

SEATTLE GENETICS INC /WA  
Form 10-Q  
August 10, 2009  
Table of Contents

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

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended June 30, 2009

OR

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

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

Commission file number 0-32405

**SEATTLE GENETICS, INC.**

(Exact name of registrant as specified in its charter)

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

**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, Washington 98021**

(Address of principal executive offices, including zip code)

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

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

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

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

Large Accelerated filer  Accelerated filer

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

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

As of August 6, 2009, there were 87,155,572 shares of the registrant's common stock outstanding.

**Table of Contents**

**Seattle Genetics, Inc.**

**For the quarter ended June 30, 2009**

**INDEX**

	<b>Page</b>
<b><u>PART I. FINANCIAL INFORMATION (Unaudited)</u></b>	
Item 1. <u>Condensed Consolidated Financial Statements</u> .....	3
<u>Condensed Consolidated Balance Sheets</u> .....	3
<u>Condensed Consolidated Statements of Operations</u> .....	4
<u>Condensed Consolidated Statements of Cash Flows</u> .....	5
<u>Notes to Condensed Consolidated Financial Statements</u> .....	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> .....	10
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u> .....	16
Item 4. <u>Controls and Procedures</u> .....	17
<b><u>PART II. OTHER INFORMATION</u></b>	
Item 1A. <u>Risk Factors</u> .....	17
Item 4. <u>Submission of Matters to a Vote of Security Holders</u> .....	29
Item 5. <u>Other Information</u> .....	29
Item 6. <u>Exhibits</u> .....	31
<b><u>SIGNATURES</u></b> .....	32
<b><u>EXHIBIT INDEX</u></b> .....	33

**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Condensed Consolidated Financial Statements**  
**Seattle Genetics, Inc.****Condensed Consolidated Balance Sheets****(Unaudited)****(In thousands, except par value)**

	<b>June 30, 2009</b>	<b>December 31, 2008</b>
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 26,591	\$ 30,800
Short-term investments	114,037	64,379
Interest receivable	1,985	1,888
Accounts receivable	6,017	8,186
Prepaid expenses and other current assets	1,762	5,463
Total current assets	150,392	110,716
Property and equipment, net	12,644	10,996
Long-term investments	49,309	65,529
Other non-current assets	476	476
Total assets	\$ 212,821	\$ 187,717
<b>Liabilities and Stockholders Equity</b>		
Current liabilities		
Accounts payable and accrued liabilities	\$ 19,159	\$ 15,879
Current portion of deferred revenue	27,658	24,341
Total current liabilities	46,817	40,220
Long-term liabilities		
Deferred revenue, less current portion	63,273	66,958
Deferred rent and other long-term liabilities	2,641	1,521
Total long-term liabilities	65,914	68,479
Commitments and contingencies		
Stockholders equity		
Preferred stock, \$0.001 par value, 5,000 shares authorized; none issued		
Common stock, \$0.001 par value, 150,000 shares authorized; 86,886 shares issued and outstanding at June 30, 2009 and 79,791 shares issued and outstanding at December 31, 2008	87	80
Additional paid-in capital	464,818	394,338
Accumulated other comprehensive loss	(1,054)	(1,378)
Accumulated deficit	(363,761)	(314,022)

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

Total stockholders' equity	100,090	79,018
Total liabilities and stockholders' equity	\$ 212,821	\$ 187,717

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

**Table of Contents**

## Seattle Genetics, Inc.

## Condensed Consolidated Statements of Operations

(Unaudited)

(In thousands, except per share amounts)

	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Revenues from collaboration and license agreements	\$ 9,408	\$ 10,004	\$ 18,550	\$ 17,089
Operating expenses				
Research and development	28,712	23,499	61,958	45,651
General and administrative	4,019	4,094	8,175	8,029
Total operating expenses	32,731	27,593	70,133	53,680
Loss from operations	(23,323)	(17,589)	(51,583)	(36,591)
Investment income, net	852	1,561	1,844	3,451
Net loss	\$ (22,471)	\$ (16,028)	\$ (49,739)	\$ (33,140)
Net loss per share basic and diluted	\$ (0.26)	\$ (0.20)	\$ (0.59)	\$ (0.43)
Shares used in computation of net loss per share basic and diluted	86,200	79,277	84,880	77,768

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

**Table of Contents**

## Seattle Genetics, Inc.

## Condensed Consolidated Statements of Cash Flows

(Unaudited)

(In thousands)

	Six months ended June 30,	
	2009	2008
<b>Operating activities</b>		
Net loss	\$ (49,739)	\$ (33,140)
Adjustments to reconcile net loss to net cash used in operating activities		
Share-based compensation expense	5,443	4,974
Depreciation and amortization	1,558	1,609
Amortization on investments	2,025	467
Deferred rent and other long-term liabilities	1,120	818
Changes in operating assets and liabilities		
Interest receivable	(97)	(1,201)
Accounts receivable	2,169	(1,604)
Prepaid expenses and other current assets	3,701	(5,679)
Accounts payable and accrued liabilities	3,280	1,338
Deferred revenue	(368)	5,535
Net cash used in operating activities	(30,908)	(26,883)
<b>Investing activities</b>		
Purchases of securities available for sale	(106,716)	(133,239)
Proceeds from maturities of securities available for sale	69,554	39,015
Proceeds from sales of securities available for sale	2,023	
Purchases of property and equipment	(3,206)	(2,671)
Net cash used in investing activities	(38,345)	(96,895)
<b>Financing activities</b>		
Net proceeds from issuance of common stock	63,927	97,628
Proceeds from exercise of stock options and employee stock purchase plan	1,117	1,414
Net cash provided by financing activities	65,044	99,042
Net decrease in cash and cash equivalents	(4,209)	(24,736)
Cash and cash equivalents, at beginning of period	30,800	59,644
Cash and cash equivalents, at end of period	\$ 26,591	\$ 34,908

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

**Table of Contents**

**Seattle Genetics, Inc.**

**Notes to Condensed Consolidated Financial Statements**

**(Unaudited)**

**1. Basis of presentation**

The accompanying unaudited condensed consolidated financial statements reflect the accounts of Seattle Genetics, Inc. and its wholly-owned subsidiary, Seattle Genetics UK, Ltd. (collectively "Seattle Genetics" or the "Company"). The year end condensed consolidated balance sheet data was derived from audited financial statements not included in this quarterly report on Form 10-Q. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission, or SEC, and generally accepted accounting principles for unaudited condensed consolidated financial information. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. The accompanying unaudited condensed consolidated financial statements reflect all adjustments consisting of normal recurring adjustments which, in the opinion of management, are necessary for a fair statement of the Company's financial position and results of its operations, as of and for the periods presented. Management has determined that the Company operates in one segment: the development of pharmaceutical products on its own behalf or in collaboration with others.

Unless indicated otherwise, all amounts presented in financial tables are presented in thousands, except for per share and par value amounts.

These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and footnotes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2008 as filed with the Securities and Exchange Commission.

The preparation of financial statements in conformity with generally accepted accounting principles in the United States of America requires management to make estimates and assumptions that affect the reported amounts. Actual results could differ from those estimates. The results of the Company's operations for the three and six month periods ended June 30, 2009 are not necessarily indicative of the results to be expected for the full year.

We have considered subsequent events through August 6, 2009, the date the financial statements were available for issuance. There were no subsequent events requiring recognition or disclosure in the financial statements.

**2. Fair Value of Financial Instruments**

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

**3. Common Stock Financings**

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

**4. Concentration of Credit Risk**

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



**5. Recent Accounting Pronouncements**

In April 2009, the Financial Accounting Standards Board (FASB) issued guidance requiring interim disclosures about fair value of financial instruments. This guidance requires disclosures about fair value of financial instruments for interim reporting periods that were previously

**Table of Contents**

only required in annual financial statements. These disclosures include the methods and significant assumptions used to estimate the fair value of financial instruments and significant concentrations of credit risk arising from all financial instruments. The Company adopted the provisions of this guidance effective for the quarter ended June 30, 2009, which did not have a material effect on its condensed consolidated financial statements.

The FASB recently replaced the various sources of U.S. Generally Accepted Accounting Principles (GAAP) with a single source of authoritative GAAP for all nongovernmental entities. This single source of GAAP is referred to as the Codification. The Codification was not intended to change GAAP but, rather, to introduce a new structure for accessing and referring to GAAP. The Codification is effective for all interim and annual financial statements issued after September 15, 2009. The Company does not anticipate that adoption of the Codification will have a material effect on its financial statements.

**6. Net Loss Per Share**

Basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period. The Company excluded all warrants and options to purchase common stock from the calculation of diluted net loss per share as such securities are antidilutive for all periods presented. The following table presents the weighted-average number of shares that were excluded from the number of shares used to calculate basic and diluted net loss per share (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Warrants to purchase common stock	1,925	1,925	1,925	1,925
Options to purchase common stock	9,211	7,583	9,126	7,513
<b>Total</b>	<b>11,136</b>	<b>9,508</b>	<b>11,051</b>	<b>9,438</b>

**7. Comprehensive Loss**

Comprehensive loss includes certain changes in equity that are excluded from net loss. Specifically, unrealized gains or losses in available-for-sale investments are included in comprehensive loss. Comprehensive loss and its components were as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Net loss	\$ (22,471)	\$ (16,028)	\$ (49,739)	\$ (33,140)
Unrealized gain (loss) on securities available for sale	522	(926)	324	(741)
<b>Comprehensive loss</b>	<b>\$ (21,949)</b>	<b>\$ (16,954)</b>	<b>\$ (49,415)</b>	<b>\$ (33,881)</b>

**8. Investments**

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

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

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

	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
<b>June 30, 2009</b>				
Corporate obligations	\$ 55,037	\$ 603	\$ (204)	\$ 55,436
Auction rate securities	14,450		(1,668)	12,782
U.S. government and agencies	82,002	154	(7)	82,149
Taxable municipal bonds	13,212	88	(20)	13,280
<b>Total</b>	<b>\$ 164,701</b>	<b>\$ 845</b>	<b>\$ (1,899)</b>	<b>\$ 163,647</b>
<b>Contractual Maturities:</b>				
Due in one year or less	\$ 114,339			\$ 114,338
Due in one to three years	35,912			36,527
Due in 2017	14,450			12,782
<b>Total</b>	<b>\$ 164,701</b>			<b>\$ 163,647</b>
<b>Reported as:</b>				
Short-term investments				\$ 114,037
Long-term investments				49,309
Other non-current assets				301
<b>Total</b>				<b>\$ 163,647</b>

**Table of Contents**

As of June 30, 2009, certain of the Company's investment securities have a fair value that is less than the Company's amortized cost of the security and are therefore carried at an unrealized loss. The aggregate estimated fair value of the Company's investments with unrealized losses were as follows (in thousands):

	Period of continuous unrealized loss			
	12 months or less		Greater than 12 months	
	Fair value	Gross unrealized losses	Fair value	Gross unrealized losses
June 30, 2009				
Corporate obligations	\$ 1,404	\$ (25)	\$ 2,726	\$ (179)
Auction rate securities	NA	NA	12,782	(1,668)
U.S. government and agencies	30,397	(7)	NA	NA
Taxable municipal bonds	3,500	(20)	NA	NA
Total	\$ 35,301	\$ (52)	\$ 15,508	\$ (1,847)

When the estimated fair value of a security is below its carrying value, the Company evaluates whether it is more likely than not that it will be required to sell the security before its anticipated recovery in market value and whether evidence indicating that the cost of the investment is recoverable within a reasonable period of time outweighs evidence to the contrary. The Company also evaluates whether or not it intends to sell the investment. If the impairment is considered to be other-than-temporary, the security is written down to its estimated fair value. In addition, the Company considers whether credit losses exist for any securities. A credit loss exists if the present value of cash flows expected to be collected is less than the amortized cost basis of the security. Other-than-temporary declines in estimated fair value and credit losses are charged to investment income. The Company has not deemed it necessary to record any charges related to other-than-temporary declines in the estimated fair values of its marketable debt securities or credit losses.

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

As of June 30, 2009, the Company held ARS valued at \$12.8 million that have failed at auction and are currently illiquid. Liquidity of these investments is subject to either a successful auction process, redemption of the investment, or a sale of the security in a secondary market. Each of the securities continues to pay interest according to the stated terms on a monthly basis. The interest rates on these ARS are no longer established based on an auction process but are established according to the terms of the issue. As of June 30, 2009, the interest rate of the ARS was set at the 30-day London Interbank Offering rate plus 225 basis points. The Company considers the market for these securities as inactive and distressed. Accordingly, fair value for the ARS has been determined based on a probability-weighted discounted cash flow. This analysis relies upon certain estimates, including the probability-weighted term to an orderly liquidation and the discount rate applied to future cash flows. The discount rate used to determine fair value is based on the observed comparable yield of securities with similar characteristics. Due to the expected time to a liquidation event, investments in ARS are presented as long-term investments in the accompanying condensed consolidated balance sheets.

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

**Table of Contents**

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

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2: Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly.

Level 3: Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

The determination of a financial instrument's level within the fair value hierarchy is based on an assessment of the lowest level of any input that is significant to the fair value measurement. The following table presents the Company's available-for-sale securities by level within the fair value hierarchy for the periods presented (in thousands):

	Fair value measurement using:			Total
	Quoted prices			
	in active markets			
	for identical assets (Level 1)	Other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
	Available-for-sale securities at December 31, 2008	\$ 301	\$ 116,525	
Available-for-sale securities at June 30, 2009	\$ 75,997	\$ 74,868	\$ 12,782	\$ 163,647

Level 1 investments, which include investments that are valued based on quoted market prices in active markets, include most U.S. government securities. Level 2 investments, which include investments that are valued based on quoted prices in markets that are not active, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency, include most high-grade corporate bonds, U.S. agency obligations, taxable municipal bonds and commercial paper. Level 3 investments consist of ARS and account for 8% of total investment securities measured at fair value as of June 30, 2009.

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

	Fair value
Balance as of December 31, 2008	\$ 13,383
Unrealized loss reflected as a component of other comprehensive income	(601)
Balance as of June 30, 2009	\$ 12,782

The Company recorded a net unrealized gain of \$0.5 million for the three months ended June 30, 2009, and \$0.3 million for the six months ended June 30, 2009, in other comprehensive income.

**Table of Contents****9. Collaborative arrangements***Agensys*

In January 2007, the Company entered into an agreement with Agensys, now a wholly-owned subsidiary of Astellas Pharma, to jointly research, develop and commercialize antibody-drug conjugates (ADCs) for the treatment of cancer. The collaboration encompasses combinations of the Company's ADC technology with antibodies developed by Agensys to proprietary cancer targets. Under the terms of the multi-year agreement, Agensys and the Company will jointly screen and select ADC product candidates to an initial target, ASG-5ME (formerly AGS-5), and will equally co-fund all development and commercialization costs and share equally in any profits of such ADC product candidates.

The Agensys collaboration agreement defines a mechanism for calculating the costs of co-development activities and for reimbursing the other party in order to maintain an equal sharing of development costs. Third-party costs are billed at actual cost and internal labor and support costs are billed at a contractual rate. Payments made by the Company to Agensys are included in research and development expense. Payments made by Agensys to the Company are reflected as a reduction in research and development expense. The following table summarizes research and development expenses incurred by the Company and payments made to, or received from, Agensys under the collaboration (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Research and development expense using contractual rates	\$ 1,312	\$ 107	\$ 1,896	\$ 174
Reimbursement payable to (receivable from) Agensys	(318)	97	102	320
<b>Total</b>	<b>\$ 994</b>	<b>\$ 204</b>	<b>\$ 1,998</b>	<b>\$ 494</b>

**Item 2. 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 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 under the caption Risk Factors set forth in Item 1A of Part II of this quarterly report on Form 10-Q, as well as 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.

---

## **Table of Contents**

### **Overview**

We are a clinical stage biotechnology company focused on the development and commercialization of monoclonal antibody-based therapies for the treatment of cancer and autoimmune disease. We initiated a pivotal trial of our lead product candidate, brentuximab vedotin (SGN-35), during the first quarter of 2009 for patients with relapsed or refractory Hodgkin lymphoma under a special protocol assessment (SPA) with the U.S. Food and Drug Administration (FDA). Brentuximab vedotin is empowered by our proprietary antibody-drug conjugate (ADC) technology comprising highly potent synthetic drugs and stable linkers for attaching the drugs to monoclonal antibodies. In addition, we have two other product candidates in ongoing late stage clinical trials: lintuzumab and dacetuzumab, and one product candidate in an early stage clinical trial: SGN-70. Dacetuzumab is being developed under a worldwide collaboration with Genentech, Inc., a wholly-owned member of the Roche Group.

We have collaborations for our ADC technology with a number of leading biotechnology and pharmaceutical companies, including Genentech, Inc., Bayer Pharmaceuticals Corporation, CuraGen Corporation, Progenics Pharmaceuticals, Inc., Daiichi Sankyo Co., Ltd., Millennium: The Takeda Oncology Company, a subsidiary of the Takeda Pharmaceutical Company Limited, and MedImmune, Inc., a subsidiary of AstraZeneca Inc. In addition, we have an ADC co-development agreement with Agensys Inc., a subsidiary of Astellas Pharma, Inc.

We do not currently have any commercial products for sale. While certain of our product candidates are advancing into later stages of development, such as brentuximab vedotin, significant further research and development, financial resources and personnel will be required to develop commercially viable products and obtain regulatory approvals. As of June 30, 2009, we had an accumulated deficit of \$363.8 million. Over the next several years, we expect that we will incur substantial expenses, primarily as a result of activities related to the potential regulatory approval and commercialization of brentuximab vedotin, including preparation for commercial manufacturing. We will also continue to invest in research, development and manufacturing as we move towards potential commercialization of our other product candidates. Our commitment of resources to the approval and commercialization activities for brentuximab vedotin and the research and continued development and potential commercialization of our other product candidates will require substantial additional funds and resources, and our operating expenses will also likely increase as a result of such activities. In addition, we may incur significant milestone payment obligations as our product candidates progress through clinical trials towards potential commercialization. We expect that a substantial portion of our revenues for the next several years will be the result of the amortization of payments already received and that are expected to be received from Genentech under our dacetuzumab collaboration agreement. Until such time as we may commercialize a product candidate, our revenues will also depend on the achievement of development and clinical milestones under our existing collaboration and license agreements, particularly our dacetuzumab collaboration agreement with Genentech, as well as entering into new collaboration and license agreements. Our results of operations may vary substantially from year to year and from quarter to quarter and, as a result, we believe that period to period comparisons of our operating results may not be meaningful and you should not rely on them as indicative of our future performance.

### ***Financial summary***

To date, we have generated revenues principally from our collaboration and license agreements. These revenues reflect upfront technology access fees, milestone payments and reimbursement for support and materials supplied to our collaborators. For the six months ended June 30, 2009, revenues increased 9% to \$18.6 million, compared to \$17.1 million for the same period in 2008. Operating expenses increased 31% to \$70.1 million, compared to \$53.7 million for the same period in 2008. Our net loss for the six-month period ended June 30, 2009 was \$49.7 million, or \$0.59 per share, compared to \$33.1 million, or \$0.43 per share, for the same period in 2008. As of June 30, 2009, we had \$189.9 million in cash, cash equivalents and short-term and long-term investments, and \$100.1 million in total stockholders' equity.

### **Results of Operations**

#### **Three months and six months ended June 30, 2009 and 2008**

##### **Revenues.**

Revenues by collaborator are summarized as follows:

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

Collaboration and license agreement revenue (\$ in thousands)	Three months ended			Six months ended		
	2009	June 30, 2008	% change	2009	June 30, 2008	% change
Genentech	\$ 8,352	\$ 7,271	15%	\$ 16,832	\$ 13,638	23%
Daiichi Sankyo	403		N/A <sup>(1)</sup>	815		N/A <sup>(1)</sup>
Millennium	338		N/A <sup>(1)</sup>	338		N/A <sup>(1)</sup>
Bayer	79	887	(91)%	221	918	(76)%
CuraGen	84	1,062	(92)%	134	1,087	(88)%
MedImmune	100	462	(78)%	100	880	(89)%
Progenics		252	(100)%	9	416	(98)%
Other	52	70	(26)%	101	150	(33)%
<b>Total</b>	<b>\$ 9,408</b>	<b>\$ 10,004</b>	<b>(6)%</b>	<b>\$ 18,550</b>	<b>\$ 17,089</b>	<b>9%</b>

(1) No amount in comparable period.



**Table of Contents**

Genentech revenues increased 15% to \$8.4 million in the second quarter of 2009 and 23% to \$16.8 million for the first six months of 2009 compared to the comparable periods in 2008. The increases primarily resulted from revenues earned under the dacetuzumab collaboration agreement with Genentech entered into in January 2007. Under the terms of this agreement, we perform research and development activities over the six-year development period of the agreement, the costs of which are reimbursed by Genentech. We are also entitled to receive milestones as dacetuzumab progresses through development and royalties on future product sales. The \$60 million upfront payment received in 2007 and all reimbursement and milestone payments received by us are deferred and recognized as revenue over the development period of the agreement using a time-based method. Genentech revenues also reflect the earned portion of payments received under our ADC collaboration agreement. Daiichi Sankyo revenues reflect the earned portion of a \$4.0 million upfront payment received by us under our ADC collaboration that began in July 2008, and reimbursable support and research materials provided to Daiichi Sankyo by us. Millennium revenues reflect the earned portion of a \$4.0 million upfront payment received by us under our ADC collaboration that began in March 2009 and reimbursable support and research materials provided to Millennium by us. Revenues attributable to our ADC collaboration agreement with Bayer decreased during both the three and six month periods of 2009 reflecting revenue earned from a collaboration extension payment we received from Bayer in the second quarter of 2008. Revenues attributable to our ADC collaboration agreement with CuraGen decreased during both the three and six month periods of 2009 reflecting revenue earned from a milestone payment triggered by CuraGen's initiation of a Phase II clinical trial in the second quarter of 2008. Revenues decreased under both our MedImmune and Progenics collaborations during both the three and six months periods of 2009 from the comparable periods in 2008. The research term has been completed for both of these agreements.

Our revenue is impacted by progress-dependent milestones, annual maintenance fees and reimbursement and support fees as our collaborators advance product candidates through the development process and the level of activity we perform under our dacetuzumab collaboration with Genentech. We expect that our collaboration and license agreement revenue will increase in 2009 compared to 2008. However, revenue may vary substantially from quarter to quarter depending on the progress made by our collaborators with their product candidates, the level of support we provide to our collaborators, the timing of milestones achieved and our ability to enter into additional collaboration agreements. In addition, we have a significant balance in deferred revenue representing prior payments from collaborators. This deferred revenue will be recognized as revenue in the future using a time-based approach as we fulfill our performance obligations under the applicable collaboration agreement.

**Research and development.**

Our research and development expenses are summarized as follows:

Research and Development (\$ in thousands)	Three months ended			Six months ended		
	2009	June 30, 2008	% change	2009	June 30, 2008	% change
Research	\$ 2,663	\$ 3,870	(31)%	\$ 6,301	\$ 7,821	(19)%
Development and contract manufacturing	10,678	6,045	77%	23,629	12,707	86%
Clinical	13,650	11,920	15%	28,609	22,057	30%
Share-based compensation expense	1,721	1,664	3%	3,419	3,066	12%
<b>Total research and development expenses</b>	<b>\$ 28,712</b>	<b>\$ 23,499</b>	<b>22%</b>	<b>\$ 61,958</b>	<b>\$ 45,651</b>	<b>36%</b>

Research expenses decreased 31% to \$2.7 million in the second quarter of 2009 and 19% to \$6.3 million in the first six months of 2009 from the comparable periods in 2008, primarily reflecting lower personnel, lab supply and services costs in 2009. Development and contract manufacturing costs increased 77% to \$10.7 million in the second quarter of 2009 and 86% to \$23.6 million in the first six months of 2009 from the comparable periods in 2008. These increases reflect increased manufacturing costs associated with supplying brentuximab vedotin for our clinical trials, including our pivotal trial in relapsed or refractory Hodgkin lymphoma initiated in the first quarter of 2009, and higher employee costs related to increased staffing levels. Clinical costs increased 15% to \$13.7 million in the second quarter of 2009 and 30% to \$28.6 million in the first six months of 2009 from the comparable periods in 2008. These increases resulted from expanded clinical trial activities for brentuximab vedotin during the second quarter of 2009 and for brentuximab vedotin, dacetuzumab and lintuzumab for the first six months of 2009, as well as higher compensation costs related to an increase in staffing levels to support ongoing clinical trials. Share-based compensation expense increased 3% during the second quarter of 2009 and 12% during the first six months of 2009 compared to the periods in 2008. The increase was due to a larger number of optioned shares subject to expense recognition during the 2009 periods as a result of increased staffing levels.

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



**Table of Contents**

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. The table also presents other costs and overhead consisting of personnel, facilities and other costs not directly allocable to development programs:

Product Candidates (\$ in thousands)	Three months ended		Six months ended		Five years ended
	June 30,		June 30,		June 30, 2009
	2009	2008	2009	2008	
Brentuximab vedotin (SGN-35)	\$ 7,701	\$ 2,293	\$ 16,290	\$ 3,941	\$ 42,419
Dacetuzumab (SGN-40)	3,685	2,818	8,313	7,754	42,400
Lintuzumab (SGN-33)	2,160	3,085	5,767	5,226	32,051
SGN-70	215	395	588	625	10,051
SGN-75	862	444	1,414	933	5,077
Total third-party costs	14,623	9,035	32,372	18,479	131,998
Other costs and overhead	12,368	12,800	26,167	24,105	182,876
Share-based compensation expense	1,721	1,664	3,419	3,067	18,353
<b>Total research and development expenses</b>	<b>\$ 28,712</b>	<b>\$ 23,499</b>	<b>\$ 61,958</b>	<b>\$ 45,651</b>	<b>\$ 333,227</b>

Our third-party costs for brentuximab vedotin increased during both the three months and six months ended June 30, 2009 from the comparable periods in 2008 as a result of increased contract manufacturing to provide clinical supplies of brentuximab vedotin drug product and expanded clinical trial activities, including our pivotal trial in relapsed or refractory Hodgkin lymphoma initiated in the first quarter of 2009. We expect to complete patient accrual into this trial in the third quarter of 2009 and to complete patient treatment and follow up in the second half of 2010. Our third-party costs for dacetuzumab increased during the three months and six months ended June 30, 2009 from the comparable periods in 2008 reflecting increased clinical trial activities. This was partially offset by lower contract manufacturing costs due to completion of a dacetuzumab drug product resupply campaign. Under our dacetuzumab collaboration agreement, Genentech reimburses us for development activities that we perform under the agreement. Expenses that we incur under the dacetuzumab collaboration are included in our research and development expense, while reimbursements of those expenses by Genentech are recognized as revenue over the six year development period of the agreement. Our third-party costs for lintuzumab decreased during the three months ended June 30, 2009, but increased slightly during the six months ended June 30, 2009, from the comparable periods in 2008. The decrease for the three-month period reflects lower expenses for clinical trial activities and lower contract manufacturing costs due to completion of our drug product resupply campaign. The increase for the six-month period was due to higher clinical trial activities, primarily due to patient enrollment during the first quarter of 2009 in the Phase IIb trial of lintuzumab in combination with low-dose cytarabine. Patient accrual into this trial was completed during the first quarter of 2009. Increased clinical trial costs were partially offset by lower contract manufacturing costs due to completion of our lintuzumab drug product resupply campaign. SGN-70 costs decreased during both the three months and six months ended June 30, 2009 from the comparable periods in 2008. We are currently conducting a Phase I clinical trial of SGN-70 in the treatment of autoimmune disease. SGN-75 costs increased during both the three months and six months ended June 30, 2009 from the comparable periods in 2008 due to increased contract manufacturing activities.

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

the number of patients who participate in the trials;

the length of time required to enroll trial participants;

the number and location of sites included in the trials;

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

the safety and efficacy profile of the product candidate;

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

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

Furthermore, our strategy 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.

**Table of Contents**

We anticipate that our total research, development, contract manufacturing and clinical expenses will increase in the foreseeable future as we prepare to seek regulatory approval and commercialization of brentuximab vedotin. However, we expect third-party costs for dacetuzumab, lintuzumab, SGN-70 and SGN-75 to decrease in 2009 compared to 2008, reflecting lower manufacturing and pharmacology/toxicology activities for these programs in 2009. In the beginning of 2010, we expect third-party costs for dacetuzumab, lintuzumab and SGN-70 to continue to decline; however, we expect that third-party costs for SGN-75 will begin to increase with the initiation of a planned Phase I clinical trial. Expenses will fluctuate based upon many factors including the degree of collaborative activities, timing of manufacturing campaigns, numbers of patients enrolled in our clinical trials and the outcome of each clinical trial event. For example, we currently anticipate that data will be available for the Phase IIB trial of lintuzumab in combination with low-dose cytarabine in the first half of 2010. If the results of this trial are positive, we expect that third-party costs associated with the program will increase.

The risks and uncertainties associated with our research and development projects are discussed more fully in the section entitled Risk Factors that appears in our periodic reports filed with the SEC, including in Item 1A of Part II of this quarterly report on Form 10-Q. As a result of the uncertainties discussed above, we are unable to determine with any degree of certainty the duration and completion costs of our research and development projects, anticipated completion dates or when and to what extent we will receive cash inflows from the commercialization and sale of a product candidate.

**General and administrative.**

General and administrative (\$ in thousands)	Three months ended			Six months ended		
	2009	June 30, 2008	% change	2009	June 30, 2008	% change
General and administrative, excluding share-based compensation expense	\$ 3,011	\$ 3,012	0%	\$ 6,151	\$ 6,122	0%
Share-based compensation expense	1,008	1,082	(7)%	2,024	1,907	6%
<b>Total general and administrative expenses</b>	<b>\$ 4,019</b>	<b>\$ 4,094</b>	<b>(2)%</b>	<b>\$ 8,175</b>	<b>\$ 8,029</b>	<b>2%</b>

General and administrative expenses varied by 2% during the three and six month periods ended June 30, 2009 from the comparable periods in 2008. The variances were due to differences in share-based compensation expense included in general and administrative expenses. We anticipate that general and administrative expenses will increase during the remainder of 2009 as a result of increased costs related to adding personnel in support of the anticipated growth of our operations.

**Investment income, net.**

Investment income, net decreased 45% to \$0.9 million in the second quarter of 2009 and decreased 47% to \$1.8 million in the first six months of 2009 from the comparable periods in 2008. The decreases resulted from lower average investment balances and lower yields on investments during the 2009 periods.

**Liquidity and capital resources.**

Selected Financial Data (\$ in thousands)	June 30, 2009	December 31, 2008
Cash, cash equivalents and investments	\$ 189,937	\$ 160,708
Working capital	103,575	70,496
Stockholders' equity	100,090	79,018

	Six months ended June 30, 2009	June 30, 2008
Cash provided by (used in):		
Operating activities	\$ (30,908)	\$ (26,883)
Investing activities	(38,345)	(96,895)

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

### Financing activities

65,044

99,042

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

---

**Table of Contents**

Our combined cash, cash equivalents and investments increased to \$189.9 million at June 30, 2009, compared to \$160.7 million at December 31, 2008. This increase reflected cash provided by financing activities, which included net proceeds of \$52.5 million from our public offering of common stock that closed in February 2009, and \$11.5 million of net proceeds from a private placement of common stock that closed in May 2009. We used \$30.9 million during the first six months of 2009 and \$26.9 million during the first six months of 2008 to fund our operating activities. Our working capital was \$103.6 million at June 30, 2009, compared to \$70.5 million at December 31, 2008, primarily reflecting an increase in shorter duration investments during the first six months of 2009. We have structured our investment portfolio to align scheduled maturities of investment securities with our working capital needs. Our cash, cash equivalents and investments are held in a variety of interest-bearing instruments and subject to investment guidelines allowing for investments in U.S. government and agency securities, high-grade corporate bonds, taxable municipal bonds, mortgage-backed securities, auction-rate securities, or ARS, commercial paper and money market accounts. As of June 30, 2009, we held ARS valued at \$12.8 million that have failed at auction and are currently illiquid. Liquidity of these investments is subject to either a successful auction process, redemption of the investment, or a sale of the security in a secondary market. Each of the securities continues to pay interest according to the stated terms on a monthly basis. The interest rates on these ARS are no longer established based on an auction process but are established according to the terms of the issue. As of the date of this filing, the interest rates of the ARS are set at the 30-day London Interbank Offering rate plus 225 basis points. Based on our available cash, expected operating cash requirements and our belief that the holdings in ARS can be liquidated in approximately one to three years at par, we believe it is more likely than not that we have the ability to hold, and intend to hold, these investments until they recover substantially all of their cost basis. This belief is based on our current assessment of our future operating plans and assessment of the individual securities and general market conditions. We periodically reassess this conclusion based on several factors, including the continued failure of future auctions, failure of the investment to be redeemed, further deterioration of the credit rating of the investment, market risk and other factors. Any such future reassessment that results in a conclusion that the unrealized losses on these investments are other than temporary would result in a write down in the fair value of these investments. Such a write down would be recognized in our operating results. These securities are valued based on significant unobservable inputs (Level 3) as further discussed in Note 8 to the condensed consolidated financial statements.

The global credit and financial markets have recently experienced a period of unusual volatility and illiquidity. Our investment portfolio is structured to provide for investment maturities and access to cash that aligns with our anticipated working capital needs. However, if our liquidity needs should be accelerated for any reason in the near term, or investments do not pay at maturity, we may be required to sell investment securities in our portfolio prior to their scheduled maturities, which may result in a loss. As of June 30, 2009, our cash, cash equivalents and investment securities are presented net of a cumulative \$1.1 million unrealized loss. This amount represents the difference between our amortized cost and the fair market value of the investments and is included in accumulated other comprehensive loss. As of June 30, 2009, we had \$140.6 million held in cash reserves or debt securities scheduled to mature within the next twelve months.

As a result of a faster than anticipated rate of patient enrollment in our brentuximab vedotin pivotal trial in relapsed or refractory Hodgkin lymphoma and the corresponding acceleration of activities related to the brentuximab vedotin program, we currently expect that our operating expenses will be near the top end of our guidance range for the year ending December 31, 2009, which was previously set at \$125 million to \$140 million. However, our 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. Certain external factors may influence our expenses including the cost of filing and enforcing patent claims and other intellectual property rights, competing technological and market developments. In addition, as a result of the private placement of common stock that closed in May 2009, and upfront cash received as a result of the ADC collaboration agreement with Millennium, partially offset by the higher spending on the brentuximab vedotin program, based on total cash, cash equivalents and investments as of June 30, 2009, we expect to end 2009 with more than \$130 million in cash, cash equivalents and investments.

At our currently planned spending rate, we believe that our financial resources, in addition to the expected fees and milestone payments earned under the dacetuzumab collaboration agreement with Genentech and other existing collaboration and license agreements will be sufficient to fund our operations into 2011. However, changes in our spending rate may occur that would consume available capital resources sooner, such as increased manufacturing and clinical trial expenses and the expansion of our sales and marketing organization preceding anticipated commercialization of a product candidate. Additionally, we may not receive the fees and milestone payments and reimbursement payments that we currently expect under our collaboration and license agreements, including the dacetuzumab collaboration agreement with Genentech, which may shorten the timeframe through which we are able to fund operations. Moreover, we expect to make additional capital outlays and to increase operating expenditures over the next several years as we hire additional employees and support our preclinical development, manufacturing and clinical trial activities, as well as position our product candidates, specifically brentuximab vedotin, for potential regulatory approval and commercial sale, and we will therefore continue to need significant amounts of additional capital. We may seek additional funding through some or all of the following methods: corporate collaborations, licensing arrangements, public or private debt or equity financings. However, the global credit markets and the financial services industry have recently been experiencing a period of unusual volatility and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the U.S. government. These events have generally made equity and debt financing more difficult to obtain. As a result of these recent events and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will obtain financing on terms favorable to us or our stockholders. If we are unable to raise additional funds when we need them, we may be required to delay, reduce the scope

of, or eliminate one or more of our development programs, which may adversely affect our business and operations.



**Table of Contents****Recent Accounting Pronouncements**

In April 2009, the Financial Accounting Standards Board (FASB) issued guidance requiring interim disclosures about fair value of financial instruments. This guidance requires disclosures about fair value of financial instruments for interim reporting periods that were previously only required in annual financial statements. These disclosures include the methods and significant assumptions used to estimate the fair value of financial instruments and significant concentrations of credit risk arising from all financial instruments. We adopted the provisions of this guidance effective for the quarter ended June 30, 2009, which did not have a material effect on our condensed consolidated financial statements.

The FASB recently replaced the various sources of U.S. Generally Accepted Accounting Principles (GAAP) with a single source of authoritative GAAP for all nongovernmental entities. This single source of GAAP is referred to as the Codification. The Codification was not intended to change GAAP but, rather, to introduce a new structure for accessing and referring to GAAP. The Codification is effective for all interim and annual financial statements issued after September 15, 2009. We do not anticipate that adoption of the Codification will have a material effect on our financial statements.

**Commitments**

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

The following table reflects our future minimum contractual commitments for the periods subsequent to June 30, 2009 (in thousands):

	Total	Remainder of 2009	2010	2011	2012	2013	Thereafter
Operating leases	\$ 26,876	\$ 1,332	\$ 2,715	\$ 2,795	\$ 2,836	\$ 2,917	\$ 14,281
Manufacturing, license & collaboration agreements	27,386	16,861	7,369	1,680	738	738	
Tenant Improvements	128	128					
Total	\$ 54,390	\$ 18,321	\$ 10,084	\$ 4,475	\$ 3,574	\$ 3,655	\$ 14,281

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

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

Our market risks during the six months ended June 30, 2009 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2008 filed with the SEC. Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. Our investment securities consisted of the following (in thousands):

June 30, 2009	December 31, 2008
------------------	----------------------

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

Short-term investments	\$ 114,037	\$ 64,379
Long-term investments	49,309	65,529
Other non-current assets	301	301
Total	\$ 163,647	\$ 130,209

---

## **Table of Contents**

Included in long-term investments as of June 30, 2009 are auction-rate securities valued at \$12.8 million that have failed at auction and are currently illiquid. Liquidity of these investments is subject to either a successful auction process, redemption of the investment, or a sale of the security in a secondary market. Given that further deterioration in the global credit and financial markets is a possibility, no assurance can be made that further downgrades, losses, failed auctions or other significant deterioration in the fair value of our cash equivalents, short-term or long-term investments will not occur. If any such further downgrades, losses, or other significant deteriorations occur, it may negatively impact or impair our current portfolio of cash equivalents, short-term or long-term investments.

We have estimated the effect on our investment portfolio of a hypothetical increase in interest rates by one percent to be a reduction of \$1.1 million in the fair value of our investments as of June 30, 2009. In addition, a hypothetical decrease of one percent in the effective yield of our investments would reduce our investment income over a one-year period by approximately \$1.5 million.

### **Item 4. Controls and Procedures**

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

(b) *Changes in internal control over financial reporting.* There were no changes in our internal control over financial reporting during the quarter ended June 30, 2009 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **Part II. Other Information**

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

You should carefully consider the following risk factors, in addition to the other information contained in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and related notes. If any of the events described in the following risk factors occurs, our business, operating results and financial condition could be seriously harmed. This Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q.

We have marked with an asterisk (\*) those risks described below that reflect substantive changes from, or additions to, the risks described in our Annual Report on Form 10-K for the year ended December 31, 2008, filed with the SEC.

### **Risks Related to Our Business**

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

We currently have no products that are approved for commercial sale. Our product candidates are in various stages of development, and significant research and development, financial resources and personnel will be required to develop commercially viable products and obtain regulatory approvals for them. A substantial portion of our efforts and expenditures over the next few years will be devoted to brentuximab vedotin, which is the subject of an ongoing pivotal clinical trial pursuant to a special protocol assessment, or SPA, with the FDA. Accordingly, our future prospects are substantially dependent on the successful development, regulatory approval and commercialization of brentuximab vedotin for the treatment of patients with relapsed or refractory Hodgkin lymphoma. Brentuximab vedotin is not expected to be commercially available for this or any other indication until at least the second half of 2011, if at all. Further, the commercial success of brentuximab vedotin will depend upon its acceptance by physicians, patients, third party payors and other key decision-makers as a therapeutic and cost-effective alternative to currently available products. In addition, the indications that we are pursuing for brentuximab vedotin have relatively low incidence rates, including Hodgkin lymphoma and anaplastic large cell lymphoma, which may limit the revenue potential of brentuximab vedotin. If we are unable to successfully develop, obtain regulatory approval for and commercialize brentuximab vedotin for the treatment of relapsed or refractory Hodgkin lymphoma and other indications, our ability to generate revenue from product sales will be significantly delayed and our business would be materially affected and we may not be able to earn sufficient revenues to continue as a going concern.



---

## **Table of Contents**

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

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

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

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

Our ability to commercialize any of our product candidates, including brentuximab vedotin, depends on first receiving required regulatory approvals, and it is possible that we may never receive regulatory approval for any of our product candidates. Even if a product candidate receives regulatory approval, the resulting product may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Assuming dacetuzumab receives regulatory approval, commercial success will depend in large part on Genentech's commercialization efforts. The degree of commercial success of any approved product will depend on a number of factors, including:

establishment and demonstration of clinical efficacy and safety;

cost-effectiveness of the product;

the product's potential advantage over alternative treatment methods;

whether the product can be produced in commercial quantities at acceptable costs; and

marketing and distribution support for the product.

We do not expect any of our current product candidates to be commercially available until at least the second half of 2011, if at all. If we fail to gain marketing approval from the FDA or to develop a commercially successful product, we may not be able to earn sufficient revenues to continue as a going concern and we will not be successful.



---

**Table of Contents**

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

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

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

If we or our collaborators receive regulatory approval for our product candidates, we will also be subject to ongoing FDA obligations and oversight, including adverse event reporting requirements, marketing restrictions and potential post-marketing obligations, all of which may result in significant expense and limit our ability to commercialize such products. The FDA's policies may also change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we may be subject to civil and criminal penalties, we may not be permitted to market our products and our business could suffer. Any delay in or failure to receive or maintain regulatory approval for any of our product candidates could harm our business and prevent us from ever generating meaningful revenues or achieving profitability.

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

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

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate, through extensive preclinical studies and clinical trials, that the product candidate is safe and effective in humans. Ongoing and future clinical trials of our product candidates may not show sufficient safety or efficacy to obtain requisite regulatory approvals. The clinical data from our phase I trials of brentuximab vedotin are limited and the results of our brentuximab vedotin pivotal trial, which was initiated in the first quarter of 2009, will be blinded to us until completion of the trial. In addition, we still only have limited data from our phase I and II clinical trials of dacetuzumab and lintuzumab and our phase I trial of SGN-70. Phase I and phase II clinical trials are not primarily designed to test the efficacy of a product candidate but rather are designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the product candidate's side effects at various doses and dosing schedules. Furthermore, success in preclinical and early clinical trials does not ensure that later large-scale trials will be successful nor does it predict final results. Acceptable results in early trials may not be repeated in later trials. The pivotal trial of brentuximab vedotin requires the enrollment of 100 patients and we believe that any clinical trial designed to test the efficacy of dacetuzumab, lintuzumab or SGN-70, whether phase II or phase III, will likely involve a large number of patients to achieve statistical significance and will be expensive. As a result, we may conduct lengthy and expensive clinical trials of brentuximab vedotin, dacetuzumab, lintuzumab or SGN-75, only to learn that the product candidate is not an effective treatment or is not superior to existing approved therapies or has an unacceptable safety profile, which could prevent or significantly delay regulatory approval for such product candidate.





---

**Table of Contents**

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

We are currently conducting one pivotal trial under an SPA with the FDA for brentuximab vedotin, and multiple phase I and phase II clinical trials of our other clinical product candidates, and we expect to commence additional trials of these and other product candidates in the future. Each of our clinical trials requires the investment of substantial expense and time and the timing of the commencement, continuation and completion of these clinical trials may be subject to significant delays relating to various causes, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling patients who meet trial eligibility criteria, failure of patients to complete the clinical trial, delay or failure to obtain IRB approval to conduct a clinical trial at a prospective site, and shortages of available drug supply. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments. In addition, future and ongoing dacetuzumab 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 certain of our current and previous clinical trials and will likely experience similar delays in our future trials, particularly as we attempt to significantly increase patient size as may be required for phase III studies. We depend on medical institutions and clinical research organizations, or CROs, to conduct our clinical trials in compliance with Good Clinical Practice or GCP, and to the extent they fail to enroll patients for our clinical trials or are delayed for a significant time in achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business. In addition, we conduct clinical trials in foreign countries which may subject us to further delays and expenses as a result of increased drug shipment costs, additional regulatory requirements and the engagement of foreign CROs, as well as expose us to risks associated with foreign currency transactions insofar as we might desire to use U.S. dollars to make contract payments denominated in the foreign currency where the trial is being conducted.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

---

**Table of Contents**

In addition, we may experience significant setbacks in advanced clinical trials, even after promising results in earlier trials, such as unexpected adverse events that occur when our product candidates are combined with other therapies, which often occurs in later-stage clinical trials. For example, we are conducting phase II clinical trials with both dacetuzumab and lintuzumab combined with other therapies, including chemotherapy, and may experience unexpected adverse events as a result of these combinations. In addition, clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse medical events, including patient fatalities that may be attributable to our product candidates, during a clinical trial could cause it to be redone or terminated. Further, the phase II clinical trials of dacetuzumab and lintuzumab are overseen by a data safety monitoring board, or DSMB, and the DSMB may determine to delay or suspend one or both of these trials due to futility or safety findings based on its interpretation of the results obtained during a clinical trial.

***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 collaborations with third-parties to develop and market some of our current and future product candidates. We entered into an exclusive worldwide collaboration agreement with Genentech in January 2007 for the development and commercialization of our dacetuzumab product candidate. We also have active ADC collaborations with Genentech, Bayer, CuraGen, Progenics, MedImmune, Daiichi Sankyo and Millennium, and an ADC co-development agreement with Agensys.

Under certain conditions, our collaborators may terminate their agreements with us and discontinue use of our technologies. 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 March 2009, Roche completed its acquisition of Genentech pursuant to which Genentech became a wholly-owned member of the Roche Group, and although we are not aware of any changes to our dacetuzumab collaboration as a result of the acquisition of Genentech by Roche, we remain uncertain as to what effect this acquisition will or might have on our dacetuzumab collaboration. In particular, Genentech and/or Roche may terminate the dacetuzumab collaboration, which Genentech may do at its election for negative or inconclusive clinical results or for no reason at all and if Genentech and/or Roche determines to terminate the dacetuzumab collaboration, we would not receive milestone payments or royalties for development or sale of dacetuzumab. As a result of such termination, we would have to engage another collaborator to complete the dacetuzumab development process or complete the process ourselves internally, either of which could significantly delay the development process and increase our costs. In turn, this could significantly harm our financial position, adversely affect our stock price and require us to incur all the costs of developing and commercializing dacetuzumab, which costs are now being funded 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 have no experience in commercializing products on our own and, to the extent we do not develop this ability or contract with a third party to assist us, we may not be able to successfully commercialize our product candidates that may be approved for commercial sale.***

We do not have a sales and marketing force and may not be able to develop this capacity. If we are unable to establish sales and marketing capabilities, we will need to enter into sales and marketing agreements to market any of our product candidates that may be approved for commercial sale, except for dacetuzumab for which Genentech and/or its licensees will lead the sales and marketing efforts under the terms of our dacetuzumab collaboration, while we retain an ability to co-promote dacetuzumab in the United States. If we are unable to establish sales and marketing capabilities or successful distribution relationships with biotechnology or pharmaceutical companies, we may fail to realize the full sales potential of some of our product candidates. Even if we are able to establish distribution agreements with biotechnology or pharmaceutical companies, we generally would not have control over the resources or degree of effort that any of these third parties may devote to our collaborations, and if they fail to devote sufficient time and resources to the marketing of our product candidates, or if their performance is substandard, it will adversely affect the sale of our product candidates.



---

**Table of Contents**

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

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

We have collaborations with a limited number of companies. To date, almost all of our revenue has resulted from payments made under agreements with our corporate collaborators, and we expect that most of our future revenue will continue to come from corporate collaborations until the approval and commercialization of one or more of our product candidates and even then we may still be highly dependent on a collaborator for the approved product. For example, if dacetuzumab receives regulatory approval, our revenues will still be dependent on Genentech's ability and willingness to market the approved product. The loss of our collaborators, especially Genentech, or 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.

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

We do not currently have the internal ability to manufacture the drug products that we need to conduct our clinical trials and we rely upon a limited number of manufacturers to supply our drug products. For the monoclonal antibody used in brentuximab vedotin, we have contracted with Abbott Laboratories for clinical and potential future commercial supplies. For dacetuzumab, we have also contracted with Abbott Laboratories for clinical and potential future commercial supplies. Decisions on future dacetuzumab drug supply will be made jointly by us and Genentech through our collaboration. For lintuzumab, we received clinical-grade material from PDL BioPharma to support phase I trials and entered into a contract manufacturing arrangement with Laureate Pharma to provide later-stage clinical supplies, including for our ongoing phase IIb trial. 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 and Sigma Aldrich Fine Chemicals, or SAFC, 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.

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



**Table of Contents**

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

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

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

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

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

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

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

We have incurred substantial net losses in each of our years of operation and, as of June 30, 2009, we had an accumulated deficit of approximately \$364 million. We expect to make substantial expenditures to further develop and commercialize our product candidates, some of which are expected to be reimbursed by Genentech as part of our dacetuzumab 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 product candidates. In the near term, we expect our revenues to be derived from technology licensing fees, sponsored research fees and milestone payments under existing and future collaborative arrangements. In the longer term, our revenues may also include royalties from collaborations with current and future strategic partners and commercial product sales if any of our product candidates are approved for commercial sale. However, our revenue and profit potential is unproven and our limited operating history makes our future operating results difficult to predict. We have never been profitable and may never achieve profitability and if we do achieve profitability, it may not be sustainable.





**Table of Contents**

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

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

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

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

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

progress with clinical trials;

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; and

competing technological and market developments.

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

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

We have entered into agreements with third-party commercial and academic institutions to license technology for use in our product candidates and ADC technology. Currently, we have license agreements with Bristol-Myers Squibb, Arizona State University, Genentech, PDL BioPharma, Facet Biotech, CLB Research and Development, CMC ICOS Biologics, 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 will likely require us to secure licenses to additional technologies. We may not be able to secure these licenses on commercially reasonable terms, if at all.

---

## **Table of Contents**

***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, patent applications, and their foreign counterparts, relating to our monoclonal antibody and drug-based technologies. Our rights to these patents and patent applications are derived in part from worldwide licenses from Bristol-Myers Squibb, Arizona State University and Facet Biotech, among others. In addition, we have licensed our U.S. and foreign patents and patent applications to third parties.

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

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

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

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

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

We may face potential patent infringement suits by companies that own or control patents for products similar to our product candidates or suits alleging infringement of such companies' other intellectual property. Because patent applications can take many years to publish, there may be currently pending applications of which we are unaware that may later result in issued patents that affect the commercial development of our product candidates. In addition, we are monitoring the progress of multiple pending patent applications of other companies that, if granted, may require us to license or challenge their validity upon commercialization of our product candidates.

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

## **Table of Contents**

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

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

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

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

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

develop safer or more effective products;

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.

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

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.

---

**Table of Contents**

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

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

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

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

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

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

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

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

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

Our cash, cash equivalents and investments are held in a variety of interest-bearing instruments and subject to investment guidelines allowing for investments in U.S. government and agency securities, high-grade corporate bonds, taxable municipal bonds, mortgage-backed securities, auction rate securities, or ARS, commercial paper and money market accounts. As a result of the current adverse global credit and financial market conditions, investments in some financial instruments, such as mortgage-backed securities and ARS, may pose risks arising from liquidity and credit concerns. For example, as of June 30, 2009 we held ARS valued at \$12.8 million that have failed at auction and are currently illiquid. Given that further deterioration in the global credit and financial markets is a possibility, no assurance can be made that losses, failed auctions or other significant deterioration in the fair value of our cash equivalents, short-term or long-term investments or ARS will not occur. If any such losses, failed auctions or other significant deteriorations occur, it may negatively impact or impair our current portfolio of cash equivalents, short-term or long-term investments or ARS and our ability to fund our planned operations. Further, unless and until the current global credit and financial market crisis has been sufficiently resolved, it may be difficult for us to liquidate our investments prior to their maturity without incurring a loss.



## **Table of Contents**

### **Risks Related to Our Stock**

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

The market price of our stock has in the past been, and is likely to continue in the future to be, very volatile. During the second quarter of 2009, our closing stock price fluctuated between \$8.18 and \$10.34 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, specifically the results of our pivotal trial of brentuximab vedotin;

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

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

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

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

our ability to raise capital;

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

developments or disputes concerning our proprietary rights;

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

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

changes in government regulations; and

economic or other external factors.

The stock markets in general, and the markets for biotechnology stocks in particular, have experienced significant volatility that has often been unrelated to the operating performance of particular companies. Recently, the financial markets have faced almost unprecedented turmoil, resulting in a decline in investor confidence and concerns about the proper functioning of the securities markets, which decline in general investor confidence has resulted in depressed stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. These broad market fluctuations may adversely affect the trading price of our common stock. In the



past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs, which would hurt our financial condition and results of operations and divert management's attention and resources, which could result in delays of our clinical trials or commercialization efforts.

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

Our executive officers and directors and holders of greater than five percent of our outstanding voting stock, together with entities that may be deemed affiliates of, or related to, such persons or entities, beneficially owned approximately 44 percent of our voting power as of August 6, 2009. 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.

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

Our Board of Directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the price, rights, preferences, privileges and restrictions, including voting rights, of those shares without any further vote or action by the stockholders. The rights of the holders of common stock may be subject to, and may be adversely affected by, the rights of the holders of any preferred stock that may be issued in the future. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change of control of Seattle Genetics without further action by the stockholders and may adversely affect the voting and other rights of the holders of common stock. Further, certain provisions of our charter documents, including provisions eliminating the ability of stockholders to take action by written consent and limiting the ability of stockholders to raise matters at a meeting of stockholders without giving advance notice, may have the effect of delaying or preventing changes in control or management of Seattle Genetics, which could have an adverse effect on the market price of our stock. In addition, our charter documents provide for a classified board, which may make it more difficult for a third party to gain control of our Board of Directors. Similarly, state anti-takeover laws in Delaware and Washington related to corporate takeovers may prevent or delay a change of control of Seattle Genetics.

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

We held our annual meeting of stockholders on May 15, 2009. The following is a brief description of each matter voted upon at the annual meeting and the number of votes cast for, withheld, or against, the number of abstentions and the number of broker non-votes with respect to each matter:

1. To elect three directors to our board of directors to hold office until our 2012 annual meeting of stockholders.

Name	Number of Shares	
	For	Withheld
Clay B. Siegall	78,749,323	841,479
Felix Baker	78,161,583	1,429,219
Daniel F. Hoth	47,861,676	31,729,126

Our Class III Directors, Marc E. Lippman, Franklin M. Berger and Daniel G. Welch, will each continue to serve on our board of directors until our 2010 annual meeting of stockholders and until his successor is elected and has qualified, or until his earlier death, resignation or removal. Our Class I Directors, Srinivas Akkaraju, David W. Gryska and John P. McLaughlin, will each continue to serve on our board of directors until our 2011 annual meeting of stockholders and until his successor is elected and has qualified, or until his earlier death, resignation or removal.

2. To approve the issuance and sale of an aggregate of 1,178,163 shares of our common stock to Baker Brothers Life Sciences, L.P. and its affiliated investment funds at a purchase price of \$9.72 per share pursuant to a Stock Purchase Agreement dated as of January 27, 2009.

For	60,051,125
Against	129,146
Abstain	12,954,051
Broker Non-Vote	6,456,480

3. To ratify the appointment of PricewaterhouseCoopers LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2009.

For	79,406,761
Against	136,975
Abstain	47,066
Broker Non-Vote	0

**Item 5. Other Information**

On August 5, 2009, the Company's Board of Directors approved the amendment and restatement of the Company's Amended and Restated 1998 Stock Option Plan and the 2007 Equity Incentive Plan (collectively, the Plans). The Plans were each amended to provide for (i) the full acceleration of vesting of stock awards, including stock options, upon a change in control (as defined in the Plans) if the successor company does not assume, substitute or otherwise replace the stock awards upon

**Table of Contents**

the change in control; and (ii) the full acceleration of vesting of any stock awards, including stock options held by a holder of such stock awards, if at the time of, immediately prior to or within twelve (12) months after a change in control of the Company, the holder of such stock awards is involuntarily terminated without cause or is constructively terminated by the successor company that assumed, substituted or otherwise replaced such stock awards in connection with the change in control. The foregoing amendments to the Plans are effective for all outstanding stock awards previously granted under the Plans, as well as all stock awards that may be granted in the future under the Plans (as so amended and restated), including stock awards held by or that may be granted in the future to the Company's executive officers. The foregoing is only a brief description of the Plans, does not purport to be complete and is qualified in its entirety by reference to the full text of the Plans which are filed as Exhibit 10.1 and Exhibit 10.2 of this Form 10-Q and incorporated herein by reference.

---

**Table of Contents**

**Item 6. Exhibits**

<b>Number</b>	<b>Description</b>
3.1(1)	Fourth Amended and Restated Certificate of Incorporation of Seattle Genetics, Inc.
3.2(2)	Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation of Seattle Genetics, Inc.
3.3(3)	Amended and Restated Bylaws of Seattle Genetics, Inc.
4.1(4)	Specimen Stock Certificate.
4.2(5)	Form of Common Stock Warrant.
4.3(1)	Investor Rights Agreement dated July 8, 2003 among Seattle Genetics, Inc. and certain of its stockholders.
10.1	Amended and Restated 1998 Stock Option Plan.
10.2	Amended and Restated 2007 Equity Incentive Plan.
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 the Registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2008 and incorporated herein by reference.
(2)	Previously filed as an exhibit to the Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2008 and incorporated herein by reference.
(3)	Previously filed as an exhibit to the Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2003 and incorporated herein by reference.
(4)	Previously filed as an exhibit to the 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.
(5)	Previously filed as an exhibit to the Registrant's current report on Form 8-K filed with the Commission on May 15, 2003 and incorporated herein by reference.

**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.

By:                   /s/ Todd E. Simpson  
                          Todd E. Simpson  
                          *Duly Authorized and Chief Financial Officer*  
Date: August 10, 2009

**Table of Contents**

**EXHIBIT INDEX**

<b>Number</b>	<b>Description</b>
3.1(1)	Fourth Amended and Restated Certificate of Incorporation of Seattle Genetics, Inc.
3.2(2)	Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation of Seattle Genetics, Inc.
3.3(3)	Amended and Restated Bylaws of Seattle Genetics, Inc.
4.1(4)	Specimen Stock Certificate.
4.2(5)	Form of Common Stock Warrant.
4.3(1)	Investor Rights Agreement dated July 8, 2003 among Seattle Genetics, Inc. and certain of its stockholders.
10.1	Amended and Restated 1998 Stock Option Plan.
10.2	Amended and Restated 2007 Equity Incentive Plan.
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 the Registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2008 and incorporated herein by reference.
(2)	Previously filed as an exhibit to the Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2008 and incorporated herein by reference.
(3)	Previously filed as an exhibit to the Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2003 and incorporated herein by reference.
(4)	Previously filed as an exhibit to the 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.
(5)	Previously filed as an exhibit to the Registrant's current report on Form 8-K filed with the Commission on May 15, 2003 and incorporated herein by reference.