inc.**

**Notes to Financial Statements (Continued)**

maintenance fees, progress-dependent milestone payments and royalties on net sales of products incorporating technology licensed from the University of Miami.

*Mabtech AB*

In June 1998, the Company obtained exclusive, worldwide rights to a monoclonal antibody targeting the CD40 antigen, which is the basis for the Company's SGN-40 product candidate, from Mabtech AB, located in Sweden. Under the terms of this license, the Company is required to make a progress-dependent milestone payment and pay royalties on net sales of products incorporating technology licensed from Mabtech.

*CLB-Research and Development*

Pursuant to a license agreement the Company entered into in July 2001, the Company obtained an exclusive license to specific monoclonal antibodies that target cancer and autoimmune disease targets from CLB-Research and Development, 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, the Company has made upfront and option exercise payments and is 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, the Company entered into a license agreement with Arizona State University for a worldwide, exclusive license to the cell-killing agent Auristatin E. The Company subsequently amended this agreement in August 2004. Under the terms of the amended agreement, the Company is required to pay annual maintenance fees to Arizona State University until expiration of the licensed patents covering Auristatin E, but does not expect to pay ASU any milestones or royalties on sales of products utilizing the Company's ADC technology.

*Development, supply and other agreements:*

*Laureate Pharma*

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

In April 2006, the Company entered into an agreement with Laureate Pharma for manufacturing of its SGN-33 product candidate and the antibody component of its SGN-70 and SGN-75 product candidates. Under the terms of the agreement, Laureate Pharma will perform scale-up and cGMP manufacturing of clinical trial materials for these programs.

### *Abbott Laboratories*

In February 2004, the Company entered into an agreement with Abbott Laboratories for manufacturing of the antibody component of its SGN-30 and SGN-35 product candidates. The Company also entered into a manufacturing agreement with Abbott for manufacturing of its SGN-40 product candidate in February 2005. Under the terms of both agreements, Abbott has performed scale-up and GMP manufacturing for clinical trials, and has agreed to supply commercial-grade material to support potential regulatory approval and commercial launch.

### *Albany Molecular Research, Inc.*

In May 2005, the Company entered into a manufacturing and supply agreement with Albany Molecular Research, Inc. for GMP manufacturing of the proprietary drug-linker system employed in its SGN-35 product candidate. The volume, pricing and specifications for manufacture and supply will be determined on a project by project basis. The Company has also entered into a preferred provider agreement with Albany Molecular



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

Research to enable its ADC collaborators to order drug-linker materials directly from Albany Molecular Research to support the collaborators development of ADCs utilizing the Company's technology. The Company is entitled to receive payments from Albany Molecular Research under the preferred provider agreement.

Under the Company's license agreements, development and supply agreements, contract manufacturing agreements and other agreements, it is obligated to make payments including progress-dependent milestone payments and royalties on commercial sales of resulting products for specified periods. The minimum contractual payments to be made by the Company under its existing license, collaboration and contract manufacturing agreements are expected to aggregate to approximately \$3.8 million in 2007, \$335,000 in 2008, \$205,000 in 2009 and \$210,000 in 2010. Some of those agreements also provide for payments upon the achievement of certain milestones aggregating up to \$10.0 million, as well as the payment of royalties based on net sales of commercial products. The Company does not expect to pay any royalties on net sales of products under any of these agreements for at least the next several years.

**7. Commitments and contingencies**

In December 2000, the Company entered into an operating lease for office and laboratory space. The lease provides for monthly lease payments that began in June 2001. The initial lease term is ten years with two, seven-year renewal options, subject to certain conditions. In March 2003, the lease was amended and the Company agreed to pledge substantially all of its property and equipment and maintain restricted investments as security under the lease.

As of December 31, 2006, the Company has restricted investments totaling \$486,000 as collateral for certain obligations of the lease. These investment securities are restricted as to withdrawal and are managed by a third party. The lease terms provide for changes in the amounts pledged based upon the Company's market capitalization, stockholders' equity or cash and investments balance until the lease expiration date of May 31, 2011. In the event that the Company's market capitalization, stockholders' equity or cash and investments balance fall below specific thresholds, the Company is obligated to increase its restricted investment balance to as much as approximately \$3.4 million. As of December 31, 2006, the Company was in compliance with these thresholds.

The lease agreement contains scheduled rent increases. Accordingly, the Company has recorded a deferred rent liability of \$513,000 at December 31, 2006. The Company has also entered into operating lease obligations through July 2008 for certain office equipment.

Future minimum lease payments under all noncancelable operating leases are as follows (in thousands):

Years ending December 31,	
2007	\$ 2,197

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

2008	2,231
2009	2,253
2010	2,291
2011	962
Thereafter	
	\$ 9,934

Rent expense attributable to noncancelable operating leases totaled approximately \$2.2 million for each of the years ended December 31, 2006, 2005 and 2004.

**Table of Contents**

**Seattle Genetics, Inc.**

**Notes to Financial Statements (Continued)**

**8. Stockholders' equity**

*Series A convertible preferred stock and warrants financing*

On July 8, 2003 the Company issued 1,640,000 shares of newly designated Series A convertible preferred stock through a private placement at a purchase price of \$25.00 per share. Each share of Series A convertible preferred stock is convertible into 10 shares of common stock at a conversion price of \$2.50 per share. In addition, the purchasers of the Series A convertible preferred stock received 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.

The Series A convertible preferred stock ranks senior to the Company's common stock and will rank senior to future classes of capital stock, unless consented to by the holders of the Series A convertible preferred stock. The Series A convertible preferred stock is entitled to receive a liquidation preference in an amount equal to the greater of: (a) \$25.00 per share of Series A convertible preferred stock; or (b) the amount that would have been paid had such shares of Series A convertible preferred stock been converted into common stock. The Series A convertible preferred stock is not redeemable by the holders thereof and does not bear any dividends, except to the extent any dividends are paid on any other shares of the Company's capital stock, in which case, the holders thereof are entitled to receive dividends based on the number of shares of common stock into which such holder's shares of Series A convertible preferred stock would then convert. If the Company proposes to grant rights to acquire the Company's securities pro rata to all holders of two percent or more of the Company's outstanding common stock, the holders of Series A convertible preferred stock have the right to acquire the number of such offered securities they would have acquired had they converted their Series A convertible preferred stock into common stock at the time of such grant. In addition, if the Company offers rights to purchase its preferred stock to any stockholders, the holders of Series A convertible preferred stock have the right to acquire up to the number of securities necessary to maintain their percentage interest in the Company. The holders of Series A convertible preferred stock have certain registration rights with respect to their shares of common stock issuable upon conversion of their Series A convertible preferred stock and the common stock issuable upon exercise of their common stock warrants.

In connection with this Series A convertible preferred stock financing, the Company recorded a beneficial conversion feature on the preferred stock. The beneficial conversion feature has been treated as a preferred stock deemed dividend, which resulted in an increase to reported net loss in arriving at net loss attributable to common stockholders. The Company has recorded the non-cash accretion of preferred stock deemed dividend using the effective interest method through the date of earliest conversion, which was July 8, 2004. Accordingly, the Company recorded non-cash accretion of preferred stock deemed dividend totaling approximately \$36.6 million in 2004, which represents an increase to reported net loss in arriving at net loss attributable to common stockholders and reduced paid-in-capital and increased paid-in-capital by the same amounts. The non-cash accretion of the preferred stock deemed dividend did not have an effect on net loss or cash flows for the applicable reporting periods or have an impact on total stockholders' equity as of the applicable reporting dates.

*Common stock*

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

In February 2004, the Company completed a follow-on public offering of 7,000,000 shares of common stock. In addition, the underwriters of the public offering exercised their over-allotment option in full and purchased an additional 1,050,000 shares of common stock. Total gross proceeds from this offering were approximately \$66.4 million, with total net proceeds to the Company of approximately \$62.1 million after the deduction of the discount paid to the underwriters and other offering expenses.

In April 2006, the Company completed a public offering of 7,300,000 shares of common stock at a price of \$5.13 per share. Total net proceeds from this offering, after deducting offering expenses of \$229,000, were

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

approximately \$37.2 million. In connection with the public offering, the Company entered into a stock purchase agreement with entities affiliated with Baker Brothers Investments, which are managed by Baker Bros. Advisors, LLC. Felix Baker, Ph.D., one of the Company's directors, is a Managing Member of Baker Bros. Advisors. The Stock Purchase Agreement provided that, subject to stockholder approval and customary closing conditions, these entities would purchase a total of 1,129,015 shares of the Company's common stock at a price of \$5.25 per share. The Company's stockholders approved the issuance of these shares at the Company's annual stockholders' meeting held on May 19, 2006. As a result, the Company issued these additional shares on May 24, 2006 for total net proceeds of approximately \$5.9 million.

The Company is authorized to issue up to 100,000,000 shares of common stock. At December 31, 2006, shares of common stock reserved for future issuance are as follows (in thousands):

Series A convertible preferred stock	15,000
Stock options outstanding	6,671
Warrants outstanding	2,050
Stock options available for grant	2,046
Employee stock purchase plan shares available for issuance	736
	26,503

*Employee Stock Purchase Plan*

The Company has a 2000 Employee Stock Purchase Plan (Stock Purchase Plan) with a total of 736,156 shares of common stock reserved for issuance as of December 31, 2006. 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 of the fiscal years through 2010 that is equal to the lesser of (1) 300,000 shares; (2) 1% of the Company's outstanding common stock on the last day of the immediately preceding fiscal year; or (3) such lesser number of shares as the Board of Directors determines. A total of 96,617 shares were sold to employees during 2006 at an average purchase price of \$4.12 per share, 97,342 shares were sold to employees during 2005 at an average purchase price of \$4.21 per share and 77,750 shares were sold to employees during 2004 at an average purchase price of \$3.03 per share. 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 a purchase period, whichever is lower.

**9. Stock option plan***1998 Stock Option Plan*

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

The Company has a 1998 Stock Option Plan (Option Plan) whereby 10,372,910 shares of the Company's common stock were reserved for issuance to employees, officers, consultants and advisors of the Company as of December 31, 2006, of which 1,975,808 shares were available for future grant as of such date. The Option Plan provides for an annual increase in the number of reserved shares on the first day of each of the Company's years through 2007 that is equal to the lesser of (1) 1,200,000 shares; (2) 4% of the Company's outstanding common stock on the last day of the immediately preceding fiscal year; or (3) such lesser number of shares as the Board of Directors determines. Options granted under the Option Plan may be either incentive stock options or nonstatutory stock options as determined by the Board of Directors. The term of the Option Plan is ten years and will expire in 2007.

Incentive stock options may be issued only to employees of the Company and have a maximum term of ten years from the date of grant. The exercise price for incentive stock options may not be less than 100% of the

**Table of Contents**

**Seattle Genetics, Inc.**

**Notes to Financial Statements (Continued)**

estimated fair market value of the common stock at the time of the 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 estimated fair market value of the common stock at the time of grant, and the term of the option may not exceed five years. Options become exercisable in whole or in part from time to time as determined by the Board of Directors, which administers the Option Plan.

In 2004, the Company recorded a non-cash, stock-based compensation charge of approximately \$348,000 for accelerated vesting of stock options for employee severance.

Generally, options granted under the Option Plan vest 25% one year after the beginning of the vesting period and thereafter ratably each month over the following three years.

*2000 Directors' Stock Option Plan*

The Company has a 2000 Directors' Stock Option Plan (Directors' Plan). Under the terms of the Directors' Plan, each existing non-employee director who had not previously been granted a stock option by the Company, was granted a nonstatutory stock option to purchase 25,000 shares of common stock on the effective date of this plan, March 6, 2001. Each new non-employee director who becomes a director after the effective date of the plan will also be 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 shall vest 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. Thereafter, 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 will be granted a nonstatutory stock option to purchase 10,000 shares of common stock. Each annual option shall vest 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 400,000 shares of common stock have been reserved for issuance under the Directors' Plan. As of December 31, 2006 stock options to acquire a total of 280,000 shares of common stock were outstanding and 70,000 shares were available for grant under the Directors' Plan.

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

A summary of stock option activity for both the Option Plan and Director's Plan is as follows:

	Shares available for grant	Options outstanding Number of shares	Weighted- average exercise price per share
Balance, December 31, 2003	1,093,553	4,871,357	\$ 5.36
Additional shares reserved	1,200,000		
Granted	(1,204,875)	1,204,875	\$ 7.72
Exercised		(425,105)	\$ 3.04
Forfeited	464,992	(464,992)	\$ 6.26
Expired	135,955	(135,955)	\$ 6.14
Balance, December 31, 2004	1,689,625	5,050,180	\$ 6.02
Additional shares reserved	1,200,000		
Granted	(1,154,125)	1,154,125	\$ 5.55
Exercised		(298,550)	\$ 2.51
Forfeited	326,136	(326,136)	\$ 6.32
Expired	758,788	(758,788)	\$ 7.54
Balance, December 31, 2005	2,820,424	4,820,831	\$ 5.86
Additional shares reserved	1,200,000		
Granted	(2,498,875)	2,498,875	\$ 4.81
Exercised		(124,015)	\$ 3.12
Forfeited	317,869	(317,869)	\$ 6.10
Expired	206,390	(206,390)	\$ 6.78
Balance, December 31, 2006	2,045,808	6,671,432	\$ 5.48

The weighted average grant-date fair value of options granted with exercise prices equal to market were \$3.02, \$3.46 and \$5.37 for the years 2006, 2005 and 2004, respectively. The weighted average grant-date fair value of options granted with exercise prices greater than market was \$6.49 for 2004. For the years 2006 and 2005, there were no options granted with exercise prices greater than market. The weighted average grant-date fair value of the purchase rights existing under the Company's Stock Purchase Plan were \$2.54, \$2.52 and \$1.72 for the years 2006, 2005 and 2004, respectively.

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, 2006. The aggregate intrinsic value at December 31, 2006 for options outstanding was \$3.9 million and for options exercisable was \$2.3 million. The aggregate intrinsic value of options exercised under the Company's stock option plans was \$196,000 during 2006, \$787,000 during 2005 and \$1.8 million during 2004, determined as of the date of



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

option exercise. As of December 31, 2006, there was approximately \$5.4 million of total unrecognized compensation cost related to unvested share-based compensation arrangements, as adjusted for expected forfeitures, granted under the Company's stock award plans. That cost is expected to be recognized over a weighted-average period of 1.4 years.

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

The following table summarizes information about options outstanding for both the Option Plan and Director's Plan at December 31, 2005:

Range of exercise price	Options outstanding			Options exercisable	
	Number of shares	Weighted-average remaining contractual life (in years)	Weighted-average exercise price per share	Number of shares	Weighted-average exercise price per share
\$0.10 - \$ 0.29	84,823	2.86	\$ 0.22	84,823	\$ 0.22
\$2.33 - \$ 4.18	1,254,727	6.74	3.50	769,992	3.09
\$4.45 - \$ 5.06	1,300,448	9.15	4.54	120,386	4.93
\$5.07 - \$ 5.63	1,478,700	8.34	5.41	411,135	5.22
\$5.72 - \$ 6.63	1,225,359	6.98	6.13	824,026	6.17
\$6.72 - \$10.33	1,327,377	5.74	8.09	1,132,559	8.09
<b>\$0.10 - \$10.33</b>	<b>6,671,434</b>	<b>7.36</b>	<b>\$ 5.48</b>	<b>3,342,921</b>	<b>\$ 5.80</b>

**10. Employee benefit plan**

The Company has a 401(k) Plan for all of its employees. The Plan allows eligible employees to defer up to 15%, but no greater than \$15,000 (or \$20,000 for employees more than 50 years old) in calendar year 2006, of their pretax compensation at the discretion of the employee. The Company has a 401(k) matching program whereby the Company contributes fifty cents for each dollar an employee contributes, with a maximum contribution of 50% of the first 4% of a participant's earnings not to exceed 50% of the prescribed annual limit. Under this matching program, the Company contributed a total of approximately \$240,000 in 2006, \$203,000 in 2005 and \$167,000 in 2004.

**11. Subsequent Events**

In January 2007, the Company entered into an exclusive worldwide license agreement with Genentech for the development and commercialization of SGN-40. Under the terms of the agreement, the Company received an upfront payment of \$60 million, and is entitled to receive potential milestone payments exceeding \$800 million and escalating double-digit royalties starting in the mid-teens on annual net sales of SGN-40. The milestone payments include \$20 million in committed payments during the first two years of the agreement. Genentech will fund future research, development, manufacturing and commercialization costs for SGN-40 over an initial six year development period. The Company has agreed to continue certain phase I and phase II clinical trials and development activities for SGN-40, the costs of which will be reimbursed by Genentech. The Company also has an option to co-promote SGN-40 in the United States. Payments received from Genentech, consisting of the upfront payment, milestone payments and payments for services provided by the Company to Genentech under this agreement, will be recognized as revenue over the six year development period of the agreement using a time-based method. The Company initially licensed its anti-CD40 program to Genentech in June 1999. In March 2003, the Company entered into license agreements with Genentech providing for

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

the return to the Company of the rights relating to the anti-CD40 program as well as a license under Genentech's Cabilly patent covering the recombinant expression of antibodies. As a result of the January 2007 license, any milestone or royalty obligations of the Company pursuant to these previous license agreements were waived.

In January 2007, the Company entered into an agreement with Agensys to jointly research, develop and commercialize ADCs for cancer. The collaboration encompasses combinations of the Company's ADC technology with antibodies developed by Agensys to proprietary cancer targets. Under the terms of the multi-year agreement, Agensys and the Company will jointly screen and select ADC products to an initial target that

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

has already been selected, co-fund all preclinical and clinical development and share equally in any profits. Agensys will also conduct further preclinical studies aimed at identifying ADC products to up to three additional targets. The Company has the right to exercise a co-development option for one of these additional ADC products at IND filing, and Agensys will have the right to develop and commercialize the other two ADC products on its own, subject to paying Seattle Genetics fee, 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.

In January and February 2007, holders of the Company's Series A convertible preferred stock converted 571,500 shares of Series A convertible preferred stock into 5,715,000 shares of common stock.

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

The following table contains selected unaudited statement of operations information for each quarter of 2006 and 2005. 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 of any future period.

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

	<b>March 31</b>	<b>Three Months Ended</b>		<b>December 31</b>
		<b>June 30</b>	<b>September 30</b>	
<b>2006</b>				
Revenues	\$ 2,141	\$ 2,840	\$ 2,441	\$ 2,583
Net loss attributable to common stockholders	\$ (8,703)	\$ (8,643)	\$ (8,649)	\$ (10,020)
Net loss per share attributable to common stockholders - basic and diluted	\$ (0.21)	\$ (0.17)	\$ (0.17)	\$ (0.20)
<b>2005</b>				
Revenues	\$ 2,606	\$ 2,200	\$ 2,632	\$ 2,319
Net loss attributable to common stockholders	\$ (7,553)	\$ (8,360)	\$ (6,171)	\$ (7,349)
Net loss per share attributable to common stockholders - basic and diluted	\$ (0.18)	\$ (0.20)	\$ (0.15)	\$ (0.17)

## **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.* The Chief Executive Officer and the Chief Financial Officer have reviewed our disclosure controls and procedures prior to the filing of this annual report. Based on that review, they have concluded that, as of the end of the period covered by this annual report, these disclosure controls and procedures were, in design and operation, effective to assure that the required information has been properly recorded, processed, summarized and reported to those responsible in order that it may be included in this annual report.

(b) *Changes in internal control over financial reporting.* There have not been any changes in the Company's internal control over financial reporting during the quarter ended December 31, 2006 which have materially affected, or are reasonably likely to materially affect, the Company's 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, 2006.

Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2006 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included elsewhere in this Annual Report on Form 10-K.

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

None.

**Table of Contents**

**PART III**

The information required by Part III is omitted from this report because the Company will file a definitive proxy statement within 120 days after the end of its fiscal year pursuant to Regulation 14A for its annual meeting of stockholders to be held on May 25, 2007, and the information to be included in the proxy statement is incorporated herein by reference.

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

The information required by this item is incorporated herein by reference from the Company's definitive proxy statement which will be filed within 120 days after the end of the Company's 2006 fiscal year pursuant to Regulation 14A for its annual meeting of stockholders to be held May 25, 2007.

**Item 11. Executive Compensation.**

The information required by this item is incorporated herein by reference from the Company's definitive proxy statement which will be filed within 120 days after the end of the Company's 2006 fiscal year pursuant to Regulation 14A for its annual meeting of stockholders to be held May 25, 2007.

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

The information required by this item is incorporated herein by reference from the Company's definitive proxy statement which will be filed within 120 days after the end of the Company's 2006 fiscal year pursuant to Regulation 14A for its annual meeting of stockholders to be held May 25, 2007.

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

The information required by this item is incorporated herein by reference from the Company's definitive proxy statement which will be filed within 120 days after the end of the Company's 2006 fiscal year pursuant to Regulation 14A for its annual meeting of stockholders to be held May 25, 2007.

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

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

The information required by this item is incorporated herein by reference from the Company's definitive proxy statement which will be filed within 120 days after the end of the Company's 2006 fiscal year pursuant to Regulation 14A for its annual meeting of stockholders to be held May 25, 2007.

**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(1)	Amended and Restated Certificate of Incorporation of Seattle Genetics, Inc.
3.2(8)	Certificate of Designations of Series A Convertible Preferred Stock.
3.3(9)	Amended and Restated Bylaws of Seattle Genetics, Inc.
4.1(1)	Specimen Stock Certificate.
4.2(7)	Form of Common Stock Warrant.
4.3(7)	Investor Rights Agreement dated July 8, 2003 among Seattle Genetics, Inc. and certain of its stockholders.
4.4(9)	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.
10.8 (1)	License Agreement dated February 3, 2000 between Seattle Genetics, Inc. and the Arizona Board of Regents.



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

- 10.9 (1) Lease Agreement dated December 1, 2000 between Seattle Genetics, Inc. and WCM132-302, LLC.
- 10.10(19) Amended and Restated 1998 Stock Option Plan.
- 10.11(13) Form Notice of Grant and Stock Option Agreement under Amended and Restated 1998 Stock Option Plan.

**Table of Contents**

<b>Number</b>	<b>Description</b>
10.12(13)	Form Notice of Grant and Stock Option Agreement under 2000 Directors Stock Option Plan.
10.13(1)	2000 Directors Stock Option Plan.
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)	Collaboration Agreement dated June 4, 2001 between Seattle Genetics, Inc. and Eos Biotechnology, Inc.
10.17(3)	Executive Employment Agreement dated October 26, 2001 between Seattle Genetics, Inc. and Clay B. Siegall.
10.18 (4)	Collaboration Agreement dated April 19, 2002 between Seattle Genetics, Inc. and Genentech, Inc.
10.19 (4)	2002 Common Stock Purchase Agreement dated April 19, 2002 between Seattle Genetics, Inc. and Genentech, Inc.
10.20 (5)	Contract Manufacturing Agreement dated January 3, 2003 between Seattle Genetics, Inc. and ICOS Corporation.
10.21 (6)	License Agreement dated March 6, 2003 between Seattle Genetics, Inc. and Genentech, Inc.
10.22 (6)	Non-Exclusive Cabilly Patent License Agreement dated March 6, 2003 between Seattle Genetics, Inc. and Genentech, Inc.
10.23(7)	Securities Purchase Agreement dated May 12, 2003 among Seattle Genetics, Inc. and the purchasers of Series A Convertible Preferred Stock and Warrants named therein.
10.24(7)	Amendment No. 1 dated May 14, 2003 to Securities Purchase Agreement dated May 12, 2003 among Seattle Genetics, Inc. and the purchasers of Series A Convertible Preferred Stock and Warrants named therein.
10.25(8)	Amendment No. 2 dated June 2, 2003 to Securities Purchase Agreement dated May 12, 2003 among Seattle Genetics, Inc. and the purchasers of Series A Convertible Preferred Stock and Warrants named therein.
10.26 (9)	First Amendment to Lease dated May 28, 2003 between Seattle Genetics, Inc. and B&N 141-302, LLC.
10.27 (10)	Amendment to Collaboration Agreement dated January 9, 2004 between Seattle Genetics, Inc. and Protein Design Labs, Inc.
10.28 (10)	Patent Rights Master Agreement and Research License Agreement dated January 9, 2004 between Seattle Genetics, Inc. and Protein Design Labs, Inc.
10.29 (10)	Patent License Agreement dated January 9, 2004 between Seattle Genetics, Inc. and Protein Design Labs, Inc.
10.30 (10)	Development and Supply Agreement dated February 23, 2004 between Seattle Genetics, Inc. and Abbott Laboratories.
10.31 (11)	Collaboration Agreement dated June 22, 2004 between Seattle Genetics, Inc. and CuraGen Corporation.
10.32 (12)	Collaboration Agreement dated July 20, 2004 between Seattle Genetics, Inc. and Applera Corporation through its Celera Genomics Group.

**Table of Contents**

<b>Number</b>	<b>Description</b>
10.33 (12)	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.
10.34 (12)	Collaboration and License Agreement dated September 27, 2004 between Seattle Genetics, Inc. and Bayer Pharmaceuticals Corporation.
10.35 (14)	Development and Supply Agreement dated February 18, 2005 between Seattle Genetics, Inc. and Abbott Laboratories.
10.36 (15)	License Agreement dated April 12, 2005 between Seattle Genetics, Inc. and Protein Design Labs, Inc.
10.37 (15)	Collaboration Agreement dated April 27, 2005 between Seattle Genetics, Inc. and MedImmune, Inc.
10.38 (15)	Manufacturing and Supply Agreement dated May 4, 2005 between Seattle Genetics, Inc. and Organichem Corporation.
10.39 (15)	Collaboration Agreement dated June 14, 2005 between Seattle Genetics, Inc. and PSMA Development Company LLC.
10.40(16)	Executive Employment Agreement dated October 17, 2005 between Seattle Genetics, Inc. and Todd E. Simpson.
10.41(17)	Seattle Genetics, Inc. 2006 Senior Executive Annual Bonus Plan
10.42(18)	Stock Purchase Agreement dated March 28, 2006 by and among Seattle Genetics, Inc., Baker Brothers Investments and its affiliated funds
10.43 (20)	Biopharmaceutical Manufacturing Services Agreement dated April 24, 2006 between Seattle Genetics, Inc. and Laureate Pharma, Inc.
10.44(21)	Employment Agreement by and between the Company and Eric Dobmeier dated September 6, 2006.
10.45(21)	Employment Agreement by and between the Company and Morris Rosenberg dated September 6, 2006.
10.46(21)	Amendment No. 1 to Executive Employment Agreement by and between the Company and Clay Siegall dated September 6, 2006.
10.47	Employment Agreement by and between the Company and Pamela Trail dated May 22, 2006.
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.

(2) Previously filed as an exhibit to Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2001 and incorporated herein by reference.

(3) Previously filed as an exhibit to Registrant's annual report on Form 10-K for the year ended December 31, 2001 and incorporated herein by reference.

**Table of Contents**

- (4) Previously filed as an exhibit to Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2002 and incorporated herein by reference.
- (5) Previously filed as an exhibit to Registrant's annual report on Form 10-K for the year ended December 31, 2002 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, 2003 and incorporated herein by reference.
- (7) Previously filed as an exhibit to the Registrant's current report on Form 8-K filed with the Commission on May 15, 2003.
- (8) Previously filed as an exhibit to the Registrant's current report on Form 8-K filed with the Commission on June 5, 2003.
- (9) 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.
- (10) 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.
- (11) Previously filed as an exhibit to Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2004 and incorporated herein by reference.
- (12) 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.
- (13) 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.
- (14) 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.
- (15) 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.
- (16) Previously filed as an exhibit to the Registrant's current report on Form 8-K filed with the Commission on October 21, 2005.
- (17) Previously filed as an exhibit to the Registrant's current report on Form 8-K filed with the Commission on March 24, 2006.
- (18) Previously filed as an exhibit to the Registrant's current report on Form 8-K filed with the Commission on March 30, 2006.
- (19) Previously filed as an exhibit to the Registrant's current report on Form 8-K filed with the Commission on May 18, 2006.

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

- (20) Previously filed as an exhibit to the Registrant's current report on Form 10-Q filed with the Commission on August 8, 2006.
- (21) Previously filed as an exhibit to the Registrant's current report on Form 8-K filed with the Commission on September 8, 2006.

Confidential treatment requested as to certain portions of this Exhibit.

**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 9, 2007

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

*President & Chief Executive Officer*

*(Principal Executive Officer)*

Date: March 9, 2007

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

*Chief Financial Officer*

*(Principal Finance 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.

Signature	Title	Date
/s/ CLAY B. SIEGALL  Clay B. Siegall	Director	March 9, 2007
/s/ FRANKLIN M. BERGER  Franklin M. Berger	Director	March 9, 2007
/s/ DAVID W. GRYSKA  David W. Gryska	Director	March 9, 2007
/s/ DOUGLAS G. SOUTHERN  Douglas G. Southern	Director	March 8, 2007
/s/ MARC E. LIPPMAN  Marc E. Lippman	Director	March 9, 2007
/s/ SRINIVAS AKKARAJU	Director	March 9, 2007

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

Srinivas Akkaraju

/s/ FELIX BAKER

Director

March 9, 2007

Felix Baker

Director

March , 2007

Daniel F. Hoth