

SEATTLE GENETICS INC /WA

Form 10-Q

May 07, 2010

[Table of Contents](#)

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

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 2010

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

**91-1874389**  
(I.R.S. Employer

incorporation or organization)

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 May 5, 2010, there were 100,833,512 shares of the registrant's common stock outstanding.

**Table of Contents**

Seattle Genetics, Inc.

Form 10-Q

For the quarter ended March 31, 2010

**INDEX**

	<b>Page</b>
<b>PART I. FINANCIAL INFORMATION (Unaudited)</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>	11
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	18
Item 4. <u>Controls and Procedures</u>	18
<b>PART II. OTHER INFORMATION</b>	
Item 1A. <u>Risk Factors</u>	18
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>March 31, 2010</b>	<b>December 31, 2009</b>
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 18,332	\$ 18,486
Short-term investments	299,954	242,319
Interest receivable	2,392	1,350
Accounts receivable	13,815	80,122
Prepaid expenses and other current assets	7,528	6,302
Total current assets	342,021	348,579
Property and equipment, net	12,562	12,325
Long-term investments	12,852	26,925
Other non-current assets	475	504
Total assets	\$ 367,910	\$ 388,333
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities		
Accounts payable and accrued liabilities	\$ 14,924	\$ 19,496
Current portion of deferred revenue	48,112	85,002
Total current liabilities	63,036	104,498
Long-term liabilities		
Deferred revenue, less current portion	79,949	74,866
Deferred rent and other long-term liabilities	2,797	2,769
Total long-term liabilities	82,746	77,635
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; 100,687 shares issued and outstanding at March 31, 2010 and 100,554 shares issued and outstanding at December 31, 2009	101	101
Additional paid-in capital	607,277	603,053
Accumulated other comprehensive loss	(1,005)	(1,249)
Accumulated deficit	(384,245)	(395,705)

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

Total stockholders' equity	222,128	206,200
Total liabilities and stockholders' equity	\$ 367,910	\$ 388,333

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)**

	<b>Three months ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Revenues from collaboration and license agreements	\$ 46,455	\$ 9,142
Operating expenses		
Research and development	30,316	33,246
General and administrative	5,231	4,156
Total operating expenses	35,547	37,402
Income (loss) from operations	10,908	(28,260)
Investment income, net	552	992
Net income (loss)	\$ 11,460	\$ (27,268)
Net income (loss) per share basic	\$ 0.11	\$ (0.33)
Net income (loss) per share diluted	\$ 0.11	\$ (0.33)
Weighted-average shares used in computing:		
Net income (loss) per share basic	100,622	83,545
Net income (loss) per share diluted	103,036	83,545

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)**

	<b>Three months ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
<b>Operating activities</b>		
Net income (loss)	\$ 11,460	\$ (27,268)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities		
Share-based compensation expense	3,184	2,714
Depreciation and amortization	816	738
Amortization of investments	1,398	882
Deferred rent and other long-term liabilities	28	101
Changes in operating assets and liabilities		
Interest receivable	(1,042)	(139)
Accounts receivable	66,307	(3,694)
Prepaid expenses and other current assets	(1,226)	3,463
Other non-current assets	29	
Accounts payable and accrued liabilities	(4,572)	1,709
Deferred revenue	(31,807)	2,940
<b>Net cash provided by (used in) operating activities</b>	<b>44,575</b>	<b>(18,554)</b>
<b>Investing activities</b>		
Purchases of securities available for sale	(146,107)	(50,882)
Proceeds from maturities of securities available for sale	101,391	17,034
Proceeds from sales of securities available for sale		1,004
Purchases of property and equipment	(1,053)	(1,886)
<b>Net cash used in investing activities</b>	<b>(45,769)</b>	<b>(34,730)</b>
<b>Financing activities</b>		
Net proceeds from issuance of common stock		52,532
Proceeds from exercise of options to purchase common stock	1,040	693
<b>Net cash provided by financing activities</b>	<b>1,040</b>	<b>53,225</b>
<b>Net decrease in cash and cash equivalents</b>	<b>(154)</b>	<b>(59)</b>
Cash and cash equivalents, at beginning of period	18,486	30,800
<b>Cash and cash equivalents, at end of period</b>	<b>\$ 18,332</b>	<b>\$ 30,741</b>

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 condensed consolidated balance sheet data as of December 31, 2009 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 in the United States of America (GAAP) for unaudited condensed consolidated financial information. Accordingly, they do not include all of the information and footnotes required by GAAP 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 accompanying notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2009 as filed with the SEC.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results could differ from those estimates. The results of the Company's operations for the three-month period ended March 31, 2010 are not indicative of the results to be expected for the full year.

### **2. Recent Accounting Pronouncements**

In October 2009, the Financial Accounting Standards Board (FASB) issued an accounting standards update entitled "Multiple-Deliverable Revenue Arrangements," a consensus of the FASB Emerging Issues Task Force. This standard prescribes the accounting treatment for arrangements that contain multiple-deliverable elements and enables vendors to account for products or services (deliverables) separately rather than as a combined unit in certain circumstances. Prior to this standard, only certain types of evidence were acceptable for determining the relative selling price of the deliverables under an arrangement. If that evidence was not available, the deliverables were treated as a single unit of accounting. This updated standard expands the nature of evidence which may be used to determine the relative selling price of separate deliverables to include estimation. This standard is applicable to the Company's arrangements entered into or materially modified after December 31, 2010. Early adoption is permitted; however, if the standard is adopted early, and the period of adoption is not the beginning of a company's fiscal year, the company will be required to apply the amendments retrospectively from the beginning of the company's fiscal year. The Company has not yet adopted this standard or determined the impact of this standard on its results of operations, cash flows and financial position.

### **3. Dacetuzumab (SGN-40) product collaboration with Genentech**

In January 2007, the Company entered into a collaboration agreement with Genentech, a wholly-owned member of the Roche Group, or Genentech, for the development and commercialization of dacetuzumab. Under the terms of the agreement, the Company received an upfront payment of \$60 million, and progress-dependent milestone payments totalling \$20 million. Genentech has also funded research, development and manufacturing costs for dacetuzumab under the collaboration. In December 2009, Genentech provided notice to the Company of its decision to terminate the collaboration effective June 8, 2010, at which time all rights to dacetuzumab will be returned to the Company. Payments received from Genentech, consisting of the upfront payment, milestone payments and payments for services provided by the Company to Genentech under this agreement, are being recognized as revenue using a time-based method over the remaining development period of the agreement. Deferred revenue represents payments received in advance of the culmination of the earnings process. The Company had \$66.8 million of deferred revenue related to this collaboration as of December 31, 2009 and \$29.1 million as of March 31, 2010. Acceleration of revenue recognition as a result of the early termination of the collaboration resulted in the Company reporting net income for the quarter ended March 31, 2010. Genentech will remain responsible for funding development costs associated with completing all ongoing clinical trials for

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

dacetuzumab as of the end of the collaboration. The Company will solely fund any new development activities that it may elect to conduct after the effective date of termination. The Company's ADC collaboration with Genentech was unaffected by this termination.

**Table of Contents****Seattle Genetics, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)****4. Income Taxes**

A provision for income taxes is not necessary for the quarter ended March 31, 2010 as the Company expects to report a net loss for the full year ending December 31, 2010.

**5. Net Income (Loss) Per Share**

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common and dilutive common stock equivalent shares outstanding during the period.

The following table sets forth the computation of basic and diluted net income per share (\$ in thousands, other than per share amounts):

	<b>Three months ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
<b>Numerator</b>		
Net Income (loss)	\$ 11,460	\$ (27,268)
<b>Denominator</b>		
Weighted average shares outstanding basic	100,622	83,545
Dilutive effect of common shares from stock options and warrants	2,414	
Weighted average shares outstanding diluted	103,036	83,545
Basic net income (loss) per share	\$ 0.11	\$ (0.33)
Diluted net income (loss) per share	\$ 0.11	\$ (0.33)

Due to the net loss incurred for the three-month period ended March 31, 2009, the Company excluded all warrants and options to purchase common stock from the calculation of diluted net loss per share as such securities were antidilutive. For the period ended March 31, 2010, the Company excluded certain options to purchase common stock from the calculation of diluted net loss per share that would have resulted in an antidilutive effect. The following table presents the weighted-average number of shares that were excluded from the number of shares used to calculate diluted net income (loss) per share (in thousands):

	<b>Three months ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Warrants to purchase common stock		1,925
Options to purchase common stock	4,825	9,041
Total	4,825	10,966

**6. Comprehensive Income (Loss)**

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

	Three months ended March 31,	
	2010	2009
Net income (loss)	\$ 11,460	\$ (27,268)
Unrealized gain (loss) on securities available for sale	244	(198)
Comprehensive income (loss)	\$ 11,704	\$ (27,466)

**7. Investments**

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

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

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

	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
March 31, 2010				
U.S. government and agencies	\$ 267,348	\$ 77	\$ (18)	\$ 267,407
Corporate obligations	30,966	522		31,488
Auction rate securities	14,450		(1,598)	12,852
Taxable municipal bonds	1,347	12		1,359
Total	\$ 314,111	\$ 611	\$ (1,616)	\$ 313,106
Contractual Maturities:				
Due in one year or less	\$ 299,360			\$ 299,954
Due in one to three years	301			300
Due in 2017	14,450			12,852
Total	\$ 314,111			\$ 313,106
Reported as:				
Short-term investments				\$ 299,954
Long-term investments				12,852
Other non-current assets				300
Total				\$ 313,106

The aggregate estimated fair value of the Company's investments with unrealized losses at March 31, 2010 was 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
March 31, 2010				
U.S. government and agencies	\$ 191,831	\$ (18)	\$ NA	\$ NA
Corporate obligations	NA	NA	NA	NA
Auction rate securities	NA	NA	12,852	(1,598)
Taxable municipal bonds	NA	NA	NA	NA
Total	\$ 191,831	\$ (18)	\$ 12,852	\$ (1,598)

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

If the estimated fair value of a security is below its carrying value, the Company evaluates whether it is more likely than not that it will 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 against investment income. The Company has not deemed it necessary to record any charges related to other-than-temporary declines in the estimated fair values of its marketable debt securities or credit losses.

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

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

As of March 31, 2010, the Company held auction rate securities valued at \$12.9 million that have failed at auction and are currently illiquid. Liquidity of these investments is subject to a successful auction process, redemption of the investment, a sale of the security in a secondary market or a negotiated or adjudicated resolution. Each of the securities continues to pay interest according to the stated terms on a monthly basis. The interest rate on these auction rate securities is no longer established based on an auction process but is established according to the terms of the issue. As of March 31, 2010, the interest rate of each of the auction rate securities was set at the 30-day London Interbank Offering rate plus 225 basis points. The Company considers the market for these securities to be inactive and distressed. Accordingly, fair value for the auction rate securities has been determined based on a probability-weighted discounted cash flow analysis. This analysis relies upon certain estimates, including the probability-weighted term to an orderly liquidation and the discount rate applied to future cash flows. The discount rate used to determine fair value is based on the observed comparable yield of securities with similar characteristics, adjusted for illiquidity, credit risk and other factors. Due to the expected time to a liquidation event, investments in auction rate securities 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 auction rate securities can be liquidated in approximately one to three years at par, the Company believes it is more likely than not that it has the ability to hold, and intends to hold, these investments until they recover substantially all of their cost basis. This belief is based on a current assessment of the Company's future operating plans and assessment of the individual securities and general market conditions. The Company periodically assesses this conclusion based on several factors, including the continued failure of future auctions, failure of the investment to be redeemed, further deterioration of the credit rating of the investment, market risk and other factors. Any such future reassessment that results in a conclusion that the unrealized losses on these investments are other than temporary would result in a write down in the fair value of these investments. Such a write down would be recognized in operating results.

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	Other	Significant	
	in active	observable	unobservable	
	markets	inputs	inputs	
	for identical assets	(Level 2)	(Level 3)	
	(Level 1)			
As of March 31, 2010:				

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

Cash equivalents money market funds	\$ 15,561	\$	\$	\$ 15,561
Short-term investments:				
U.S. government and agencies	262,040	5,067		267,107
Corporate obligations		31,488		31,488
U.S. municipal bonds		1,359		1,359
Long-term investments auction rate securities			12,852	12,852
Other non-current assets U.S. government and agencies	300			300
Total	\$ 277,901	\$ 37,914	\$ 12,852	\$ 328,667

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

	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)	
As of December 31, 2009:				
Cash equivalents money market funds	\$ 14,423	\$	\$	\$ 14,423
Short-term investments:				
U.S. government and agencies	215,109	5,093		220,202
Corporate obligations		19,449		19,449
U.S. Municipal Bonds		2,668		2,668
Long-term investments:				
Corporate obligations		14,466		14,466
Auction rate securities			12,459	12,459
Other non-current assets U.S. government and agencies	299			299
<b>Total</b>	<b>\$ 229,831</b>	<b>\$ 41,676</b>	<b>\$ 12,459</b>	<b>\$ 283,966</b>

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 and taxable municipal bonds. Level 3 investments consist of ARS and accounted for 4% of total investment securities measured at fair value as of March 31, 2010. The Company did not transfer any investments into or out of Levels 1, 2 and 3 during the quarter ended March 31, 2010.

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

	Fair value
Balance as of December 31, 2009	\$ 12,459
Unrealized gain reflected as a component of other comprehensive income	393
<b>Balance as of March 31, 2010</b>	<b>\$ 12,852</b>

The Company recorded a net unrealized gain of \$0.2 million related to its investment portfolio for the three months ended March 31, 2010 in other comprehensive income.

## **Table of Contents**

### **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.

#### ***Overview***

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

In December 2009, we entered into a collaboration agreement with Millennium: The Takeda Oncology Company, or Millennium, to develop and commercialize brentuximab vedotin, under which Seattle Genetics has United States and Canadian commercial rights and Millennium has commercial rights in the rest of the world. We also have collaborations for our ADC technology with a number of leading biotechnology and pharmaceutical companies, including Bayer Pharmaceuticals Corporation, or Bayer; Celldex Therapeutics, Inc., or Celldex; Daiichi Sankyo Co., Ltd., or Daiichi Sankyo; Genentech, Inc., a wholly-owned member of the Roche Group, or Genentech; GlaxoSmithKline LLC, or GSK; MedImmune, Inc., a subsidiary of AstraZeneca Biopharmaceuticals Inc., or MedImmune; Millennium, and PSMA Development Company LLC, a subsidiary of Progenics Pharmaceuticals Inc., or Progenics; as well as an ADC co-development agreement with Agensys Inc., an affiliate of Astellas Pharma Inc., or Agensys.

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 March 31, 2010, we had an accumulated deficit of \$384.2 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 plan to move toward potential commercialization of our other product candidates. Our commitment of resources to the approval and commercialization activities for brentuximab vedotin and the research and continued development and potential commercialization of our other product candidates will require substantial additional funds and resources, and our operating expenses will also likely increase as a result of such activities. In addition, we may incur significant milestone payment obligations as our product candidates progress through clinical trials towards potential commercialization. We expect that a substantial portion of our revenues for the next several years will be the result of amortization of payments already received and expected to be received pursuant to our collaboration agreements. Until such time as we have commercialized a product candidate, our revenues will also depend on the achievement of development and clinical milestones under our existing collaboration and license agreements, particularly our brentuximab vedotin collaboration with Millennium, as well as entering into new collaboration and license agreements. The majority of our revenues for the past three years resulted from our dacetuzumab collaboration agreement with Genentech. In December 2009, Genentech informed us of its decision to terminate the collaboration effective June 8, 2010. This has resulted in a substantial acceleration of revenue recognition for amounts previously received and recorded as deferred revenue on our balance sheet. During the quarter ended March 31, 2010, we recognized \$39.9 million related to the dacetuzumab collaboration resulting in net income for the quarter. As of March 31, 2010, we had remaining deferred revenue of \$29.1 million recorded on our balance sheet related to the dacetuzumab collaboration. We expect to recognize this amount as revenue, along with amounts billable to Genentech for additional collaboration activities, during the quarter ending June 30, 2010. In addition, as a result of the termination, if we decide to conduct further development of dacetuzumab, we will be responsible for and will be required to solely fund any new dacetuzumab development and clinical trial activities undertaken after the collaboration ends. Our results of operations may vary substantially from year to

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

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 three months ended March 31, 2010, revenues increased to \$46.5 million, compared to \$9.1 million for the same period in 2009. This increase was primarily due to accelerated revenue recognition during the first quarter of 2010 related to the termination of our dacetuzumab collaboration with Genentech, which will be effective on June 8, 2010. For the three months ended March 31, 2010, total operating expenses decreased 5% to \$35.5 million, compared to \$37.4 million for the same period in 2009. Our net income for the three-month period ended March 31, 2010 was \$11.5 million compared to a net loss of \$27.3 million for the same period in 2009, which was driven by the accelerated recognition of amounts previously received under our dacetuzumab collaboration with Genentech. As of March 31, 2010, we had \$331.1 million in cash, cash equivalents and short-term and long-term investments, and \$222.1 million in total stockholders' equity.

**Table of Contents****Results of Operations****Three months ended March 31, 2010****Revenues.**

Revenues by collaborator are summarized as follows:

Collaboration and license agreement revenue (\$ in thousands)	Three months ended		
	2010	March 31, 2009	% change
Genentech	\$ 41,839	\$ 8,480	393%
Millennium	2,784		N/A <sup>(1)</sup>
GSK	750		N/A <sup>(1)</sup>
Agensys	474	49	867%
Daiichi Sankyo	442	412	7%
Other	166	201	(17)%
<b>Total</b>	<b>\$ 46,455</b>	<b>\$ 9,142</b>	<b>408%</b>

(1) No amount in comparable period.

Genentech revenues increased 393% to \$41.8 million in the first quarter of 2010 compared to the first quarter of 2009. The increase primarily resulted from the accelerated recognition of revenues earned under the dacetuzumab collaboration agreement with Genentech entered into in January 2007 and that will end on June 8, 2010. Under the terms of this agreement, we received an upfront payment of \$60 million and progress-dependent milestone payments of \$20 million. Genentech has also funded ongoing research, development and manufacturing costs for dacetuzumab under the collaboration. In December 2009, Genentech informed us that it had elected to terminate the collaboration effective June 8, 2010, at which time all rights to dacetuzumab will be returned to us. Genentech will remain responsible for funding development costs associated with completing all clinical trials for dacetuzumab that are ongoing as of the end of the collaboration. We will fund any new development and clinical trial activities that we may decide to conduct after the effective date of the termination.

Prior to Genentech's election to discontinue the dacetuzumab collaboration, we had been recognizing amounts received from Genentech under this collaboration as revenue over the six year development period of the agreement using a time-based method. Upon receipt of Genentech's notice to terminate the collaboration, the remaining term of the collaboration period was reduced to six months and the remaining amounts of previously deferred revenue are being recognized over this remaining period. We recognized \$39.9 million in revenue related to the dacetuzumab collaboration during the quarter ended March 31, 2010. Genentech revenues also reflect the earned portion of payments received under our ADC collaboration agreement with Genentech. Our ADC collaboration with Genentech was unaffected by the termination of the dacetuzumab collaboration.

Millennium revenue reflects amounts earned under our December 2009 brentuximab vedotin collaboration agreement and our March 2009 ADC collaboration agreement. Millennium revenue includes the earned portion of a \$60.0 million up front payment received by us in the first quarter of 2010 related to the brentuximab vedotin collaboration agreement and payments to us for development activities conducted under the collaboration and reimbursed by Millennium. Millennium revenue also includes the earned portion of a \$4.0 million upfront payment received in the second quarter of 2009 related to our ADC collaboration agreement with Millennium, and reimbursable support and research materials provided to Millennium by us under the agreements. GSK revenue reflects the earned portion of a \$12.0 million upfront payment received by us in the first quarter of 2010, and reimbursable support provided to GSK by us under the ADC collaboration agreement we entered into with GSK during the fourth quarter of 2009. Agensys revenue increased during the first quarter of 2010 compared to the first quarter of 2009. This increase reflects the earned portion of a \$12.0 million payment received by us in the fourth quarter of 2009 related to an amendment to our collaboration agreement that expanded the scope and extended the research term of the agreement.

Revenues earned under our dacetuzumab and ADC collaborations with Genentech represented 90% of our total revenues for the quarter ended March 31, 2010 and 93% of our total revenues for the quarter ended March 31, 2009. Our revenues are impacted by progress-dependent milestones, annual maintenance fees and reimbursement of materials and support services as our collaborators advance their ADC product

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

candidates through the development process. In the case of our brentuximab vedotin collaboration with Millennium, our revenues are also impacted by the level of development activities that we perform. Revenue may vary substantially from year to year and quarter to quarter depending on the progress made by our collaborators with their ADC product candidates, the level of support we provide to our collaborators, the timing of milestones achieved and our ability to enter into

**Table of Contents**

additional collaboration agreements. Revenues are expected to be higher during the first half of 2010 compared to the second half of the year as a result of the accelerated recognition of previously deferred revenue totalling approximately \$66.8 million as of December 31, 2009 related to the dacetuzumab collaboration. Further, we expect the concentration of revenue recognized from Genentech to decrease significantly after the first half of 2010 as a result of the termination of the dacetuzumab collaboration and to increase with respect to Millennium as a result of the brentuximab vedotin collaboration. In addition to amounts related to the dacetuzumab collaboration with Genentech, we have a significant balance of deferred revenue, representing prior payments from collaborators that have not yet been recognized as revenue. This deferred revenue will be recognized as revenue in future periods using a time-based approach as we fulfill our performance obligations.

**Research and development.**

Our research and development expenses are summarized as follows:

Research and Development (\$ in thousands)	Three months ended		
	2010	March 31, 2009	% change
Research	\$ 3,427	\$ 3,638	(6)%
Development and contract manufacturing	9,816	12,951	(24)%
Clinical	15,141	14,959	1%
Share-based compensation expense	1,932	1,698	14%
Total research and development expenses	\$ 30,316	\$ 33,246	(9)%

Development and contract manufacturing costs decreased 24% to \$9.8 million in the first quarter of 2010 compared to the first quarter of 2009. The decrease reflects lower contract manufacturing costs for brentuximab vedotin related to the timing of manufacturing campaigns. Contract manufacturing costs are expected to increase later in 2010 due to planned manufacturing activities for brentuximab vedotin related to pre-commercialization activities. Clinical costs for brentuximab vedotin increased during the quarter ended March 31, 2010 as we expanded the scope of our clinical program. Clinical trial expenses for dacetuzumab decreased in the quarter ended March 31, 2010 as we reduced clinical activities under the Genentech collaboration and were lower for lintuzumab as we approached completion of activities related to our phase IIb trial of lintuzumab in combination with low-dose cytarabine chemotherapy. Share-based compensation expense increased 14% during the first quarter of 2010 compared to the first quarter of 2009. The increase was due to a larger number of optioned shares subject to expense recognition during the first quarter of 2010 as a result of increased staffing levels and a higher average value per optioned share primarily attributable to increases in the weighted average stock price.

Certain amounts reported for the first quarter of 2009 in the table above have been reclassified to conform with the 2010 presentation as it relates to the categorization of certain expenses.

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

Product Candidates (\$ in thousands)	Three months ended		Five years ended
	2010	March 31, 2009	March 31, 2010
Brentuximab vedotin (SGN-35)	\$ 10,594	\$ 8,589	\$ 65,409
Dacetuzumab (SGN-40)	1,560	4,628	48,026
Lintuzumab (SGN-33)	1,244	3,607	37,132
ASG-5ME	531	576	4,464
SGN-75	375	552	6,419
SGN-70	83	373	10,386

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

Total third-party costs	14,387	18,325	171,836
Other costs and overhead	13,997	13,223	195,174
Share-based compensation expense	1,932	1,698	24,061
 Total research and development expenses	 \$ 30,316	 \$ 33,246	 \$ 391,071

Our third-party costs for brentuximab vedotin increased during the first quarter of 2010 from the first quarter of 2009 as a result of expanded clinical trial activities, which was partially offset by lower contract manufacturing costs during the 2010 period. Our third-party costs for dacetuzumab decreased during the first quarter of 2010 from the first quarter of 2009 reflecting decreased clinical trial activities and lower contract manufacturing costs, as the collaboration comes to a close. Genentech will remain responsible for funding development costs associated with completing all clinical trials for dacetuzumab that are ongoing as of the end of the collaboration.

## **Table of Contents**

Expenses that we incur under the dacetuzumab collaboration are included in research and development expense, while reimbursements of those expenses by Genentech are recognized as revenue over the development period of the agreement. Our third-party costs for lintuzumab decreased during the first quarter of 2010 compared to the first quarter of 2009. The decrease reflects lower clinical trial costs as patient enrollment in the phase IIb trial of lintuzumab in combination with low-dose cytarabine chemotherapy was completed during the first quarter of 2009. Data from this trial are expected between late-second quarter and mid-third quarter of 2010. Manufacturing costs for lintuzumab increased during the first quarter of 2010 reflecting preparatory activities for possible additional manufacturing following review and analysis of the data from our phase IIb trial.

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

the number of patients who participate in the trials;

the length of time required to enroll trial participants;

the number and location of sites included in the trials;

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

the safety and efficacy profile of the product candidate;

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

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

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

We anticipate that our total research, development, contract manufacturing and clinical expenses will increase in the foreseeable future as we prepare to seek regulatory approval for and potentially commercialize brentuximab vedotin, as well as continue our preclinical activities and advance new product candidates into clinical trials. In particular, we expect that development costs for brentuximab vedotin will increase in 2010 compared to 2009, reflecting clinical development and manufacturing activities as well as chemistry, manufacturing and control, or CMC, activities associated with our plan to submit a new drug application, or NDA, to the FDA for brentuximab vedotin in 2011 if the results of our brentuximab vedotin pivotal trial are supportive. We expect our development costs for dacetuzumab to decrease in 2010 compared to 2009, reflecting lower manufacturing and clinical trials activities for this program following the completion of the collaboration with Genentech. 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 chemotherapy in the late-second to mid-third quarter of 2010. If the results of this trial support further development, we expect that third-party costs associated with the lintuzumab program will increase.

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

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.

**Table of Contents****General and administrative.**

General and administrative (\$ in thousands)	Three months ended		
	2010	March 31, 2009	% change
General and administrative, excluding share-based compensation expense	\$ 3,979	\$ 3,140	27%
Share-based compensation expense	1,252	1,016	23%
<b>Total general and administrative expenses</b>	<b>\$ 5,231</b>	<b>\$ 4,156</b>	<b>26%</b>

General and administrative expenses, excluding share-based compensation expense, increased during the first quarter of 2010 compared to the first quarter of 2009. The increase resulted primarily from costs incurred in expanding our commercial operations in preparation for the potential launch of brentuximab vedotin. Share-based compensation expense increased during the first quarter of 2010 from the first quarter of 2009. This resulted from a larger number of optioned shares subject to expense recognition during the first quarter of 2010 as a result of increased staffing levels and a higher average value per optioned share primarily attributable to increases in the weighted average stock price.

**Investment income, net.**

Investment income, net decreased 44% to \$0.6 million in the first quarter of 2010 compared to the first quarter of 2009. The decrease resulted from lower yields on investments during 2010, partially offset by higher average balances.

**Liquidity and capital resources.**

Selected cash flow and balance sheet data (\$ in thousands)	March 31, 2010	December 31, 2009
	2010	2009
Cash, cash equivalents and investments	\$ 331,138	\$ 287,730
Working capital	278,985	244,081
Stockholders' equity	222,128	206,200

  

	Three months ended	
	March 31, 2010	March 31, 2009
Cash provided by (used in):		
Operating activities	\$ 44,575	\$ (18,554)
Investing activities	(45,769)	(34,730)
Financing activities	1,040	53,225

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, our brentuximab vedotin collaboration agreement with Millennium and our ADC collaborations. To a lesser degree, we have also financed our operations through interest earned on cash, cash equivalents and investment securities. These financing sources have historically allowed us to maintain adequate levels of cash and investments.

Our combined cash, cash equivalents and investment securities increased to \$331.1 million at March 31, 2010, compared to \$287.7 million at December 31, 2009. This increase reflects receipt of upfront payments of \$60 million from our brentuximab vedotin collaboration with Millennium and \$12 million from our ADC collaboration with GSK. As a result of these cash payments received, we generated \$44.6 million in cash flow from operating activities in the first quarter of 2010 compared to \$18.6 million used in operating activities during the first quarter of 2009. Our working capital was \$279.0 million at March 31, 2010, compared to \$244.1 million at December 31, 2009. We have structured our investment portfolio to provide working capital as needed. Our cash, cash equivalents and investments are held in a variety of interest-bearing instruments and subject to investment guidelines allowing for holdings in U.S. government and agency securities, corporate bonds, taxable municipal bonds, mortgage-backed securities, auction rate securities, commercial paper and money market accounts. As of March 31, 2010, we held auction rate securities valued at \$12.9 million that have failed at auction and are currently illiquid. Liquidity of these investments is subject to either a successful auction process, redemption of the investment, sale of the security in a secondary market or a negotiated or adjudicated resolution. Each of the securities continues to pay interest according to the stated terms on a monthly basis. The interest rate on these auction rate

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

securities is no longer established based on an auction process but is established according to the terms of the issue, which as of the date of this filing, is set at the 30-day London Interbank Offering rate plus 225 basis points. Based on our available cash, expected operating cash requirements and our belief that the holdings in auction rate securities will likely be liquidated in approximately one to three years at par, we believe it is more likely than not that we have the ability to hold, and we intend to hold, these investments until they recover substantially all of their cost basis. This belief is based on our current assessment of our future operating plans and assessment of the individual securities and general market conditions. We periodically reassess this conclusion

## **Table of Contents**

based on several factors, including the continued failure of future auctions, failure of the investments to be redeemed, further deterioration of the credit rating of the investments, market risk and other factors. Any such future reassessment that results in a conclusion that the unrealized losses on these investments are other than temporary would result in a write down in the fair value of these investments. Such a write down would be recognized in our operating results. These securities are valued based on unobservable inputs (Level 3) and represent 4% of total investment securities measured at fair value as of March 31, 2010, as further discussed in Note 7 to the condensed consolidated financial statements.

Our investment portfolio is structured to provide for investment maturities and access to cash to fund 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 March 31, 2010, our cash, cash equivalents and investment securities are presented net of a cumulative \$1.0 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 March 31, 2010, we had \$318.3 million held in cash reserves or debt securities scheduled to mature within the next twelve months.

At our currently planned spending rate, we believe that our financial resources, in addition to the expected reimbursement, fees and milestone payments received under our existing collaboration and license agreements, including the brentuximab vedotin agreement with Millennium, will be sufficient to fund our operations into at least 2012. During this time, we expect to report data from our brentuximab vedotin pivotal trial in Hodgkin lymphoma and our phase IIb trial of lintuzumab in combination with low-dose cytarabine chemotherapy. If data from our brentuximab vedotin pivotal trial are supportive, we also intend to submit our NDA in the first half of 2011. Changes in our spending rate may occur that would consume available capital resources sooner, such as increased manufacturing and clinical trial expenses and the expansion of our sales and marketing organization preceding commercialization of a product candidate. Additionally, we may not receive the reimbursement, fees and milestone payments that we currently expect under our existing collaboration and license agreements, including the brentuximab vedotin collaboration agreement with Millennium, which may shorten the timeframe through which we are able to fund operations. For example, in the event of a termination of the brentuximab vedotin collaboration agreement with Millennium, we would not receive reimbursement payments, nor would we receive milestone payments or royalties for the development or sale of brentuximab vedotin. In addition, as a result of the termination of the dacetuzumab collaboration agreement with Genentech, if we decide to continue development of dacetuzumab, we will be responsible for and will be required to solely fund any new dacetuzumab development and clinical trial activities undertaken after the effective date of the termination. If we determine instead to discontinue the development of dacetuzumab, we will not receive any future return on our investment from that product candidate.

**Table of Contents**

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 and financial markets have recently experienced a period of unusual volatility and upheaval, which, along with current economic conditions, may make it more difficult for us to raise equity and debt financing. As a result of these 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.

*Commitments*

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

The following table reflects our future minimum contractual commitments for the periods subsequent to March 31, 2010 (in thousands):

	Total	Remainder of 2010	2011	2012	2013	2014	Thereafter
Operating leases	\$ 24,872	\$ 2,043	\$ 2,795	\$ 2,836	\$ 2,917	\$ 3,014	\$ 11,267
Manufacturing, license & collaboration agreements	21,922	17,753	2,262	951	956		
Tenant improvements	415	415					
Total	\$ 47,209	\$ 20,211	\$ 5,057	\$ 3,787	\$ 3,873	\$ 3,014	\$ 11,267

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 Good Manufacturing Practices, or GMP, manufacturing for our product candidates for use in our clinical trials. The above table excludes royalties and up to approximately \$9.4 million in potential future milestone payments to third parties under manufacturing, license and collaboration agreements for our current development programs, which generally become due and payable only upon achievement of certain developmental, clinical, regulatory and/or commercial milestones. Because the achievement of these milestones is neither probable nor reasonably estimable with respect to timing, such contingent payments have not been included in the above table and will not be included until the event triggering such payment has occurred.

*Recent Accounting Pronouncements.*

In October 2009, the Financial Accounting Standards Board (FASB) issued an accounting standards update entitled Multiple-Deliverable Revenue Arrangements, a consensus of the FASB Emerging Issues Task Force. This standard prescribes the accounting treatment for arrangements that contain multiple-deliverable elements and enables vendors to account for products or services (deliverables) separately rather than as a combined unit in certain circumstances. Prior to this standard, only certain types of evidence were acceptable for determining the relative selling price of the deliverables under an arrangement. If that evidence was not available, the deliverables were treated as a single unit of accounting. This updated standard expands the nature of evidence which may be used to determine the relative selling price of separate deliverables to include estimation. This standard is applicable to our arrangements entered into or materially modified after December 31, 2010. Early adoption is permitted; however, if the standard is adopted early, and the period of adoption is not the beginning of our fiscal year, we would be required to apply the amendments retrospectively from the beginning of our fiscal year. We have not yet adopted this standard or determined the impact of this standard on our results of operations, cash flows and financial position.

**Table of Contents****Item 3. Quantitative and Qualitative Disclosures About Market Risk*****Interest Rate Risk***

Our exposure to market risk for changes in interest rates during the three months ended March 31, 2010 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2009 filed with the SEC. Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. We invest in high quality interest-bearing instruments consisting of U.S. government and agency securities, corporate bonds, taxable municipal bonds, auction rate securities, or ARS, commercial paper and money market accounts. Our investment securities consisted of the following (in thousands):

	March 31, 2010	December 31, 2009
Short-term investments	\$ 299,954	\$ 242,319
Long-term investments	12,852	26,925
Other non-current assets	300	299
Total	\$ 313,106	\$ 269,543

As more fully described in Note 7 to the condensed consolidated financial statements, included in long-term investments as of March 31, 2010 are ARS valued at \$12.9 million that have failed at auction and are currently illiquid. Liquidity of these investments is subject to a successful auction process, redemption of the investment, a sale of the security in a secondary market or a negotiated or adjudicated resolution. Given that further deterioration in the global credit and financial markets is a possibility, no assurance can be made that further downgrades, losses or other significant deterioration in the fair value of our cash equivalents, short-term or long-term investments will not occur. If any such further downgrades, losses, or other significant deteriorations occur, it may negatively impact or impair our current portfolio of cash equivalents, short-term or long-term investments.

We have estimated the effect on our investment portfolio of a hypothetical increase in interest rates by one percent to be a reduction of \$1.6 million in the fair value of our investments as of March 31, 2010. In addition, a hypothetical decrease of 10% in the effective yield of our investments would reduce our expected investment income by approximately \$0.2 million over the next twelve months.

***Foreign Currency Risk***

All of our revenues and the majority of our expenses are denominated in U.S. dollars and as a result, we have not experienced significant foreign currency transaction gains and losses to date. We have conducted some transactions in foreign currencies during the quarter ended March 31, 2010, primarily related to contract manufacturing and ex-U.S. clinical trial activities, and we expect to continue to do so. Our primary exposure is to fluctuations in the Euro and British Pound. We do not anticipate that foreign currency transaction gains or losses will be significant at our current level of operations. However, transaction gains or losses may become significant in the future as we continue to expand our operations internationally. We have not engaged in foreign currency hedging to date; however, we may do so in the future.

**Item 4. Controls and Procedures**

(a) *Evaluation of disclosure controls and procedures.* Our Chief Executive Officer and our 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 March 31, 2010 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.

## **Table of Contents**

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, 2009, filed with the SEC.

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

***Our near-term prospects are substantially dependent on our lead product candidate, brentuximab vedotin (SGN-35). If we are unable to successfully develop and obtain regulatory approval for brentuximab vedotin for the treatment of patients with relapsed or refractory Hodgkin lymphoma, our ability to generate revenue from product sales will be significantly delayed.***

We currently have no products that are approved for commercial sale. Our product candidates are in various stages of development, and significant research and development, financial resources and personnel will be required to develop commercially viable products and obtain regulatory approvals for them. A substantial portion of our efforts and expenditures over the next few years will be devoted to brentuximab vedotin, which is the subject of an ongoing pivotal clinical trial under a special protocol assessment, or SPA, with the U.S. Food and Drug Administration, or 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. In addition, in December 2009, we entered into an agreement with Millennium to develop and commercialize brentuximab vedotin, under which we have United States and Canadian commercial rights and Millennium has commercial rights in the rest of the world. The success of this collaboration and the activities of Millennium will significantly impact the commercialization of brentuximab vedotin in countries other than the United States and Canada. Brentuximab vedotin is not expected to be commercially available for this or any other indication until at least the second half of 2011, if at all. Further, the commercial success of brentuximab vedotin will depend upon its acceptance by physicians, patients, third party payors and other key decision-makers as a therapeutic and cost-effective alternative to currently available products. In addition, the indications that we and Millennium are pursuing for brentuximab vedotin have relatively low incidence rates, including relapsed and refractory Hodgkin lymphoma and systemic anaplastic large cell lymphoma (sALCL), which may limit the revenue potential of brentuximab vedotin. If we and Millennium are unable to successfully develop, obtain regulatory approval for and commercialize brentuximab vedotin for the treatment of relapsed or refractory Hodgkin lymphoma and other indications, our ability to generate revenue from product sales will be significantly delayed and our business would be materially affected and we may not be able to earn sufficient revenues to continue as a going concern.

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

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

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

Other than brentuximab vedotin, our product candidates are in relatively early stages of development. These product candidates will require significant further development, financial resources and personnel to obtain regulatory approval and develop into commercially viable products, if at all. Currently, lintuzumab (SGN-33), dacetuzumab (SGN-40), SGN-70 and SGN-75 are in clinical trials, and ASG-5ME and SGN-19A are in preclinical development. We expect that much of our effort and many of our expenditures over the next few years will be devoted to registration and commercialization activities associated with brentuximab vedotin, which may restrict or delay our ability to develop our other clinical and preclinical product candidates.

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

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

---

**Table of Contents**

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

establishment and demonstration of clinical efficacy and safety;

cost-effectiveness of the product;

the product's potential advantage over alternative treatment methods;

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

marketing and distribution support for the product.

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

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

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. Neither we nor our collaborators are permitted to market our product candidates in the United States or foreign countries until we obtain marketing approval from the FDA or other foreign regulatory authorities, and we or our collaborators may never receive regulatory approval for the commercial sale of any of our product candidates. Obtaining marketing approval is a lengthy, expensive and uncertain process and approval is never assured, and we have only limited experience in preparing and filing the applications necessary to gain regulatory approvals. Further, the FDA and other foreign regulatory agencies have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for any product candidate we develop. In this regard, even if we believe the data collected from clinical trials of our product candidates are promising, such data, including data from our pivotal trial of brentuximab vedotin, may not be sufficient to support approval by the FDA or any other 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 U.S. 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.

**Table of Contents**

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

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

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

We are currently conducting multiple clinical trials for our clinical product candidates, including a pivotal trial under an SPA with the FDA for brentuximab vedotin, and we expect to commence additional trials of this 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, many of our future and ongoing brentuximab vedotin clinical trials will be coordinated with Millennium, which may delay the commencement or affect the continuation or completion of these trials. We have experienced enrollment-related delays in certain of our current and previous clinical trials and will likely experience similar delays in our future trials, particularly as we attempt to significantly increase patient size as may be required for phase III studies. We depend on medical institutions and clinical research organizations, or CROs, to conduct our clinical trials in compliance with Good Clinical Practice or GCP, and to the extent they fail to enroll patients for our clinical trials or are delayed for a significant time in achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business. In addition, we conduct clinical trials in foreign countries which may subject us to further delays and expenses as a result of increased drug shipment costs, additional regulatory requirements and the engagement of foreign CROs, as well as expose us to risks associated with less experienced clinical investigators who are unknown to the FDA, different standards of medical care, and foreign currency transactions insofar as changes in the relative value of the U.S. dollar to the foreign currency where the trial is being conducted may impact our actual costs.

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:

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

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;

## **Table of Contents**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Under certain conditions, our collaborators may terminate their agreements with us and discontinue use of our technologies. For example, in December 2009, Genentech notified us that it had elected to terminate our collaboration agreement for dacetuzumab effective June 8, 2010 and, as a result, we will not receive any milestone payments, cost reimbursements or royalties for the development or sale of dacetuzumab from Genentech. If we decide to continue development of dacetuzumab, we will be responsible for and will be required to solely fund any new dacetuzumab development and clinical trial activities undertaken after June 8, 2010, which will increase our costs and could result in a significant delay in the dacetuzumab development process. If we determine instead to discontinue the development of dacetuzumab, we will not receive any future return on our investment from that product candidate. In addition, we cannot control the amount and timing of resources our collaborators may devote to products incorporating our technology. Moreover, our relationships with our collaborators divert significant time and effort of our scientific staff and management team and require effective allocation of our resources to multiple internal and collaborative projects. Our collaborators

## **Table of Contents**

may separately pursue competing products, therapeutic approaches or technologies to develop treatments for the diseases targeted by us or our collaborators. Even if our collaborators continue their contributions to the collaborative arrangements, they may nevertheless determine not to actively pursue the development or commercialization of any resulting products. Our collaborators may fail to perform their obligations under the collaboration agreements or may be slow in performing their obligations. If any of our collaborators terminate or breach our agreements with them, or otherwise fail to complete their obligations in a timely manner, it may have a detrimental effect on our financial position by reducing or eliminating the potential for us to receive technology access and license fees, milestones and royalties, reimbursement of development costs, as well as possibly requiring us to devote additional efforts and incur costs associated with pursuing internal development of product candidates. In particular, if Millennium were to terminate the collaboration at its election, we would not receive milestone payments, co-funded development payments or royalties for the sale of brentuximab vedotin. As a result of such termination, we may have to engage another collaborator to complete the brentuximab vedotin development process or complete the process ourselves internally, either of which could significantly delay the development process and increase our costs. In turn, this could significantly harm our financial position, adversely affect our stock price and require us to incur all the costs of developing and commercializing brentuximab vedotin, which are now being co-funded by Millennium. Furthermore, if our collaborators do not prioritize and commit substantial resources to programs associated with our product candidates, we may be unable to commercialize our product candidates, which would 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 have only recently begun the process to establish such capabilities, and may not be able to develop this capacity. If we are unable to establish sales and marketing capabilities, we will need to enter into sales and marketing agreements to market any of our product candidates that may be approved for commercial sale. If we are unable to establish sales and marketing capabilities or successful distribution relationships with logistics, wholesalers, 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 such companies, we generally would not have control over the resources or degree of effort that any of these third parties may devote to our product candidates, and if they fail to devote sufficient time and resources to the marketing of such product candidates, or if their performance is substandard, it will adversely affect the sale of our product candidates.

***Healthcare law and policy changes, based on recently enacted legislation, may have a material adverse effect on us. \****

In March 2010, the President signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the Healthcare Reform Act. This legislation substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Healthcare Reform Act contains a number of provisions that may impact our business and operations, including those relating to the approvability of biosimilar products, the increased use of comparative effectiveness research on healthcare products, changes to enrollment in federal healthcare programs, reimbursement changes and fraud and abuse provisions, all of which will impact existing government healthcare programs and will result in the development of new programs. While it is too early to predict specifically what effect the recently enacted Healthcare Reform Act and its implementation or any future legislation or policies will have on our business, the Healthcare Reform Act and/or such future legislation or policies may have a material adverse effect on our business and financial condition.

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

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



## **Table of Contents**

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

We do not currently have the 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 and we recently entered into a manufacturing and supply agreement with Pierre Fabre Medicament Production, S.A.S. for the cGMP fill/finish manufacture of commercial quantities of brentuximab vedotin. For brentuximab vedotin and other ADCs, several contract manufacturers, including Albany Molecular and SAFC, supply us with drug-linker and other contract manufacturers, including Piramal, perform conjugation of the drug-linker to the antibody. For dacetuzumab, we have also contracted with Abbott Laboratories for clinical and potential future commercial supplies. For lintuzumab, we entered into a contract manufacturing arrangement with Laureate Pharma to provide later-stage clinical supplies. We have also contracted with Laureate Pharma to manufacture the antibody component of SGN-70 and SGN-75 for clinical trials. In addition, we rely on other third parties to perform additional steps in the manufacturing process, including vialing and storage of our product candidates. For the foreseeable future, we expect to continue to rely on contract manufacturers and other third parties to produce, vial and store sufficient quantities of our product candidates for use in our clinical trials. If our contract manufacturers or other third parties fail to deliver our product candidates for clinical use on a timely basis, with sufficient quality, and at commercially reasonable prices, and we fail to find replacement manufacturers or to develop our own manufacturing capabilities, we may be required to delay or suspend clinical trials or otherwise discontinue development and production of our product candidates. In addition, we depend on outside vendors for the supply of raw materials used to produce our product candidates. If the third-party suppliers were to cease production or otherwise fail to supply us with quality raw materials and we were unable to contract on acceptable terms for these raw materials with alternative suppliers, our ability to have our product candidates manufactured and to conduct preclinical testing and clinical trials of our product candidates would be adversely affected.

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

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

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

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.

## **Table of Contents**

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

Our ADC technology, utilizing proprietary stable linkers and highly potent cell-killing drugs, has not been incorporated into a commercial product and is still at a relatively early stage of development. This ADC technology is used in our brentuximab vedotin, SGN-75, ASG-5ME and SGN-19A product candidates and is the basis of our collaborations with Agensys, Bayer, Celldex, Daiichi Sankyo, Genentech, GSK, MedImmune, Millennium and Progenics. We and our corporate collaborators are conducting toxicology, pharmacology, pharmacokinetics and other preclinical studies and, although we and our collaborators have initiated clinical trials of ADC product candidates, including a pivotal trial with brentuximab vedotin, 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 sustained profitability for some time, if at all. \****

We have incurred substantial net losses in each of our years of operation and, as of March 31, 2010, we had an accumulated deficit of approximately \$384 million. We expect to make substantial expenditures to further develop and commercialize our product candidates, and we anticipate that our rate of spending will accelerate as the result of the increased costs and expenses associated with research, development, clinical trials, manufacturing, regulatory approvals and commercialization of our product candidates. In the near term, we expect our revenues to be derived from technology licensing fees, sponsored research fees and milestone payments under existing and future collaborative arrangements. In the longer term, our revenues may also include royalties from collaborations with current and future strategic partners and commercial product sales if any of our product candidates are approved for commercial sale. However, our revenue and profit potential is unproven and our limited operating history makes our future operating results difficult to predict. Although we reported net income during the quarter ended March 31, 2010 as a result of the accelerated recognition of revenue related to the termination of our dacetuzumab collaboration with Genentech, we have never achieved sustained profitability and if we do achieve sustained profitability in the future, it may not be maintainable.

***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 shared with Millennium as part of our brentuximab vedotin collaboration, we will continue to need significant amounts of additional capital. We may seek additional funding through public or private financings, including equity financings, and through other means, such as collaborations and license agreements. However, the global credit and financial markets have recently experienced a period of unusual volatility and upheaval, which, along with current economic conditions, may make it more difficult for us to raise equity and debt financing. As a result of these 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;

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

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

progress with clinical trials;

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

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

---

## **Table of Contents**

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

the potential costs associated with state and federal taxes;

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

competing technological and market developments.

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

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

We have entered into agreements with third-party commercial and academic institutions to license technology for use in our product candidates and ADC technology. Currently, we have license agreements with Bristol-Myers Squibb, Arizona State University, Genentech, PDL BioPharma, Facet, CLB Research and Development, CMC ICOS Biologics, Mabtech, and the University of Miami, among others. Some of these license agreements contain diligence and milestone-based termination provisions, in which case our failure to meet any agreed upon diligence requirements or milestones may allow the licensor to terminate the agreement. Many of our license agreements grant us exclusive licenses to the underlying technologies. If our licensors terminate our license agreements or if we are unable to maintain the exclusivity of our exclusive license agreements, we may be unable to continue to develop and commercialize our product candidates. In addition, continued development and commercialization of our product candidates will likely require us to secure licenses to additional technologies. We may not be able to secure these licenses on commercially reasonable terms, if at all.

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

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

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

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

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

trade secrets or other proprietary information.

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

## **Table of Contents**

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

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

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

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

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

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

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

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

develop safer or more effective products;

implement more effective approaches to sales and marketing;

develop less costly products;

obtain quicker regulatory approval;

have access to more manufacturing capacity;

## **Table of Contents**

form more advantageous strategic alliances; or

establish superior proprietary positions.

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

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

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

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

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

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

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

***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 and expenses, 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.

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

Our cash, cash equivalents and investments are held in a variety of interest-bearing instruments and subject to investment guidelines allowing for investments in U.S. government and agency securities, high-grade corporate bonds, taxable municipal bonds, mortgage-backed securities, auction rate securities, or ARS, commercial paper and money market accounts. As a result of the current adverse global credit and financial

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

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 March 31, 2010 we held ARS valued at \$12.9 million that have failed at auction and are currently illiquid. Given that future 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

## **Table of Contents**

equivalents, short-term or long-term investments or ARS will not occur. If any such losses, failed auctions or other significant deteriorations occur, it may negatively impact or impair our current portfolio of cash equivalents, short-term or long-term investments or ARS and our ability to fund our planned operations. Further, unless and until the current global credit and financial market crisis has been sufficiently resolved, it may be difficult for us to liquidate our investments prior to their maturity without incurring a loss.

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

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

The market price of our stock has in the past been, and is likely to continue in the future to be, very volatile. During the first quarter of 2010, our closing stock price fluctuated between \$9.34 and \$12.59 per share. As a result of fluctuations in the price of our common stock, you may be unable to sell your shares at or above the price you paid for them. The market price of our common stock may be subject to substantial volatility in response to many risk factors listed in this section, and others beyond our control, including:

announcements regarding the results of discovery efforts and preclinical and clinical activities by us or our competitors, especially the results of our pivotal trial of brentuximab vedotin for patients with relapsed or refractory Hodgkin lymphoma as well as the results of our phase IIb trial of lintuzumab in combination with low-dose cytarabine chemotherapy;

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

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

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

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

our ability to raise capital;

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.

## **Table of Contents**

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

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

Our executive officers and directors and holders of greater than five percent of our outstanding voting stock, together with entities that may be deemed affiliates of, or related to, such persons or entities, beneficially owned approximately 53 percent of our voting power as of May 5, 2010. As a result, these stockholders, acting together, may be able to control our management and affairs and matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as mergers, consolidations or the sale of substantially all of our assets. Consequently, this concentration of ownership may have the effect of delaying, deferring or preventing a change in control, including a merger, consolidation, takeover or other business combination involving us or discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control, which might affect the market price of our common stock.

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

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

## **Table of Contents**

### **Item 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(6)	Seattle Genetics, Inc. 2010 Senior Executive Annual Bonus Plan.
10.2(7)	Seattle Genetics, Inc. 2000 Directors' Stock Option Plan, as amended February 5, 2010.
10.3(7)	2010 Compensation Information for Executive Officers and Directors.
10.4(7)	Seattle Genetics, Inc. Long Term Incentive Plan effective March 11, 2010.
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 (File No. 000-32405) 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 (File No. 000-32405) 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 (File No. 333-50266) 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 (File No. 333-50266) and incorporated herein by reference.
(6)	Previously filed as an exhibit to the Registrant's current report on Form 8-K filed with the Commission on February 12, 2010 (File No. 000-32405) and incorporated herein by reference.
(7)	Previously filed as an exhibit to the Registrant's annual report on Form 10-K for the year ended December 31, 2009 (File No. 333-50266) 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: May 7, 2010

**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(6)	Seattle Genetics, Inc. 2010 Senior Executive Annual Bonus Plan.
10.2(7)	Seattle Genetics, Inc. 2000 Directors' Stock Option Plan, as amended February 5, 2010.
10.3(7)	2010 Compensation Information for Executive Officers and Directors.
10.4(7)	Seattle Genetics, Inc. Long Term Incentive Plan effective March 11, 2010.
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 (File No. 000-32405) 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 (File No. 000-32405) 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 (File No. 333-50266) 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 (File No. 333-50266) and incorporated herein by reference.
(6)	Previously filed as an exhibit to the Registrant's current report on Form 8-K filed with the Commission on February 12, 2010 (File No. 000-32405) and incorporated herein by reference.
(7)	Previously filed as an exhibit to the Registrant's annual report on Form 10-K for the year ended December 31, 2009 (File No. 333-50266) and incorporated herein by reference.