

SEATTLE GENETICS INC /WA  
Form 10-Q  
November 05, 2010  
Table of Contents

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

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 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  
incorporation or organization)

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

**21823 30<sup>th</sup> Drive SE**

**Bothell, Washington 98021**

(Address of principal executive offices, including zip code)

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

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

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

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

Large Accelerated filer  Accelerated filer

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

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

As of November 3, 2010, there were 101,384,595 shares of the registrant's common stock outstanding.

**Table of Contents**

Seattle Genetics, Inc.

Quarterly Report on Form 10-Q

For the quarter ended September 30, 2010

**INDEX**

	<b>Page</b>
<b><u>PART I. FINANCIAL INFORMATION (Unaudited)</u></b>	
Item 1. <u>Condensed Consolidated Financial Statements</u>	3
<u>Condensed Consolidated Balance Sheets</u>	3
<u>Condensed Consolidated Statements of Operations</u>	4
<u>Condensed Consolidated Statements of Cash Flows</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	20
Item 4. <u>Controls and Procedures</u>	20
<b><u>PART II. OTHER INFORMATION</u></b>	
Item 1A. <u>Risk Factors</u>	21
Item 6. <u>Exhibits</u>	33
<b><u>SIGNATURES</u></b>	34
<b><u>EXHIBIT INDEX</u></b>	35

**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)

	September 30, 2010	December 31, 2009
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 22,771	\$ 18,486
Short-term investments	280,142	242,319
Interest receivable	1,052	1,350
Accounts receivable	15,262	80,122
Prepaid expenses and other current assets	3,441	6,302
Total current assets	322,668	348,579
Property and equipment, net	12,834	12,325
Long-term investments	12,736	26,925
Other non-current assets	478	504
Total assets	\$ 348,716	\$ 388,333
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities		
Accounts payable and accrued liabilities	\$ 26,980	\$ 19,496
Current portion of deferred revenue	24,203	85,002
Total current liabilities	51,183	104,498
Long-term liabilities		
Deferred revenue, less current portion	104,836	74,866
Deferred rent and other long-term liabilities	2,910	2,769
Total long-term liabilities	107,746	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; 101,340 shares issued and outstanding at September 30, 2010 and 100,554 shares issued and outstanding at December 31, 2009	101	101
Additional paid-in capital	618,648	603,053

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

Accumulated other comprehensive loss	(1,538)	(1,249)
Accumulated deficit	(427,424)	(395,705)
<b>Total stockholders' equity</b>	<b>189,787</b>	<b>206,200</b>
Total liabilities and stockholders' equity	\$ 348,716	\$ 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 September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
Revenues from collaboration and license agreements	\$ 15,991	\$ 11,646	\$ 99,324	\$ 30,196
Operating expenses				
Research and development	44,287	28,263	113,890	90,221
General and administrative	7,038	3,956	18,736	12,131
<b>Total operating expenses</b>	<b>51,325</b>	<b>32,219</b>	<b>132,626</b>	<b>102,352</b>
Loss from operations	(35,334)	(20,573)	(33,302)	(72,156)
Investment income, net	478	746	1,583	2,590
Net loss	\$ (34,856)	\$ (19,827)	\$ (31,719)	\$ (69,566)
Net loss per share basic and diluted	\$ (0.34)	\$ (0.21)	\$ (0.31)	\$ (0.79)
Weighted-average shares used in computing net loss per share basic and diluted	101,221	93,460	100,922	87,771

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>Nine months ended September 30,</b>	
	<b>2010</b>	<b>2009</b>
<b>Operating activities</b>		
Net loss	\$ (31,719)	\$ (69,566)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities		
Share-based compensation expense	10,098	8,489
Depreciation and amortization	2,624	2,414
Amortization and accretion on investments	2,948	2,851
Deferred rent and other long-term liabilities	141	1,144
Changes in operating assets and liabilities		
Interest receivable	298	519
Accounts receivable	64,860	4,192
Prepaid expenses and other current assets	2,861	3,417
Other non-current assets	31	(55)
Accounts payable and accrued liabilities	7,484	6,067
Deferred revenue	(30,829)	(5,036)
<b>Net cash provided by (used in) operating activities</b>	<b>28,797</b>	<b>(45,564)</b>
<b>Investing activities</b>		
Purchases of securities available for sale	(328,923)	(229,365)
Proceeds from maturities of securities available for sale	299,981	121,279
Proceeds from sales of securities available for sale	2,066	2,092
Purchases of property and equipment	(3,133)	(3,883)
<b>Net cash used in investing activities</b>	<b>(30,009)</b>	<b>(109,877)</b>
<b>Financing activities</b>		
Net proceeds from issuance of common stock		192,141
Proceeds from exercise of stock options and employee stock purchase plan	5,497	4,560
<b>Net cash provided by financing activities</b>	<b>5,497</b>	<b>196,701</b>
Net increase in cash and cash equivalents	4,285	41,260
Cash and cash equivalents, at beginning of period	18,486	30,800
Cash and cash equivalents, at end of period	\$ 22,771	\$ 72,060

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 were 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, or 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 and nine month periods ended September 30, 2010 are not necessarily indicative of the results to be expected for the full year.

**2. Recent accounting pronouncements**

In March 2010, the Financial Accounting Standards Board, or FASB, completed an accounting standards update entitled "Milestone Method of Revenue Recognition." This standard allows the milestone method to be used in the application of the proportional performance model when applied to revenue arrangements. Under this pronouncement, an accounting policy election can be made to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. This standard is effective for the Company beginning January 1, 2011, and may be applied either prospectively to milestones achieved after the adoption date or retrospectively for all periods presented. The Company has not yet adopted this standard and is assessing the impact of this new accounting standard on its consolidated financial statements.

In October 2009, the 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 may enable the Company 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 the 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 and is assessing the impact of this new accounting standard on its consolidated financial statements.

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

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

In January 2007, the Company entered into a collaboration agreement with Genentech, Inc., a 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, progress-dependent milestone payments totaling \$20 million, and reimbursement funding for development activities performed under the collaboration. The Company recognized these payments as revenue over the development period of the collaboration, which initially extended to February 2013. In December 2009, Genentech provided the requisite six-month notice to the Company of its election to terminate the collaboration effective June 8, 2010. As a result, the remaining performance obligation period for the Company under the collaboration was shortened to six months. All deferred revenue, representing payments received in advance of the culmination of the earnings process (\$66.8 million as of December 31, 2009), was fully recognized as revenue using a time-based method over the remaining term of the agreement. Genentech remains responsible for funding development costs associated with completing all clinical trials for dacetuzumab ongoing as of the end of the collaboration. Such funding will be recorded as revenue in the period that costs are incurred and reimbursement becomes due from Genentech. All product rights to dacetuzumab were returned to the Company upon completion of the collaboration. The Company is responsible for, and will solely fund, any new dacetuzumab development activities that it may elect to conduct.

**Table of Contents****Seattle Genetics, Inc.****Notes to Condensed Consolidated Financial Statements****(Unaudited)****4. Net loss per share**

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

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
Warrants to purchase common stock	1,113	1,651	1,113	1,833
Options to purchase common stock	11,463	9,758	10,935	9,339
<b>Total</b>	<b>12,576</b>	<b>11,409</b>	<b>12,048</b>	<b>11,172</b>

**Table of Contents****Seattle Genetics, Inc.****Notes to Condensed Consolidated Financial Statements****(Unaudited)****5. Comprehensive loss**

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

	Three months ended September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
Net loss	\$ (34,856)	\$ (19,827)	\$ (31,719)	\$ (69,566)
Unrealized gain (loss) on securities available for sale	753	581	(289)	905
<b>Comprehensive loss</b>	<b>\$ (34,103)</b>	<b>\$ (19,246)</b>	<b>\$ (32,008)</b>	<b>\$ (68,661)</b>

**6. 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.

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

	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
September 30, 2010				
U.S. government and agencies	\$ 259,279	\$ 32	\$ (7)	\$ 259,304
Corporate obligations	20,648	149		20,797
Auction rate securities	14,450		(1,714)	12,736
Taxable municipal bonds	342	2		344
<b>Total</b>	<b>\$ 294,719</b>	<b>\$ 183</b>	<b>\$ (1,721)</b>	<b>\$ 293,181</b>
<b>Contractual Maturities:</b>				
Due in one year or less	\$ 279,967			\$ 280,142
Due in one to three years	302			303
Due in 2017	14,450			12,736
<b>Total</b>	<b>\$ 294,719</b>			<b>\$ 293,181</b>

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

Reported as:

Short-term investments	\$ 280,142
Long-term investments	12,736
Other non-current assets	303
Total	\$ 293,181

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

	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
December 31, 2009				
U.S. government and agencies	\$ 220,442	\$ 109	\$ (51)	\$ 220,500
Corporate obligations	33,253	674	(11)	33,916
Auction rate securities	14,450		(1,991)	12,459
Taxable municipal bonds	2,647	21		2,668
Total	\$ 270,792	\$ 804	\$ (2,053)	\$ 269,543
Contractual Maturities:				
Due in one year or less	\$ 241,979			\$ 242,319
Due in one to three years	14,363			14,765
Due in 2017	14,450			12,459
Total	\$ 270,792			\$ 269,543
Reported as:				
Short-term investments				\$ 242,319
Long-term investments				26,925
Other non-current assets				299
Total				\$ 269,543

The aggregate estimated fair value of the Company's investments with unrealized losses 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
September 30, 2010				
U.S. government and agencies	\$ 99,412	\$ (7)	\$	\$
Auction rate securities			12,736	(1,714)
Total	\$ 99,412	\$ (7)	\$ 12,736	\$ (1,714)
December 31, 2009				
U.S. government and agencies	\$ 127,347	\$ (51)	\$	\$
Corporate obligations			986	(11)

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

Auction rate securities	12,459	(1,991)		
<b>Total</b>	<b>\$ 127,347</b>	<b>\$ (51)</b>	<b>\$ 13,445</b>	<b>\$ (2,002)</b>

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.

**Table of Contents**

**Seattle Genetics, Inc.**

**Notes to Condensed Consolidated Financial Statements**

**(Unaudited)**

Realized gains, realized losses and declines in the value of securities judged to be other than temporary, are included in investment income. The cost of investments for purposes of computing realized and unrealized gains and losses is 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.

As of September 30, 2010, the Company held auction rate securities valued at \$12.7 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 September 30, 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.

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 available cash, expected operating cash requirements, 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.



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

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 financial assets by level within the fair value hierarchy for the periods presented (in thousands):

	Fair Value Measurement Using:			Total
	Quoted prices in active markets for identical assets (Level 1)	Other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
As of September 30, 2010:				
Cash equivalents money market funds	\$ 10,715	\$	\$	\$ 10,715
Short-term investments:				
U.S. government and agencies	256,999	2,002		259,001
Corporate obligations		20,797		20,797
U.S. municipal bonds		344		344
Long-term investments auction rate securities			12,736	12,736
Other non-current assets U.S. government and agencies	303			303
<b>Total</b>	<b>\$ 268,017</b>	<b>\$ 23,143</b>	<b>\$ 12,736</b>	<b>\$ 303,896</b>

	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 auction rate securities and accounted for 4% and 5% of total investment securities measured at fair value as of September 30, 2010 and December 31, 2009, respectively. The Company did not transfer any investments

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

into or out of Levels 1, 2 and 3 during the three or nine month periods ended September 30, 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):

	<b>Fair value</b>
Balance as of December 31, 2009	\$ 12,459
Unrealized gain reflected as a component of other comprehensive income	277
Balance as of September 30, 2010	\$ 12,736

The Company recorded a net unrealized gain of \$0.8 million and a net unrealized loss of \$0.3 million related to its investment portfolio for the three and nine month periods ended September 30, 2010, respectively, in other comprehensive loss.

**Table of Contents**

**Seattle Genetics, Inc.**

**Notes to Condensed Consolidated Financial Statements**

**(Unaudited)**

**7. Collaborative arrangements**

In August 2010, the Company expanded its antibody-drug conjugate, or ADC, collaboration agreement with Genentech. The Company received a \$12.0 million upfront payment in exchange for rights to utilize its ADC technology with additional antigens to be named by Genentech. The Company is eligible to receive additional fees and progress dependent milestone payments as well as annual maintenance fees and research support payments for assistance provided to Genentech under the collaboration. Payments received will be recorded as revenue over the development period of the collaboration using a time-based approach. The Company is also entitled to receive royalties on product sales from any products commercialized by Genentech under the agreement.

**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, goal, estimate, predict, potential, intend or continue, the negative of terms like the, comparable terminology, and other words or terms of similar meaning in connection with any discussion of future operating or financial performance. These statements are only predictions. All forward-looking statements included in this document are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Any or all of our forward-looking statements in this document may turn out to be wrong. Actual events or results may differ materially. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. In evaluating these statements, you should specifically consider various factors, including the risks outlined 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. We recently announced top-line data from a pivotal clinical trial of our lead product candidate, brentuximab vedotin (SGN-35) for patients with relapsed or refractory Hodgkin lymphoma. The trial was conducted under a special protocol assessment, or SPA, with the U.S. Food and Drug Administration, or FDA. We reported positive top-line data from the pivotal trial in September 2010, with 75% of the patients in the trial achieving an objective response as assessed by an independent central review, which was the primary endpoint in the trial, and with a median duration of response of greater than six months. In addition, in October 2010 we reported positive top-line data from a phase II clinical trial of brentuximab vedotin for patients with relapsed or refractory systemic anaplastic large cell lymphoma, or sALCL, with 86% of the patients in the trial achieving an objective response as assessed by an independent central review, which was the primary end point in the trial. The median duration of response for the phase II sALCL clinical trial has not yet been reached at a median follow up on study of approximately six months. We plan to discuss the regulatory path forward with the FDA later in 2010 with the goal of including both the relapsed or refractory Hodgkin lymphoma and relapsed or refractory sALCL indications in a Biologics License Application, or BLA, submission to the FDA in the first half of 2011. 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 clinical-stage programs: SGN-75, ASG-5ME, dacetuzumab (SGN-40), and SGN-70. In September 2010, we announced that our phase IIb clinical trial of lintuzumab (SGN-33) in combination with low-dose cytarabine chemotherapy in older patients with acute myeloid leukemia did not meet its primary endpoint of extending overall survival. As a result of the negative outcome of this trial, we have discontinued our lintuzumab development program.

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 commercial rights in the United States and its territories and Canada, 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 member of the Roche Group, or Genentech; GlaxoSmithKline LLC, or GSK; Millennium, and PSMA Development Company LLC, a subsidiary of Progenics Pharmaceuticals Inc., or Progenics; as well as ADC co-development agreements with Agensys Inc., an affiliate of Astellas Pharma Inc., or Agensys, and Genmab A/S, or Genmab.

We do not currently have any commercial products for sale. While brentuximab vedotin has advanced into later stages of development, significant further research and development, financial resources and personnel will be required to develop commercially viable products and obtain regulatory approvals. As of September 30, 2010, we had an accumulated deficit of \$427.4 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 activities for commercial manufacturing. We will also continue to invest in research, development and manufacturing as we plan to move toward potential regulatory approval and 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

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

agreements. Until such time as we may commercialize a product candidate, our revenues will also depend on reimbursement of development activities and 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

**Table of Contents**

December 2009, Genentech provided the requisite six-month notice of its election to terminate the collaboration effective June 8, 2010. This resulted in a substantial acceleration of revenue recognition for amounts previously received and recorded as deferred revenue on our balance sheet. During the six months ended June 30, 2010, we recognized approximately \$70 million in revenue related to the dacetuzumab collaboration. Our results of operations may vary substantially from year to year and from quarter to quarter and, as a result, we believe that period to period comparisons of our operating results may not be meaningful and you should not rely on them as indicative of our future performance.

*Financial summary*

To date, we have generated revenues principally from our collaboration and license agreements. These revenues reflect upfront technology access fees, milestone payments, reimbursement for support and materials supplied to our collaborators, and development cost-sharing under our brentuximab vedotin collaboration with Millennium. For the nine months ended September 30, 2010, revenues increased to \$99.3 million, compared to \$30.2 million for the same period in 2009. This increase was primarily due to accelerated revenue recognition during the first half of 2010 related to the termination of our dacetuzumab collaboration with Genentech. For the nine months ended September 30, 2010, total operating expenses increased 30% to \$132.6 million, compared to \$102.4 million for the same period in 2009. Our net loss for the nine-month period ended September 30, 2010 was \$31.7 million compared to a net loss of \$69.6 million for the same period in 2009, which decrease was driven by the accelerated recognition of revenues earned under the dacetuzumab collaboration agreement with Genentech during the 2010 period. As of September 30, 2010, we had \$315.6 million in cash, cash equivalents and short-term and long-term investments, and \$189.8 million in total stockholders' equity.

*Results of operations***Three months and nine months ended September 30, 2010 and 2009***Revenues.*

Revenues by collaborator are summarized as follows:

Collaboration and license agreement revenues (\$ in thousands)	Three months ended September 30,			Nine months ended September 30,		
	2010	2009	% change	2010	2009	% change
Genentech	\$ 8,929	\$ 8,512	5%	\$ 81,744	\$ 25,343	223%
Millennium	4,705	357	1,218%	11,175	695	1,508%
GSK	754		N/A <sup>(1)</sup>	2,256		N/A <sup>(1)</sup>
Agensys	806	63	1179%	1,753	164	969%
Daiichi Sankyo	563	481	17%	1,561	1,296	20%
Other	234	2,233	(90)%	835	2,698	(69)%
<b>Total</b>	<b>\$ 15,991</b>	<b>\$ 11,646</b>	<b>37%</b>	<b>\$ 99,324</b>	<b>\$ 30,196</b>	<b>229%</b>

(1) No amount in comparable period.

Genentech revenues increased 5% to \$8.9 million in the third quarter of 2010 and 223% to \$81.7 million for the first nine months of 2010 compared to the comparable periods in 2009. The increase for the third quarter of 2010 resulted primarily from the expansion of our ADC collaboration agreement with Genentech during the quarter. The increase in Genentech revenues for the nine month period ended September 30, 2010 primarily resulted from the accelerated recognition of revenues earned under the dacetuzumab collaboration agreement with Genentech entered into in January 2007. In December 2009, Genentech provided the requisite six-month notice to us of its election to terminate the collaboration effective June 8, 2010. As a result, the remaining performance obligation period under the collaboration was shortened to six months. All deferred revenue, representing payments received in advance of the culmination of the earnings process (\$66.8 million as of December 31, 2009) was fully recognized as revenue using a time-based method over the remaining term of the agreement.

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

Millennium revenues reflect amounts earned under our December 2009 brentuximab vedotin collaboration agreement and our March 2009 ADC collaboration agreement. Millennium revenues increased in the third quarter and nine months ended September 30, 2010 compared to the corresponding periods of 2009 primarily as a result of the recognition of 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 amounts payable to us for development activities conducted under the brentuximab vedotin collaboration that are reimbursed by Millennium. Millennium revenues also include the earned portion of a \$4.0 million upfront payment and reimbursable support and research materials we provided to Millennium under our ADC collaboration agreement entered into in March 2009.

GSK revenues for the three and nine month periods ended September 30, 2010 reflect the earned portion of a \$12.0 million upfront payment and reimbursable support we provided to GSK under our ADC collaboration agreement with GSK entered into in December 2009.

**Table of Contents**

Daiichi Sankyo revenues increased during both the three and nine month periods ended September 30, 2010 as a result of the earned portion of a \$4.0 million upfront payment and reimbursable support we provided to Daiichi Sankyo under our ADC collaboration agreement entered into in July 2008. Agensys revenues increased in the third quarter and nine months ended September 30, 2010 compared to the corresponding periods of 2009. This increase primarily resulted from the recognition of the earned portion of a \$12.0 million payment we received 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.

Our revenues are impacted by progress-dependent milestones, annual maintenance fees and reimbursement of materials and support services as our collaborators advance their ADC product candidates through the development process. In the case of our brentuximab vedotin collaboration with Millennium, our revenues are also impacted by the level of development activities that we perform. Revenues may vary substantially from year to year and quarter to quarter depending on the progress made by our collaborators with their ADC product candidates, the level of support we provide to our collaborators, the timing of milestones achieved, and our ability to enter into additional collaboration agreements. We expect revenues related to Millennium to increase as a result of the recognition of amounts earned as we fulfill our performance obligations under the brentuximab vedotin collaboration agreement. However, total revenues are expected to be substantially lower in the second half of 2010 compared to the first half of 2010 as a result of revenue recognized in the first half of 2010 related to the dacetuzumab collaboration with Genentech that has ended. 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 September 30,			Nine months ended September 30,		
	2010	2009	% change	2010	2009	% change
Research	\$ 8,652	\$ 3,052	183%	\$ 15,763	\$ 9,353	69%
Development and contract manufacturing	20,448	9,896	107%	47,551	33,525	42%
Clinical	13,097	13,433	(3)%	44,690	42,042	6%
Share-based compensation expense	2,090	1,882	11%	5,886	5,301	11%
<b>Total research and development expenses</b>	<b>\$ 44,287</b>	<b>\$ 28,263</b>	<b>57%</b>	<b>\$ 113,890</b>	<b>\$ 90,221</b>	<b>26%</b>

Research expenses increased 183% to \$8.7 million in the third quarter of 2010 and 69% to \$15.8 million in the first nine months of 2010 from the comparable periods in 2009. These increases primarily related to amounts paid for technology access fees. Development and contract manufacturing expenses increased 107% to \$20.4 million in the third quarter of 2010 and 42% to \$47.6 million in the first nine months of 2010 from the comparable periods of 2009. The increase reflects higher contract manufacturing costs for brentuximab vedotin and lintuzumab. The increase in contract manufacturing costs for brentuximab vedotin in 2010 reflects our ongoing manufacturing activities in preparation for our planned BLA submission for brentuximab vedotin. Clinical expenses decreased 3% to \$13.1 million in the third quarter of 2010 and increased 6% to \$44.7 million in the first nine months of 2010 from the comparable periods in 2009. Clinical costs for brentuximab vedotin increased during the three and nine month periods ended September 30, 2010 as we expanded the scope of our clinical program. Clinical trial expenses for dacetuzumab and lintuzumab decreased during the three and nine month periods ended September 30, 2010 as trials were completed. Share-based compensation expense increased 11% during the third quarter and first nine months of 2010 from the comparable periods in 2009. The increase was due to a higher average value per optioned share primarily attributable to increases in our stock price.

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 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 that are not directly allocable to development programs:



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

Product Candidates (\$ in thousands)	Three months ended September 30,		Nine months ended September 30,		Five years ended September 30, 2010
	2010	2009	2010	2009	
Brentuximab vedotin (SGN-35)	\$ 15,612	\$ 7,315	\$ 43,836	\$ 23,605	\$ 97,128
Lintuzumab (SGN-33)	8,533	1,535	11,061	7,302	46,897
SGN-75	1,738	408	2,696	1,822	8,574
Dacetuzumab (SGN-40)	260	2,781	2,342	11,094	46,100
ASG-5ME	248	1,219	2,241	2,131	6,174
SGN-70	16	77	165	665	10,387
Total third-party costs	26,407	13,335	62,341	46,619	215,260
Other costs and overhead	15,790	13,046	45,663	38,301	214,199
Share-based compensation expense	2,090	1,882	5,886	5,301	28,015
Total research and development expenses	\$ 44,287	\$ 28,263	\$ 113,890	\$ 90,221	\$ 457,474

## Table of Contents

Our third-party costs for brentuximab vedotin increased during both the three months and nine months ended September 30, 2010 from the comparable periods in 2009 as a result of expanded clinical trial and manufacturing activities. Our third-party costs for lintuzumab increased during both the three months and nine months ended September 30, 2010 from the comparable periods in 2009. These increases were due to higher manufacturing costs for lintuzumab, partially offset by 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. Based on the negative results of the phase IIb trial, we discontinued further development of lintuzumab. Third party costs for SGN-75 increased during both the three month and nine month periods ended September 30, 2010. The increases were due to increased clinical trials costs as a result of our phase I clinical trial that was initiated in November 2009. Also, manufacturing expenses for SGN-75 increased during the three month period ended September 30, 2010 compared to the comparable period in 2009. Our third-party costs for dacetuzumab decreased during both the three months and nine months ended September 30, 2010 from the comparable periods in 2009 reflecting decreased clinical trial activities and lower contract manufacturing costs following the termination of our collaboration with Genentech. Our third party costs for ASG-5ME decreased during the three months ended September 30, 2010 compared to 2009 as a result of lower manufacturing activities in 2010. Our third party costs for ASG-5ME increased during the nine months ended September 30, 2010 as compared to the same periods in 2009 reflecting higher phase I clinical trial activities. Third party costs for SGN-70 decreased during both the three months and nine months ended September 30, 2010 due to completion of our phase I clinical 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, which already

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

exceed the full year spending in 2009, will continue to 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 BLA to the FDA for brentuximab vedotin in the first half of 2011. We expect our development costs for dacetuzumab to decrease in 2010 compared to 2009, reflecting lower manufacturing and clinical trials activities for this program as a result of the termination of the collaboration with Genentech. We expect our development costs for lintuzumab to decrease in the fourth quarter of 2010 as we have ceased development of lintuzumab following the negative results of our phase IIb clinical trial that were reported in September 2010. Expenses will fluctuate based upon many factors including the degree of collaborative activities, timing of manufacturing campaigns, numbers of patients enrolled in our clinical trials and the outcome of each clinical trial event.

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			Nine months ended		
	September 30, 2010	September 30, 2009	% change	September 30, 2010	September 30, 2009	% change
General and administrative, excluding share-based compensation expense	\$ 5,392	\$ 2,792	93%	\$ 14,524	\$ 8,943	62%
Share-based compensation expense	1,646	1,164	41%	4,212	3,188	32%
<b>Total general and administrative expenses</b>	<b>\$ 7,038</b>	<b>\$ 3,956</b>	<b>78%</b>	<b>\$ 18,736</b>	<b>\$ 12,131</b>	<b>54%</b>

General and administrative expenses, excluding share-based compensation expense, increased during both the three months and nine months ended September 30, 2010 from the comparable periods. The increase resulted primarily from costs incurred in preparation for the potential commercial launch of brentuximab vedotin. Share-based compensation expense increased during both the three months and nine months ended September 30, 2010 from the comparable periods in 2009. This resulted from a larger number of optioned shares subject to expense recognition during both the three months and nine months ended September 30, 2010 as a result of increased staffing levels and a higher average value per optioned share primarily attributable to increases in our stock price.

**Investment income, net.**

Investment income, net decreased 36% to \$0.5 million in the third quarter of 2010, and decreased 39% to \$1.6 million in the first nine months of 2010 from the comparable periods of 2009. The decreases resulted from lower yields on investments during 2010, partially offset by higher average balances.

**Liquidity and capital resources.**

Selected balance sheet and cash flow data (\$ in thousands)	September 30,	December 31,
	2010	2009
Cash, cash equivalents and investments	\$ 315,649	\$ 287,730
Working capital	271,485	244,081
Stockholders equity	189,787	206,200
	<b>Nine months ended September 30,</b>	<b>September 30,</b>
	<b>2010</b>	<b>2009</b>
Cash provided by (used in):		
Operating activities	\$ 28,797	\$ (45,564)
Investing activities	(30,009)	(109,877)
Financing activities	5,497	196,701

We have financed the majority of our operations through the issuance of equity securities and by amounts received under 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 \$315.6 million at September 30, 2010, compared to \$287.7 million at December 31, 2009. This increase reflects our receipt of an upfront payment of \$60 million from our brentuximab vedotin collaboration with Millennium and \$40.5 million in payments received under our ADC collaborations during the nine months ended September 30, 2010. As a result of these payments, we generated \$28.8 million in cash flow from operating activities in the first nine months of 2010 compared to \$45.6 million used in operating activities during the first nine months of 2009. Our working capital was \$271.5 million at September 30, 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.

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

As of September 30, 2010, we held auction rate securities valued at \$12.7 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, sale of the security in a secondary market or a negotiated or adjudicated resolution. Each of the securities continues to pay interest according to the stated terms on a monthly basis. The interest rate on these auction rate securities is no longer established based on an auction process but is established according to the terms of the issue, which as of the date of this filing, is set at the 30-day London Interbank Offering rate plus 225 basis points. 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 available cash, expected operating cash requirements, future operating plans and assessment of the individual securities and general market conditions. We periodically reassess this conclusion based on several factors, including the continued failure of future auctions, failure of the investments to be redeemed, further deterioration of the credit rating of the investments, market risk and other factors. Any such future reassessment that results in a conclusion that the unrealized losses on these investments are other than temporary would result in a write down in the fair value of these investments. Such a write down would be

**Table of Contents**

recognized in our operating results. These securities are valued based on unobservable inputs (Level 3) and represented 4% and 5% of total investment securities measured at fair value as of September 30, 2010 and December 31, 2009, respectively, as further discussed in Note 6 to the condensed consolidated financial statements.

Our investment portfolio is structured to provide for 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 September 30, 2010, our cash, cash equivalents and investment securities are presented net of a \$1.5 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 September 30, 2010, we had \$302.9 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 our brentuximab vedotin agreement with Millennium, will be sufficient to fund our operations into at least 2012. During this time, we plan to submit a BLA to the FDA for brentuximab vedotin 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 the potential commercialization of brentuximab vedotin. 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 our 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 outside the U.S. and Canada.

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 continue to need significant amounts of additional capital. We may seek additional funding through some or all of the following methods: product collaborations, licensing arrangements, public or private debt or equity financings. We do not know whether additional capital will be available when needed, or that, if available, we will obtain financing on terms favorable to us or our stockholders. If we are unable to raise additional funds when needed, 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.

In connection with the expansion of our ADC collaboration with Genentech in August 2010, we received a \$12 million upfront payment, a portion of which was recognized as revenue in the quarter ended September 30, 2010 and the remainder of which will be recognized over the development period of the collaboration. As a result, we expect that our revenues for 2010 will exceed the top end of our previous revenue guidance range of \$95 million to \$105 million and that we will end 2010 with more than \$280 million in cash and investments. We also expect an increase in the use of cash to fund our operating activities in 2011 compared to 2010 as a result of substantial cash upfront payments received in 2010 and higher expected operating expenses in 2011.

*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 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 as of September 30, 2010 (in thousands):

	Total	Remainder of 2010	2011	2012	2013	2014	Thereafter
Operating leases	\$ 23,515	\$ 686	\$ 2,795	\$ 2,836	\$ 2,917	\$ 3,014	\$ 11,267
Manufacturing, license & collaboration agreements	34,660	16,715	16,028	956	961		
<b>Total</b>	<b>\$ 58,175</b>	<b>\$ 17,401</b>	<b>\$ 18,823</b>	<b>\$ 3,792</b>	<b>\$ 3,878</b>	<b>\$ 3,014</b>	<b>\$ 11,267</b>

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

Operating lease obligations do not assume the exercise by us of any termination or extension options. Approximately 90% of the minimum payments under manufacturing, license and collaboration agreements 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 and for future potential commercial operations. The above table excludes royalties and up to approximately \$26.7 million in potential future milestone payments to third parties under 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. Milestone payments under these agreements to date have totaled \$1.3 million. The above table also excludes purchase commitments under manufacturing agreements to which we become obligated upon commercialization of brentuximab vedotin. Because the achievement of future milestones and product commercialization are 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.

**Table of Contents**

*Recent accounting pronouncements*

In March 2010, the Financial Accounting Standards Board (FASB) completed an accounting standards update entitled Milestone Method of Revenue Recognition. This standard allows the milestone method to be used in the application of the proportional performance model when applied to revenue arrangements. Under this pronouncement an accounting policy election can be made to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. This standard is effective for us beginning January 1, 2011, and may be applied either prospectively to milestones achieved after the adoption date or retrospectively for all periods presented. We have not yet adopted this standard and we are currently assessing the impact of this new accounting standard on our consolidated financial statements.

In October 2009, the 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 may enable us 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 will be required to apply the amendments retrospectively from the beginning of our fiscal year. We have not yet adopted this standard and we are currently assessing the impact of this new accounting standard on our consolidated financial statements.



**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 nine months ended September 30, 2010 has 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, commercial paper and money market accounts. Our investment securities consisted of the following (in thousands):

	September 30, 2010	December 31, 2009
Short-term investments	\$ 280,142	\$ 242,319
Long-term investments	12,736	26,925
Other non-current assets	303	299
Total	\$ 293,181	\$ 269,543

As more fully described in Note 6 to the condensed consolidated financial statements, included in long-term investments as of September 30, 2010 are auction rate securities valued at \$12.7 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. 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 and 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 \$1.0 million in the fair value of our investments as of September 30, 2010. In addition, a hypothetical decrease of 10% in the effective yield of our investments would reduce our expected investment income by approximately \$0.1 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 nine months ended September 30, 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 September 30, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.



---

**Table of Contents**

**Part II. Other Information**

**Item 1A. Risk Factors**

You should carefully consider the following risk factors, in addition to the other information contained in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and related notes. If any of the events described in the following risk factors occurs, our business, operating results and financial condition could be seriously harmed. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Quarterly Report on Form 10-Q.

We have marked with an asterisk (\*) those risks described below that reflect substantive changes from, or additions to, the risks described in our Annual Report on Form 10-K for the year ended December 31, 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 obtain regulatory approval for and commercialize brentuximab vedotin for the treatment of patients with relapsed or refractory Hodgkin lymphoma or relapsed or refractory systemic anaplastic large cell lymphoma, or sALCL, our ability to generate revenue from product sales will be significantly delayed. \****

We currently have no products that are approved for commercial sale. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to our lead product candidate, brentuximab vedotin, which is the subject of a pivotal clinical trial in relapsed or refractory Hodgkin lymphoma patients that was conducted under a special protocol assessment, or SPA, with the United States Food and Drug Administration, or FDA, and a phase II clinical trial in relapsed or refractory sALCL patients. Accordingly, our near-term prospects are substantially dependent on our ability to successfully obtain regulatory approval for and commercialize brentuximab vedotin. In September 2010, we announced positive top-line results from the pivotal clinical trial. In addition, in October 2010 we reported positive top-line results from the phase II clinical trial in relapsed or refractory sALCL. We plan to discuss the regulatory path forward with the FDA later in 2010 with the goal of including both the relapsed or refractory Hodgkin lymphoma and relapsed or refractory sALCL indications in a Biologics License Application, or BLA, submission to the FDA in the first half of 2011. The design of these trials or data collected from either of these trials may not be adequate to demonstrate the safety and efficacy of brentuximab vedotin for the treatment of patients with either relapsed or refractory Hodgkin lymphoma or relapsed or refractory sALCL, or otherwise may not be sufficient to support FDA or any foreign regulatory approval for either or both of these indications. For example, the FDA may disagree with our interpretation of the results of the trials and determine that the data from the trials are not sufficient to support approval. If we fail to obtain regulatory approval for brentuximab vedotin, we will be unable to market and sell brentuximab vedotin and therefore may never generate any revenue from product sales or become profitable.

Even if we and Millennium receive the required regulatory approvals to market brentuximab vedotin, we may not be able to successfully commercialize brentuximab vedotin. In December 2009, we entered into an agreement with Millennium to develop and commercialize brentuximab vedotin, under which we have commercial rights in the United States and its territories and Canada, 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 potential commercialization of brentuximab vedotin in countries other than the United States and Canada. Brentuximab vedotin is not expected to be commercially available for any indication until at the earliest the second half of 2011, if at all. Further, if it is approved for commercial sale, 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 or refractory Hodgkin lymphoma and relapsed or refractory sALCL, which may limit the revenue potential of brentuximab vedotin. If we and Millennium are unable to successfully obtain regulatory approval for and commercialize brentuximab vedotin for the treatment of relapsed or refractory Hodgkin lymphoma and relapsed or refractory sALCL in a timely manner or at all, our ability to generate revenue from product sales would 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. \****

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

The protocol for the brentuximab vedotin pivotal trial in relapsed or refractory Hodgkin lymphoma 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 BLA, 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 though we believe that the data from the pivotal trial are supportive, our SPA with the FDA is not a guarantee or indication of approval for the relapsed or refractory Hodgkin lymphoma indication, 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 for that indication or any other indication. 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 have failed to comply with the agreed upon trial protocol for the pivotal trial. 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

**Table of Contents**

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, whether the FDA will require that we conduct one or more additional clinical trials to support potential approval, or whether brentuximab vedotin will receive any regulatory approvals. In addition, our phase II clinical trial in relapsed or refractory sALCL was not conducted under an SPA with the FDA and therefore our SPA with regards to relapsed or refractory Hodgkin lymphoma will not have any bearing on the review of the protocol, data or results of the phase II clinical trial in relapsed or refractory sALCL. As a result, despite the potential benefits of the SPA agreement, significant uncertainty remains regarding the regulatory approval process for brentuximab vedotin for the treatment of relapsed or refractory Hodgkin lymphoma and relapsed or refractory sALCL, and it is possible that we might never receive any regulatory approvals for brentuximab vedotin.

***Although we reported positive results in our clinical trials for brentuximab vedotin, regulatory authorities may not approve brentuximab vedotin, or we may face post-approval problems that require withdrawal of brentuximab vedotin from the market. \****

Although we reported positive results from our pivotal trial and our phase II clinical trial of brentuximab vedotin in relapsed or refractory Hodgkin lymphoma and relapsed or refractory sALCL, respectively, and we believe that the data from these trials are supportive, we might never receive any regulatory approvals for brentuximab vedotin. Regulatory agencies, including the FDA, or their advisors, may disagree with our interpretations of data from preclinical studies and clinical trials of brentuximab vedotin. The FDA has substantial discretion in the approval process, and when or whether regulatory approval will be obtained for brentuximab vedotin or any other drug we develop. For example, even though our Hodgkin lymphoma pivotal trial was conducted under an SPA with the FDA, there is no guarantee that the data generated from this trial will be adequate to support FDA approval. Regulatory agencies also may approve brentuximab vedotin for fewer conditions than requested or may grant approval subject to the performance of post-marketing studies or risk evaluation and mitigation strategies for brentuximab vedotin. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of brentuximab vedotin.

Even if we receive regulatory approval, brentuximab vedotin may later produce adverse events that limits or prevents its widespread use or that force us or Millennium to withdraw brentuximab vedotin from the market. In addition, a marketed brentuximab vedotin product would continue to be subject to strict regulation after approval and may be required to undergo post-approval studies. Any unforeseen problems with an approved brentuximab vedotin product or any violation of regulations could result in restrictions on the approved product, including its withdrawal from the market. Any delay in or failure to receive or maintain regulatory approval for brentuximab vedotin could harm our business and prevent us from ever achieving profitability.

***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, we have four other clinical-stage programs, SGN-75, ASG-5ME, dacetuzumab (SGN-40), and SGN-70, and multiple preclinical programs, including SGN-19A. We expect that much of our effort and many of our expenditures over the next few years will be devoted to registration and commercialization activities associated with brentuximab vedotin, which may restrict or delay our ability to develop our other clinical and preclinical product candidates.

Our ability to commercialize any of our product candidates, including brentuximab vedotin, depends on first receiving required regulatory approvals, and it is possible that we may never receive regulatory approval for any of our product candidates. Even if a product candidate receives regulatory approval, the resulting product may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Assuming that brentuximab vedotin receives the required regulatory approvals in the United States and Canada, commercial success outside of these countries 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, obtain regulatory approval for, 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

**Table of Contents**

and approval is never assured, and we have only limited experience in preparing and submitting 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 the data collected from our pivotal trial of brentuximab vedotin in relapsed or refractory Hodgkin lymphoma and data collected from our phase II trial of brentuximab vedotin in relapsed or refractory sALCL, 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 or risk evaluation and mitigation strategies 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, including brentuximab vedotin.

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

If we or our collaborators receive regulatory approval for our product candidates, we will also be subject to ongoing FDA obligations and oversight, including adverse event reporting requirements, marketing restrictions and potential post-marketing obligations, all of which may result in significant expense and limit our ability to commercialize such products. The FDA's policies may also change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we may be subject to civil and criminal penalties, we may not be permitted to market our products and our business could suffer. Any delay in or failure to receive or maintain regulatory approval for any of our product candidates could harm our business and prevent us from ever generating any revenues from product sales or achieving profitability. We and our collaborators will need to obtain regulatory approval from authorities in foreign countries to market our product candidates in those countries. Neither we nor our collaborative partners have filed for regulatory approval to market our product candidates in any foreign jurisdictions. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. If we or our collaborative partners fail to obtain approvals from foreign jurisdictions, the geographic market for our product candidates would be limited.

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

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate, through extensive preclinical studies and clinical trials, that the product candidate is safe and effective in humans. Ongoing and future clinical trials of our product candidates may not show sufficient safety or efficacy to obtain requisite regulatory approvals. Moreover, we still only have limited data from our phase I and phase II clinical trials of dacetuzumab, and our phase I trials of SGN-75, ASG-5ME, and SGN-70. 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 SGN-75, ASG-5ME, dacetuzumab (SGN-40), or SGN-70, 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, or has an unacceptable safety profile, which could prevent or significantly delay regulatory approval for such product candidate. For example, in September 2010, we announced that our phase IIb clinical trial of lintuzumab in combination with low-dose cytarabine chemotherapy in older patients with acute myeloid leukemia did not meet its primary endpoint of extending overall survival. As a result of the negative outcome of this trial, we have discontinued our lintuzumab development program and we will not receive any return in our investment in that product candidate.

***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, and we expect to commence additional trials of brentuximab vedotin and our other product candidates in the future. Each of our clinical trials requires the investment of substantial expense and

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

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 are being or will be



## Table of Contents

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 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 United States 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:

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

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

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

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

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

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

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

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

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

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

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

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 September 2010, we announced the discontinuation of our lintuzumab development program as a result of the negative outcome in our phase IIb clinical trial of lintuzumab combined with low-dose cytarabine chemotherapy. 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 independent data monitoring committee, or IDMC, and an IDMC may determine to delay or suspend one or more of these trials due to safety or futility findings based on events occurring during a clinical trial.

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

We have established and intend to continue to establish collaborations with third parties to develop and market some of our current and future product candidates. We entered into a collaboration agreement with Millennium in December 2009 to globally develop and commercialize our brentuximab vedotin product candidate. We also have ADC collaborations with Bayer, Celldex, Daiichi Sankyo, GSK, Genentech, Millennium, and Progenics, and ADC co-development agreements with Agensys and Genmab.

**Table of Contents**

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 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, 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 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 brentuximab vedotin collaboration, we would not receive milestone payments, co-funded development payments or royalties for the sale of brentuximab vedotin outside the United States and Canada. 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 successfully 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 have only recently begun the process to establish a sales and marketing organization and we may not be able to successfully develop adequate sales and marketing capabilities. 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. Many of the implementing regulations of the Healthcare Reform Act are currently being drafted by federal agencies, including FDA, and 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, they 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.*

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

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

**Table of Contents**

market the approved product outside of the United States and Canada. The loss of our collaborators, especially Millennium, or the failure of our collaborators to perform their obligations under their agreements with us, including paying license or technology fees, milestone payments, royalties or reimbursements, could have a material adverse effect on our financial performance. Payments under our existing and future collaboration agreements are also subject to significant fluctuations in both timing and amount, which could cause our revenue to fall below the expectations of securities analysts and investors and cause a decrease in our stock price.

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

We do not currently have the internal ability to manufacture the drug products that we need to conduct our clinical trials and we rely upon a limited number of manufacturers to supply our drug products. For the monoclonal antibody used in brentuximab vedotin, we have contracted with Abbott Laboratories for clinical and potential future commercial supplies and we have 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 clinical supply of our other product candidates, we have contracted with several suppliers, including Abbott Laboratories, Albany Molecular, Baxter, Laureate Pharma, and SAFC. 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 or as the result of regulatory actions 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 and commercial product candidates under GMP in order to meet acceptable standards for use in our clinical trials and for commercial sale, as applicable. If such standards change, the ability of contract manufacturers to produce our product candidates on the schedule we require for our clinical trials or to meet potential sales projections 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 any of our products that may be approved for commercial sale 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.

---

**Table of Contents**

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

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

***Our ADC technology has not been incorporated into a commercial product. \****

Our ADC technology, utilizing proprietary stable linkers and highly potent cell-killing drugs, has not been incorporated into a commercial product. 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, Genmab, GSK, Millennium, and Progenics. We and our corporate collaborators are conducting toxicology, pharmacology, pharmacokinetics and other preclinical studies and, although we and our collaborators have conducted clinical trials of ADC product candidates, including a pivotal trial with brentuximab vedotin, additional studies may be required before any approval of an ADC product candidate. 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 profitability for some time, if at all. \****

We have incurred substantial net losses in each of our years of operation and, as of September 30, 2010, we had an accumulated deficit of approximately \$427.4 million. We expect to make substantial expenditures to further develop and potentially 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, and potential regulatory approvals and commercialization of our product candidates. Until the approval and commercialization of one or more of our product candidates, 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 potential future strategic partners and commercial product sales if any of our product candidates are approved for commercial sale. However, our revenue and profit potential is unproven and our limited operating history makes our future operating results difficult to predict.

***We 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 continue to experience unusual uncertainty, 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;

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

progress with clinical trials;

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

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

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



---

**Table of Contents**

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 or if we fail to sustain and further build our intellectual property rights, we may not be able to commercialize our product candidates, and 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 PDL BioPharma, 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 laws 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.

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

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

***We may incur substantial costs and lose important rights or may not be able to commercialize our product candidates as a result of litigation or other proceedings relating to patent and other intellectual property rights and may be required to obtain patent and other intellectual property rights from others.***

We may face potential lawsuits by companies alleging infringement of their 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.

We are from time to time involved in the defense and enforcement of our patent or other intellectual property rights in a court of law, U.S. Patent and Trademark Office interference or reexamination proceeding, foreign opposition proceeding or related legal and administrative proceeding in the United States and elsewhere. These proceedings are costly and time consuming. Successful challenges to our patent or other intellectual property rights through these proceedings could result in a loss of rights in the relevant jurisdiction. Furthermore, if such challenges to our rights are not resolved promptly in our favor, our existing business relationships may be jeopardized and we could be delayed or prevented from entering into new collaborations or from commercializing potential products, which could adversely affect our business and results of operations. In addition, we may challenge the patent or other intellectual property rights of third parties and if we are unsuccessful in actions we bring against the rights of such parties, through litigation or otherwise, and it is determined that we infringe the intellectual property rights of such parties, we may be prevented from commercializing potential products in the relevant jurisdiction, or may be required to obtain licenses to those rights or develop or obtain alternative technologies, any of which could harm our business.

## **Table of Contents**

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

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

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

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

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. We are aware of many pharmaceutical and biotechnology companies that are actively engaged in research and development in areas related to antibody therapy or that are otherwise developing various approaches to cancer and autoimmune disease therapy. Some of these competitors have successfully commercialized antibody products or are developing or testing product candidates that do or may in the future compete directly with our product candidates. For example, we believe that companies including Allos Therapeutics, Amgen, Bayer, Biogen IDEC, Bristol-Myers Squibb, Celgene, Cephalon, Eisai, Genentech, Genzyme, ImmunoGen, Millennium, Micromet, Novartis, and Pfizer are developing and/or marketing products or technologies that may compete with ours, and some of these companies, including Bristol-Myers Squibb, ImmunoGen and Pfizer, 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;

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.*

---

**Table of Contents**

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.

***If any of our facilities are damaged or our clinical, research and development or other business processes interrupted, our business could be seriously harmed.\****

We conduct our business in a limited number of facilities in a single geographical location in Bothell, Washington. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

***If we experience a significant disruption in our information technology systems our business could be adversely affected.\****

We rely on information technology systems to keep financial records, maintain laboratory and corporate records, communicate with staff and external parties and operate other critical functions. If we were to experience a prolonged system disruption in the information technology systems, it could result in the delay of development of our product candidates, which could adversely affect our business. In addition, in order to maximize our information technology efficiency, we have physically consolidated our primary corporate data and computer operations. This concentration, however, exposes us to a greater risk of disruption to our internal information technology systems. Although we maintain local offsite back ups of our data, if operations at our facilities were disrupted, it would likely cause a material disruption in our business.

***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 United States government and agency securities, high-grade corporate bonds, taxable municipal bonds, mortgage-

## **Table of Contents**

backed securities, auction rate securities, or ARS, commercial paper and money market accounts. As a result of the uncertain global credit and financial market conditions, investments in some financial instruments, such as mortgage-backed securities and ARS, pose risks arising from liquidity and credit concerns. For example, as of September 30, 2010 we held ARS valued at \$12.7 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 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 and long-term investments 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 third quarter of 2010, our closing stock price fluctuated between \$11.44 and \$15.53 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;

our ability to properly prepare and timely submit a BLA to the FDA for brentuximab vedotin or any other regulatory submissions we may in the future plan or determine to make;

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;

announcements of FDA approval or non-approval of our product candidates or the recommendations of any FDA advisory committees regarding the approval or non-approval of any of our product candidates, or delays in the FDA review process;

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

our ability to raise capital;

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

developments or disputes concerning our proprietary rights;

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



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

changes in government regulations; and

economic or other external factors.

The stock markets in general, and the markets for biotechnology stocks in particular, have experienced significant volatility that has often been unrelated to the operating performance of particular companies. The financial markets continue to face 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 fifty-six percent of our voting power as of November 3, 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.

**Table of Contents**

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

Our Board of Directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the price, rights, preferences, privileges and restrictions, including voting rights, of those shares without any further vote or action by the stockholders, which authority could be used to adopt a poison pill that could act to prevent a change of control of Seattle Genetics that has not been approved by our Board of Directors. 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.
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.

**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: November 5, 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.
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.