

SEATTLE GENETICS INC /WA
Form 10-Q
August 05, 2011
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2011

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 30th Drive SE

Bothell, Washington 98021

(Address of principal executive offices, including zip code)

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

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

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

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

Large Accelerated filer Accelerated filer

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

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

As of August 1, 2011, there were 114,730,639 shares of the registrant's common stock outstanding.

Table of Contents

Seattle Genetics, Inc.

Quarterly Report on Form 10-Q

For the quarter ended June 30, 2011

INDEX

	Page
<u>PART I. FINANCIAL INFORMATION (Unaudited)</u>	
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>	12
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	18
Item 4. <u>Controls and Procedures</u>	18
<u>PART II. OTHER INFORMATION</u>	
Item 1A. <u>Risk Factors</u>	20
Item 6. <u>Exhibits</u>	33
<u>SIGNATURES</u>	35
<u>EXHIBIT INDEX</u>	36

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)**

	June 30, 2011	December 31, 2010
Assets		
Current assets		
Cash and cash equivalents	\$ 79,797	\$ 21,127
Short-term investments	331,322	260,682
Interest receivable	1,192	782
Accounts receivable	11,011	19,279
Prepaid expenses and other current assets	4,363	2,246
Total current assets	427,685	304,116
Property and equipment, net	12,125	12,311
Long-term investments	13,144	13,031
Other non-current assets	681	478
Total assets	\$ 453,635	\$ 329,936
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued liabilities	\$ 33,836	\$ 25,783
Current portion of deferred revenue	35,678	29,038
Total current liabilities	69,514	54,821
Long-term liabilities		
Deferred revenue, less current portion	116,894	110,630
Deferred rent and other long-term liabilities	3,199	2,967
Total long-term liabilities	120,093	113,597
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$0.001 par value, 5,000 shares authorized; none issued and outstanding	0	0
Common stock, \$0.001 par value, 250,000 shares authorized at June 30, 2011 and 150,000 shares authorized at December 31, 2010; 114,419 shares issued and outstanding at June 30, 2011 and 101,607 shares issued and outstanding at December 31, 2010	114	102
Additional paid-in capital	811,268	624,759
Accumulated other comprehensive loss	(1,204)	(1,373)
Accumulated deficit	(546,150)	(461,970)

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

Total stockholders' equity	264,028	161,518
Total liabilities and stockholders' equity	\$ 453,635	\$ 329,936

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

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

	Three months ended		Six months ended	
	June 30,		June 30,	
	2011	2010	2011	2010
Revenue from collaboration and license agreements	\$ 13,054	\$ 36,878	\$ 25,225	\$ 83,333
Operating expenses				
Research and development	49,643	39,287	82,077	69,603
General and administrative	15,197	6,467	27,910	11,698
Total operating expenses	64,840	45,754	109,987	81,301
Income (loss) from operations	(51,786)	(8,876)	(84,762)	2,032
Investment income, net	280	553	582	1,105
Net income (loss)	\$ (51,506)	\$ (8,323)	\$ (84,180)	\$ 3,137
Net income (loss) per share - basic	\$ (0.45)	\$ (0.08)	\$ (0.76)	\$ 0.03
Net income (loss) per share - diluted	\$ (0.45)	\$ (0.08)	\$ (0.76)	\$ 0.03
Weighted-average shares used in computing:				
Net income (loss) per share - basic	113,996	100,919	111,270	100,771
Net income (loss) per share - diluted	113,996	100,919	111,270	103,468

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

Table of Contents

Seattle Genetics, Inc.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(In thousands)

	Six months ended June 30,	
	2011	2010
Operating activities		
Net income (loss)	\$ (84,180)	\$ 3,137
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities		
Share-based compensation expense	8,530	6,362
Depreciation and amortization	1,771	1,690
Amortization and accretion on investments	2,125	2,348
Deferred rent and other long-term liabilities	232	99
Changes in operating assets and liabilities		
Interest receivable	(410)	191
Accounts receivable	8,268	64,942
Prepaid expenses and other current assets	(2,117)	2,855
Other non-current assets	(203)	30
Accounts payable and accrued liabilities	8,053	1,408
Deferred revenue	12,904	(43,744)
Net cash provided by (used in) operating activities	(45,027)	39,318
Investing activities		
Purchases of securities available for sale	(323,619)	(210,044)
Proceeds from maturities of securities available for sale	250,910	200,091
Purchases of property and equipment	(1,585)	(2,257)
Net cash used in investing activities	(74,294)	(12,210)
Financing activities		
Net proceeds from issuance of common stock	168,053	0
Proceeds from exercise of stock options and employee stock purchase plan	9,938	3,899
Net cash provided by financing activities	177,991	3,899
Net increase in cash and cash equivalents	58,670	31,007
Cash and cash equivalents, at beginning of period	21,127	18,486
Cash and cash equivalents, at end of period	\$ 79,797	\$ 49,493

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 and summary of significant accounting policies

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, 2010 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, 2010, 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 six month periods ended June 30, 2011 are not necessarily indicative of the results to be expected for the full year.

Revenue recognition

The Company has entered into licensing and collaboration agreements that contain multiple revenue elements including upfront payments, license fees, milestone payments, royalties, maintenance fees and payments for the delivery of supplies or services. Each agreement may contain some or all of these elements. Revenue recognition is predicated upon persuasive evidence of an agreement existing, delivery of materials or services being rendered, amounts payable being fixed or determinable, and collectibility being reasonably assured.

Agreements that include multiple elements are evaluated to determine whether the associated deliverables can be considered separate units of accounting. To date, the deliverables under the Company's license and collaboration agreements have not qualified as separate units of accounting. Accordingly, all amounts received or due are typically recognized as revenue over the performance obligation periods of each agreement, which range from two to eight years for the Company's current agreements. The Company generally uses a time-based proportional performance model to recognize revenue over the Company's performance period. The assessment of multiple element arrangements requires judgment in order to determine the appropriate point in time, or period of time, that revenue should be recognized.

The Company adopted Accounting Standards Update 2009-13 entitled "Multiple-Deliverable Revenue Arrangements, a consensus of the FASB Emerging Issues Task Force" on a prospective basis in the first quarter of 2011. Adoption of this standard did not have a material impact on the Company's financial statements.

2. Net income (loss) per share

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

Table of Contents

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

	Three months ended June 30,		Six months ended June 30,	
	2011	2010	2011	2010
Numerator				
Net income (loss)	\$ (51,506)	\$ (8,323)	\$ (84,180)	\$ 3,137
Denominator				
Weighted average shares outstanding - basic	113,996	100,919	111,270	100,771
Dilutive effect of common shares from stock options and warrants	0	0	0	2,697
Weighted average shares outstanding - diluted	113,996	100,919	111,270	103,468
Basic net income (loss) per share	\$ (0.45)	\$ (0.08)	\$ (0.76)	\$ 0.03
Diluted net income (loss) per share	\$ (0.45)	\$ (0.08)	\$ (0.76)	\$ 0.03

Except for the six month period ended June 30, 2010, the Company incurred a net loss for each period presented. Accordingly, the Company excluded all warrants and options to purchase common stock from the calculation of diluted net loss per share as such securities were antidilutive. For the six month period ended June 30, 2010, the Company excluded certain options to purchase common stock from the calculation of diluted net income per share that would have resulted in an antidilutive effect. The following table presents the weighted-average number of shares that were excluded from the number of shares used to calculate diluted net income (loss) per share (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2011	2010	2011	2010
Warrants to purchase common stock	1,113	1,113	1,113	0
Options to purchase common stock	12,490	10,657	12,643	4,200
Total	13,603	11,770	13,756	4,200

3. Comprehensive income (loss)

Comprehensive income (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 income (loss) is comprised of net income (loss) and unrealized gains or losses on investments as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2011	2010	2011	2010
Net income (loss)	\$ (51,506)	\$ (8,323)	\$ (84,180)	\$ 3,137
Unrealized gain (loss) on securities available-for-sale	(40)	(1,286)	169	(1,042)
Comprehensive income (loss)	\$ (51,546)	\$ (9,609)	\$ (84,011)	\$ 2,095

4. Common stock

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

In February 2011, the Company completed an underwritten public offering of 11,500,000 shares of its common stock. The public offering price of \$15.50 per share resulted in net proceeds to the Company of approximately \$168 million, after deducting underwriting discounts and commissions and offering expenses.

5. Investments

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

Table of Contents

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

	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
June 30, 2011				
U.S. treasury securities	\$ 331,524	\$ 102	\$ 0	\$ 331,626
Auction rate securities	14,450	0	(1,306)	13,144
Total	\$ 345,974	\$ 102	\$ (1,306)	\$ 344,770
Contractual Maturities				
Due in one year or less	\$ 331,524			\$ 331,626
Due in 2017	14,450			13,144
Total	\$ 345,974			\$ 344,770
Reported as:				
Short-term investments				\$ 331,322
Long-term investments				13,144
Other non-current assets				304
Total				\$ 344,770

	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
December 31, 2010				
U.S. treasury securities	\$ 249,580	\$ 10	\$ (11)	\$ 249,579
Corporate obligations	11,358	48	0	11,406
Auction rate securities	14,450	0	(1,419)	13,031
Total	\$ 275,388	\$ 58	\$ (1,430)	\$ 274,016
Contractual Maturities				
Due in one year or less	\$ 260,938			\$ 260,985
Due in 2017	14,450			13,031
Total	\$ 275,388			\$ 274,016
Reported as:				
Short-term investments				\$ 260,682
Long-term investments				13,031
Other non-current assets				303
Total				\$ 274,016

Table of Contents

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
June 30, 2011				
Auction rate securities	\$ NA	\$ NA	\$ 13,144	\$ (1,306)
December 31, 2010				
U.S. treasury securities	\$ 122,581	\$ (11)	\$ NA	\$ NA
Auction rate securities	NA	NA	13,031	(1,419)
Total	\$ 122,581	\$ (11)	\$ 13,031	\$ (1,419)

6. Fair Value

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

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

The determination of a financial instrument's level within the fair value hierarchy is based on an assessment of the lowest level of any input that is significant to the fair value measurement. The Company considers observable data to be market data which is readily available, regularly distributed or updated, reliable and verifiable, not proprietary, and provided by independent sources that are actively involved in the relevant market.

Level 1 investments, which include investments that are valued based on quoted market prices in active markets, consisted of U.S. treasury 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, consisted of high-grade corporate obligations as of December 31, 2010. Level 3 investments consisted of auction rate securities. The Company did not transfer any investments into or out of Levels 1, 2 and 3 during the six month period ended June 30, 2011.

Table of Contents

The following table presents the Company's financial assets by level within the fair value hierarchy for the periods presented (in thousands):

	Quoted prices in active markets for identical assets (Level 1)	Fair value measurement using:		Total
		Other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
As of June 30, 2011:				
Cash equivalents - money market funds	\$ 68,531	\$ 0	\$ 0	\$ 68,531
Short-term investments - U.S. treasury securities	331,322	0	0	331,322
Long-term investments - auction rate securities	0	0	13,144	13,144
Other non-current assets - U.S. treasury note	304	0	0	304
Total	\$ 400,157	\$ 0	\$ 13,144	\$ 413,301

	Quoted prices in active markets for identical assets (Level 1)	Fair value measurement using:		Total
		Other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
As of December 31, 2010:				
Cash equivalents - money market funds	\$ 10,613	\$ 0	\$ 0	\$ 10,613
Short-term investments:				
U.S. treasury securities	249,276	0	0	249,276
Corporate obligations	0	11,406	0	11,406
Long-term investments - auction rate securities	0	0	13,031	13,031
Other non-current assets - U.S. treasury note	303	0	0	303
Total	\$ 260,192	\$ 11,406	\$ 13,031	\$ 284,629

As of June 30, 2011, the Company held auction rate securities valued at \$13.1 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 June 30, 2011, 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. 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 recovery of substantially all of the cost basis of the securities. 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.

Table of Contents

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

	Fair value
Balance as of December 31, 2010	\$ 13,031
Unrealized gain reflected as a component of other comprehensive income	113
Balance as of June 30, 2011	\$ 13,144

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. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than statements of historical facts are forward-looking statements for purposes of these provisions, including those relating to future events or our future financial performance and financial guidance. In some cases, you can identify forward-looking statements by terminology such as may, might, will, should, expect, plan, anticipate, project, believe, estimate, predict, potential, intend or continue, the negative of terms like 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 biotechnology company focused on the development and commercialization of monoclonal antibody-based therapies for cancer. Our lead product candidate, ADCETRIS™ (brentuximab vedotin; SGN-35), is being developed for the treatment of diseases that express an antigen called CD30 present on multiple cancer types, including Hodgkin lymphoma and systemic anaplastic large cell lymphoma, or sALCL. The U.S. Food and Drug Administration, or FDA, has accepted for filing and established an action date of August 30, 2011 under the Prescription Drug User Fee Act, or PDUFA, for two biologics license applications, or BLAs, for brentuximab vedotin under which we are seeking approval for the treatment of patients with relapsed or refractory Hodgkin lymphoma and relapsed or refractory sALCL. On July 14, 2011, the FDA's Oncologic Drugs Advisory Committee, or ODAC, voted unanimously to recommend that the FDA grant accelerated approval of brentuximab vedotin for the treatment of patients with Hodgkin lymphoma who relapse after autologous stem cell transplant, or ASCT. In addition, ODAC voted unanimously to recommend that the FDA grant accelerated approval of brentuximab vedotin for the treatment of patients with relapsed or refractory sALCL. The FDA has also provided conditional acceptance for ADCETRIS™ as the proposed proprietary name for brentuximab vedotin.

We submitted the BLAs to the FDA based primarily on data announced in the fall of 2010 from a pivotal trial in Hodgkin lymphoma patients who had relapsed following ASCT and a phase II trial in relapsed or refractory patients with sALCL. The Hodgkin lymphoma pivotal trial was conducted under a special protocol assessment, or SPA, with the FDA. In the pivotal trial, 75 percent of the patients achieved an objective response as assessed by an independent central review, which was the primary endpoint in the trial. The median duration of response was 29 weeks as assessed by independent central review. Thirty-four percent of the patients participating in the pivotal trial achieved a complete remission. In the phase II sALCL trial, 86 percent of the patients achieved an objective response as assessed by an independent central review, which was the primary endpoint in the trial. In June 2011, we reported that the median duration of response in the phase II sALCL trial was 12.6 months by independent central review and that 57 percent of the patients in the phase II sALCL trial achieved a complete remission. Brentuximab vedotin is empowered by our proprietary antibody-drug conjugate, or ADC, technology comprising potent synthetic drugs and stable linkers for attaching the drugs to monoclonal antibodies. In addition, we have three other clinical-stage ADC programs, which consist of SGN-75, ASG-5ME, and ASG-22ME, as well as several preclinical product candidates, including SGN-19A.

In December 2009, we entered into a collaboration agreement with Millennium: The Takeda Oncology Company, or Millennium, to develop and commercialize brentuximab vedotin. Under this collaboration, Seattle Genetics has retained commercial rights for brentuximab vedotin in the United States and its territories and in Canada, and Millennium has commercial rights in the rest of the world. In June 2011, Millennium's Marketing Authorization Application, or MAA, submission seeking regulatory approval to market brentuximab vedotin for the treatment of relapsed or refractory Hodgkin lymphoma and relapsed or refractory sALCL in the European Union was accepted by the European Medicines Agency, or EMA, which is currently reviewing the application. We also have collaborations for our ADC technology with a number of biotechnology and pharmaceutical companies, including Abbott Biotechnology Ltd., or Abbott; 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, Pfizer, Inc., or Pfizer, 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.

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

Although ODAC recommended accelerated approval of our two BLAs and the FDA has established an action date of August 30, 2011 for each BLA, we cannot predict with certainty when, or whether, and under what conditions regulatory approval will be received or, if approval is granted, the commercial success of brentuximab vedotin. The FDA is not bound by the recommendations of its advisory committees, and even if the FDA grants accelerated approval of either or both of our BLAs, we would be subject to post-marketing compliance requirements, including providing confirmatory evidence of clinical benefit by completing additional clinical studies on a post-approval basis. Further, we do not currently have any commercial products for sale and our other product candidates are in relatively early stages of development. As of June 30, 2011, we had an accumulated deficit of \$546.2 million. Over the next several years, we expect that we

Table of Contents

will incur substantial expenses, primarily as a result of activities related to the potential regulatory approval, commercialization and continued development of brentuximab vedotin. We will also continue to invest in research, development and manufacturing of our product candidates. Our commitment of resources to the approval and commercialization activities for brentuximab vedotin and the research, continued development and manufacturing of our other product candidates may require us to raise substantial amounts of additional capital and our operating expenses will fluctuate 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 amounts earned from our collaboration agreements will continue to be an important source of our revenues. Until such time as we have successfully commercialized a product candidate, if ever, our revenues will also depend on development funding and the achievement of development and clinical milestones under our existing collaboration and license agreements, including, in particular, our brentuximab vedotin collaboration with Millennium, as well as entering into new collaboration and license agreements. Our results of operations may vary substantially from year to year and from quarter to quarter and, as a result, we believe that period to period comparisons of our operating results may not be meaningful and you should not rely on them as indicative of our future performance.

In addition, we recently announced that we have discontinued development of our dacetuzumab (SGN-40) and SGN-70 clinical-stage programs to allow us to focus resources on our pipeline of ADC product candidates. Dacetuzumab is an anti-CD40 monoclonal antibody for hematologic malignancies and SGN-70 is an anti-CD70 monoclonal antibody for autoimmune diseases. Both programs were closed to allow us to focus resources on our pipeline of ADC product candidates.

Financial summary

To date, we have generated revenues principally from our collaboration and license agreements. These revenues reflect the earned amount of upfront technology access fees, milestone payments, reimbursement for support and materials supplied to our collaborators, and development cost-sharing under our product collaborations. For the six months ended June 30, 2011, revenues decreased to \$25.2 million, compared to \$83.3 million for the same period in 2010. This decrease was primarily due to \$70.0 million of revenue earned in the first half of 2010 related to our former dacetuzumab collaboration with Genentech that ended in June 2010. For the six months ended June 30, 2011, total operating expenses increased 35% to \$110 million, compared to \$81.3 million for the same period in 2010. This reflects increased pre-commercialization, clinical development and manufacturing costs for brentuximab vedotin and increased spending on our other clinical-stage and preclinical-stage product candidates. As of June 30, 2011, we had \$424.3 million in cash, cash equivalents and short-term and long-term investments, and \$264.0 million in total stockholders' equity.

*Results of operations***Three months and six months ended June 30, 2011 and 2010***Revenues.*

Revenues by collaborator are summarized as follows:

Collaboration and license agreement revenues by collaborator (\$ in thousands)	Three months ended			Six months ended		
	2011	June 30, 2010	% Change	2011	June 30, 2010	% Change
Millennium	\$ 7,335	\$ 3,686	99%	\$ 14,562	\$ 6,470	125%
Genentech	1,462	30,976	(95%)	2,881	72,815	(96%)
Pfizer	1,000		N/A (1)	2,000		N/A (1)
Other	3,257	2,216	47%	5,782	4,048	43%
Total	\$ 13,054	\$ 36,878	(65%)	\$ 25,225	\$ 83,333	(70%)

(1) No amount in comparable period.

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

Millennium revenues increased 99% to \$7.3 million in the second quarter and 125% to \$14.6 million for the first six months of 2011 compared to the comparable periods in 2010. Millennium revenues reflect amounts earned under our brentuximab vedotin collaboration agreement and our ADC collaboration agreement. Millennium revenues attributable to both agreements increased in the second quarter and for the first six months ended June 30, 2011 compared to the corresponding periods in 2010. Revenues in the second quarter of 2011 also reflect the earned portion of a \$5.0 million milestone payment from Millennium triggered by the EMA acceptance of the MAA for brentuximab vedotin for the treatment of relapsed or refractory Hodgkin lymphoma and relapsed or refractory sALCL. Revenues for the six month period ended June 30, 2011 also increased over comparable periods in 2010 due to the earned portion of a payment received from Millennium upon its exercise of an option to take an exclusive license to a second antigen target under the ADC collaboration.

Genentech revenues decreased 95% to \$1.5 million in the second quarter and 96% to \$2.9 million for the first six months of 2011 compared to the comparable periods in 2010. During 2011, Genentech revenues reflect amounts earned under our ADC collaboration agreement. During 2010, Genentech revenues reflect our ADC collaboration and former dacetuzumab collaboration agreements. The decrease in Genentech revenues for the three and six month periods ended June 30, 2011 reflects \$30.0 million and \$70.0 million of revenues in the second quarter and six months ended June 30, 2010, respectively, earned under the dacetuzumab collaboration that ended in June 2010.

Table of Contents

Pfizer revenues for the three and six month periods ended June 30, 2011 reflect the earned portion of an \$8 million upfront payment under our ADC collaboration agreement that we entered into in December 2010.

Other revenues consist of amounts earned under our ADC collaborations with other companies that generated lower amounts of revenue during the periods presented. This revenue reflects the earned portion of fees and payments received under these ADC collaboration agreements, which generally include some or all of upfront license payments, renewal fees, milestones and payments for research and development support that we may provide to our collaborators. These payments are recognized as revenue over the development period of the collaboration.

Our collaboration revenues are impacted by the term and duration of our collaboration agreements and by progress-dependent milestones, annual maintenance fees and reimbursement of materials and support services as our collaborators advance their product candidates through development. Collaboration revenues may vary substantially from year to year and quarter to quarter depending on the progress made by our collaborators with their product candidates, the timing of milestones achieved, our ability to enter into additional collaboration agreements and the level of support we provide to our collaborators. We expect Millennium collaboration revenues will increase during 2011 compared to 2010 as a result of the recognition of amounts earned under the brentuximab vedotin collaboration agreement. However, total collaboration revenues are expected to be substantially lower in 2011 compared to 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 our 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			Six months ended		
	2011	2010	% Change	2011	2010	% Change
Research	\$ 8,342	\$ 3,684	126%	\$ 11,829	\$ 7,111	66%
Development and contract manufacturing	22,334	17,287	29%	33,126	27,103	22%
Clinical	16,818	16,452	2%	32,681	31,593	3%
Share-based compensation expense	2,149	1,864	15%	4,441	3,796	17%
Total research and development expenses	\$ 49,643	\$ 39,287	26%	\$ 82,077	\$ 69,603	18%

Research expenses increased 126% to \$8.3 million in the second quarter and 66% to \$11.8 million for the first six months of 2011 from the comparable periods in 2010. The increase in research expenses is primarily the result of increasing costs associated with the advancement of our ASG-22ME clinical-stage product candidate and our SGN-19A preclinical product candidate.

Development and contract manufacturing expenses increased 29% to \$22.3 million in the second quarter and 22% to \$33.1 million for the six month period ended June 30, 2011 from the comparable periods in 2010. The increase reflects higher contract manufacturing costs for brentuximab vedotin and for our SGN-19A preclinical program.

Clinical expenses increased 2% to \$16.8 million in the second quarter and 3% to \$32.7 million for the six month period ended June 30, 2011 from the comparable periods in 2010. This increase reflects higher regulatory costs in support of our BLA submissions for brentuximab vedotin partially offset by lower third party clinical trial costs.

Share-based compensation expense increased in both the three and six month periods ended June 30, 2011 from the comparable periods in 2010. The increase was due to a higher average value per optioned share primarily attributable to increases in our stock price and a larger number of optioned shares subject to expense recognition as a result of increased staffing levels.

Table of Contents

The following table shows expenses incurred for research, contract manufacturing of our product candidates 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 charged to development programs:

Product candidates (\$ in thousands)	Three months ended June 30,		Six months ended June 30,		Five years ended June 30, 2011
	2011	2010	2011	2010	
Brentuximab vedotin (SGN-35)	\$ 20,617	\$ 17,630	\$ 29,506	\$ 28,224	\$ 134,933
ASG-22ME	4,000		4,000		4,000
SGN-19A	1,012	21	2,065	30	3,598
SGN-75	803	583	1,644	958	11,764
ASG-5ME	648	357	1,040	873	5,475
	27,080	18,591	38,255	30,085	159,770
Other costs and overhead	20,414	18,832	39,381	35,722	350,904
Share-based compensation expense	2,149	1,864	4,441	3,796	33,602
Total research and development	\$ 49,643	\$ 39,287	\$ 82,077	\$ 69,603	\$ 544,276

Our third-party costs for brentuximab vedotin increased during the three and six months ended June 30, 2011 from the comparable periods in 2010 primarily due to higher manufacturing costs in the 2011 periods as we manufactured drug supply in anticipation of a potential commercial launch. In June 2011, we exercised an option under our ADC co-development agreement with Agensys to co-develop ASG-22ME. In addition to the payment of an option fee, we now co-fund one-half of the development costs of this program. Our third party costs for SGN-19A increased during the three and six months ended June 30, 2011 from the comparable periods in 2010 reflecting increased manufacturing activities in preparation for potential clinical trials. Third party costs for SGN-75 increased during the three and six month periods ended June 30, 2011 related to manufacturing and clinical costs incurred to support our phase I clinical trial. Our third party costs for ASG-5ME increased during the three and six months ended June 30, 2011 compared to the 2010 periods as a result of higher manufacturing costs in the 2011 periods.

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

the number of patients who participate in the trials;

the length of time required to enroll trial participants;

the number and location of sites included in the trials;

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

the safety and efficacy profile of the product candidate;

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

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

Furthermore, our strategy has included 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 expect that aggregate development costs for our product candidates will increase in 2011 compared to 2010. However, if brentuximab vedotin is approved for commercial sale by the FDA, the costs associated with manufacturing would no longer be expensed but rather, would be recorded as inventory. Such approval would result in a decrease in research and development expenses for brentuximab vedotin. Expenses will fluctuate based upon many factors including timing of potential regulatory approvals, degree of collaborative activities, timing of manufacturing campaigns, numbers of patients enrolled in our clinical trials and the outcome of each clinical trial.

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

Table of Contents**General and administrative.**

General and administrative (\$ in thousands)	Three months ended			Six months ended		
	2011	June 30, 2010	% Change	2011	June 30, 2010	% Change
General and administrative, excluding share-based compensation expense	\$ 13,084	\$ 5,153	154%	\$ 23,821	\$ 9,132	161%
Share-based compensation expense	2,113	1,314	61%	4,089	2,566	59%
Total general and administrative expenses	\$ 15,197	\$ 6,467	135%	\$ 27,910	\$ 11,698	139%

General and administrative expenses, excluding share-based compensation expense, increased during the three and six months ended June 30, 2011 from the comparable periods in 2010. The increases resulted primarily from increased staffing levels and contracted activities in preparation for the potential commercial launch of brentuximab vedotin. Share-based compensation expense increased during the three and six months ended June 30, 2011 from the comparable periods in 2010. This resulted from a higher average value per optioned share primarily attributable to increases in our stock price and a larger number of optioned shares subject to expense recognition as a result of increased staffing levels.

Investment income, net.

Investment income, net decreased 49% to \$0.3 million in the second quarter and 47% to \$0.6 million for the first six months of 2011 from the comparable periods in 2010. The decrease resulted from lower yields on investments during 2011, partially offset by higher average balances.

Liquidity and capital resources.

Selected balance sheet and cashflow data (\$ in thousands)	June 30,	December 31,
	2011	2010
Cash, cash equivalents and investments	\$ 424,263	\$ 294,840
Working capital	358,171	249,295
Stockholders equity	264,028	161,518
	Six months ended June 30,	
	2011	2010
Cash provided by (used in):		
Operating activities	\$ (45,027)	\$ 39,318
Investing activities	(74,294)	(12,210)
Financing activities	177,991	3,899

We have financed the majority of our operations through the issuance of equity securities and by amounts received pursuant to our product development collaborations 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 \$424.3 million at June 30, 2011, compared to \$294.8 million at December 31, 2010 and our working capital was \$358.2 million at June 30, 2011, compared to \$249.3 million at December 31, 2010. These increases reflect net proceeds from the sale of common stock in an underwritten public offering totaling \$168.0 million in February 2011. During the first six months of 2011, we used \$45.0 million of cash in our operating activities compared to \$39.3 million generated from operating activities during the first six months of 2010. Our cash provided by (used in) operating activities included upfront payments under new collaboration agreements of \$16 million and \$72 million during the six month periods ended June 30, 2011 and 2010, respectively.

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

We have structured our investment portfolio to provide working capital as needed to fund our operations. 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, auction rate securities, commercial paper and money market accounts. As of June 30, 2011, we held auction rate securities valued at \$13.1 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 June 30, 2011, the interest rate of each of the auction rate securities was set at the 30-day London Interbank Offering Rate plus 225 basis points. We consider the market for these securities to be inactive and distressed. Accordingly, fair value for the auction

Table of Contents

rate securities has been determined based on a probability-weighted discounted cash flow analysis. This analysis relies upon significant unobservable inputs referred to as level 3 inputs within the fair value hierarchy, as described in Note 6 to the condensed consolidated financial statements, 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. Investments valued based on level 3 inputs consisted of auction rate securities and accounted for 4% and 5% of total investment securities measured at fair value as of June 30, 2011 and December 31, 2010, respectively. 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.

We believe it is more likely than not that we have the ability to hold, and intend to hold, these investments until recovery of substantially all of the cost basis of the investments. 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 assess this conclusion based on several factors, including the continued failure of future auctions, failure of the investment to be redeemed, further deterioration of the credit rating of the investment, market risk and other factors. Any such future reassessment that results in a conclusion that the unrealized losses on these investments are other than temporary would result in a write down in the fair value of these investments. Such a write down would be recognized in our operating results.

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 June 30, 2011, we had \$411.1 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, together with the fees, milestone payments and reimbursements we expect to earn under our existing collaboration and license agreements will be sufficient to fund our operations into 2013. This expectation does not take into account revenues from potential sales of brentuximab vedotin, which may extend the sufficiency of our financial resources. Although ODAC recommended accelerated approval of our two BLAs for brentuximab vedotin and the FDA has established an action date of August 30, 2011 for each BLA, we cannot predict with certainty when, or whether, and under what conditions regulatory approval will be received or, if approval is granted, the commercial success of brentuximab vedotin. The FDA is not bound by the recommendations of its advisory committees, and even if the FDA grants accelerated approval of either or both of our BLAs, we would be subject to post-marketing compliance requirements, including providing confirmatory evidence of clinical benefit by completing additional clinical studies on a post-approval basis. Changes in our spending rate may occur that would consume available capital resources sooner, such as increased development, manufacturing and clinical trial expenses, including in connection with any required post-approval confirmatory studies for brentuximab vedotin, and the increases in our sales and marketing expenses in connection with the potential commercialization of brentuximab vedotin. Additionally, we may not receive the payments that we currently expect under our existing collaboration agreements, including the brentuximab vedotin collaboration agreement with Millennium, which may shorten the timeframe through which we are able to fund operations. For example, in the event of a termination of the brentuximab vedotin collaboration agreement with Millennium, we would not receive development cost sharing payments, nor would we receive milestone payments or royalties for the development or international sale of brentuximab vedotin.

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 may therefore need to raise significant amounts of additional capital. We may seek additional funding through some or all of the following methods: corporate collaborations, licensing arrangements and 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 we need them, we may be required to delay, reduce the scope of, or eliminate one or more of our development programs, which may adversely affect our business and operations.

Primarily as a result of higher than expected collaborations activities, we are increasing our 2011 collaboration revenue guidance to be in the range of \$45 to \$50 million. These factors have also resulted in a decrease to our guidance for net cash used to fund operating activities in 2011 to be in the range of \$140 to \$160 million and we now expect to end the year with more than \$300 million in cash and investments.

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

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

make milestone payments or if we receive regulatory approvals or achieve commercial sales and are required to pay royalties.

In May 2011, the Company entered into an operating lease for approximately 81,000 square feet of a facility to be used for general office purposes. The lease term began on July 1, 2011. The lease includes an abated rent period and a tenant improvement allowance to be applied toward improvements to the facility. The approximate aggregate base rent due over the initial term of the lease is \$7.7 million. The lease expires in June 2018 with two extension options of five years each.

Table of Contents

The following table reflects our future minimum contractual commitments as of June 30, 2011 (in thousands):

	Total	Remainder of					Thereafter
		2011	2012	2013	2014	2015	
Operating leases	\$ 29,128	\$ 1,412	\$ 3,676	\$ 4,071	\$ 4,208	\$ 4,348	\$ 11,413
Manufacturing, license & collaboration agreements	41,170	36,661	3,311	1,198			
Total	\$ 70,298	\$ 38,073	\$ 6,987	\$ 5,269	\$ 4,208	\$ 4,348	\$ 11,413

Operating lease obligations do not assume the exercise by us of any termination or extension options. A substantial portion of the minimum payments under manufacturing, license and collaboration agreements represents contractual obligations related to manufacturing our product candidates for use in our clinical trials and for future potential commercial operations. The above table excludes royalties and up to approximately \$19.7 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 through June 30, 2011 have totaled \$6.2 million. The above table also excludes purchase commitments under manufacturing agreements to which we become obligated upon commercialization of brentuximab vedotin. These contingent payments have not been included in the above table and will not be included until the event triggering such payment or obligation has occurred.

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

Our exposure to market risk for changes in interest rates during the six months ended June 30, 2011 has not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2010 filed with the SEC. Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. We currently have holdings in U.S. government securities, auction rate securities and money market accounts. Our investment securities consisted of the following (in thousands):

	June 30, 2011	December 31, 2010
Short-term investments	\$ 331,322	\$ 260,682
Long-term investments	13,144	13,031
Other non-current assets	304	303
Total	\$ 344,770	\$ 274,016

As more fully described in Note 6 to the condensed consolidated financial statements, included in long-term investments as of June 30, 2011 are auction rate securities valued at \$13.1 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, failed auctions or other significant deterioration in the fair value of our cash equivalents, short-term or long-term investments will not occur. If any such further downgrades, losses, 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.

We have estimated the effect on our investment portfolio of a hypothetical increase in interest rates by one percent to be a reduction of \$1.4 million in the fair value of our investments as of June 30, 2011. 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 based on our investment balance at June 30, 2011.

Foreign Currency Risk

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

All of our revenues and most 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 six months ended June 30, 2011, 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.

Table of Contents

(b) *Changes in internal control over financial reporting.* There were no changes in our internal control over financial reporting during the quarter ended June 30, 2011 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, 2010, filed with the SEC.

Risks Related to Our Business

Our near-term prospects are substantially dependent on our lead product candidate, ADCETRIS (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. The U.S. Food and Drug Administration, or FDA, accepted for filing our two biologics license applications, or BLAs, under which we are seeking approval of brentuximab vedotin in two indications and established an action date of August 30, 2011 under the Prescription Drug User Fee Act, or PDUFA. Accordingly, our near-term prospects are substantially dependent on our ability to successfully obtain regulatory approval for and commercialize brentuximab vedotin. Brentuximab vedotin was 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 FDA and a phase II clinical trial in relapsed or refractory sALCL patients. On July 14, 2011, the FDA's Oncologic Drugs Advisory Committee, or ODAC, recommended unanimously that the FDA grant accelerated approval of brentuximab vedotin for the treatment of patients with Hodgkin lymphoma who relapse after autologous stem cell transplant, or ASCT, and patients with relapsed or refractory sALCL. Although the FDA generally follows the advice of its advisory committees, it is not bound by the recommendations of any of its advisory committees and 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 these patients, 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 will not generate any revenue from product sales in the near term, if at all. If the FDA grants accelerated approval of brentuximab vedotin, we would be subject to post-marketing compliance requirements, including providing confirmatory evidence of clinical benefit by completing additional clinical studies on a post-approval basis, and we would also be required to have all our product promotional materials pre-cleared by the FDA until regular approval of brentuximab vedotin is granted, if at all. If we and the FDA are unable to reach agreement on the design, number and scope of these confirmatory studies prior to August 30, 2011, FDA approval of brentuximab vedotin in one or both of the indications we are seeking approval for may be delayed or denied. Even if we reach agreement with the FDA on these confirmatory studies and the FDA grants accelerated approval of brentuximab vedotin, failure to conduct these studies, or to confirm a clinical benefit during these post-approval studies, could result in the FDA withdrawing brentuximab vedotin from the market, which would seriously harm our business.

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 later in the third quarter 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 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. Moreover, the FDA could require us to strengthen the warnings and precautions included in the label of brentuximab vedotin as a result of data collected from any required post-approval studies, which could further limit the revenue potential of brentuximab vedotin. If we and Millennium are unable to successfully obtain regulatory

approval for and commercialize brentuximab vedotin 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 reached agreement with the FDA on an SPA relating to our brentuximab vedotin pivotal trial in relapsed or refractory Hodgkin lymphoma, 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. **

Table of Contents

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 of approval and ODAC has recommended that the FDA grant accelerated approval of brentuximab vedotin, 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 discretion in interpreting the terms of the SPA agreement and the data and results from the pivotal trial. In addition, the FDA is not bound by the recommendations of any of its advisory committees. 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 prior to any such approval, whether we will be able to reach agreement with the FDA on the design, number and scope of any confirmatory studies required as part of any accelerated approval in a timely manner or at all, or whether brentuximab vedotin will receive any regulatory approvals at all. 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, 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 or might be delayed in receiving regulatory approvals for brentuximab vedotin.

Although we reported positive results in our clinical trials for brentuximab vedotin and ODAC has recommended accelerated approval of brentuximab vedotin, regulatory authorities may not approve brentuximab vedotin, the FDA may not act on our BLAs by the PDUFA date, or we may face post-approval issues 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 ODAC has recommended that the FDA grant accelerated approval of brentuximab vedotin for patients with Hodgkin Lymphoma who relapse after ASCT and patients with relapsed or refractory sALCL, we might never receive any regulatory approvals for brentuximab vedotin. Regulatory agencies, including the FDA, may disagree with our interpretations and those of their respective advisors of data from preclinical studies and clinical trials of brentuximab vedotin. The FDA has substantial discretion in the approval process, and when or whether, and under what conditions, regulatory approval will be obtained for brentuximab vedotin or any other drug we develop. In addition, the FDA is not bound by the recommendations of its advisory committees and the FDA may decline to follow ODAC's recommendations for any or no reason. If the FDA grants accelerated approval of brentuximab vedotin, we would be subject to post-marketing compliance requirements, including providing confirmatory evidence of clinical benefit by completing additional clinical studies on a post-approval basis, and we would also be required to have all our product promotional materials pre-cleared by the FDA until regular approval of brentuximab vedotin is granted, if at all. If we and the FDA are unable to reach agreement on the design, number and scope of these confirmatory studies prior to August 30, 2011, FDA approval of brentuximab vedotin in one or both of the indications we are seeking approval for may be delayed or denied. Even if we reach agreement with the FDA on these confirmatory studies and the FDA grants accelerated approval of brentuximab vedotin, failure to conduct these studies, or to confirm a clinical benefit during these post-approval studies, could result in the FDA withdrawing brentuximab vedotin from the market, which would seriously harm our business. Regulatory agencies also may approve brentuximab vedotin for fewer conditions than requested or may grant approval subject to the performance of confirmatory and other post-approval studies or REMS 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, and they could also require us to strengthen the warnings and precautions included in the label of brentuximab vedotin as a result of data collected from any post-approval studies.

In addition, changes in the regulatory approval policy or requirements during the development period, changes in, or the enactment of additional, regulations or statutes or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application for marketing approval. For example, in 2008, the FDA announced that, due to staffing and resource limitations, it had given its managers discretion to miss certain timing goals for completing reviews of BLAs under PDUFA. Although the FDA has since publicly expressed a recommitment to meeting PDUFA deadlines, it remains unclear whether and to what extent the FDA will adhere to PDUFA deadlines in the future. If the FDA were to miss a PDUFA timing goal for brentuximab vedotin, including as a result, our inability to reach agreement with the FDA prior to August 30, 2011 on the design, number and scope of the confirmatory studies required as part of any grant of accelerated approval, development and commercialization could be delayed. Likewise, regulatory changes may require us to amend clinical trial protocols to reflect these changes.

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

Even if we receive regulatory approval, brentuximab vedotin may later produce adverse events that limit or prevent 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 confirmatory and other 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.

Table of Contents

*Even if brentuximab vedotin receives regulatory approval, we will be subject to extensive ongoing post-marketing regulation. **

If we or Millennium receive regulatory approval for brentuximab vedotin in the United States or other jurisdictions, we and Millennium will be subject to extensive ongoing obligations and continued regulatory review from the FDA and other applicable regulatory agencies, such as continued adverse event reporting requirements and, in the event the FDA grants accelerated approval of brentuximab vedotin, the completion of confirmatory post-approval studies and the requirement to have all of our promotional materials pre-cleared by the FDA. There may also be additional FDA post-marketing obligations, all of which may result in significant expense and limit the ability to commercialize brentuximab vedotin in the United States or other jurisdictions.

If the FDA or other regulatory agencies approve brentuximab vedotin, the labeling, packaging, adverse event reporting, storage, advertising and promotion for brentuximab vedotin will be subject to extensive regulatory requirements all of which may result in significant expense and limit our ability to commercialize brentuximab vedotin. We and the manufacturers of brentuximab vedotin are also required to comply with Current Good Manufacturing Practices, or cGMP, regulations, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory agencies must approve these manufacturing facilities before they can be used to manufacture brentuximab vedotin, and these facilities are subject to ongoing regulatory inspections. In addition, regulatory agencies subject an approved product, its manufacturer and the manufacturer's facilities to continual review and inspections. The subsequent discovery of previously unknown problems with brentuximab vedotin, including adverse events of unanticipated severity or frequency, or problems with the facility where brentuximab vedotin is manufactured, may result in restrictions on the marketing of brentuximab vedotin, up to and including withdrawal of brentuximab vedotin from the market if it is approved for commercial sale. If our manufacturing facilities or those of our suppliers fail to comply with applicable regulatory requirements, such noncompliance could result in regulatory action and additional costs to us. Failure to comply with applicable FDA and other regulatory requirements may, either before or after product approval, if any, subject us to administrative or judicially imposed sanctions, including:

issuance of Form 483 notices or Warning Letters by the FDA or other regulatory agencies;

imposition of fines and other civil penalties;

criminal prosecutions;

injunctions, suspensions or revocations of regulatory approvals;

suspension of any ongoing clinical trials;

total or partial suspension of manufacturing;

delays in commercialization;

refusal by the FDA to approve pending applications or supplements to approved applications filed by us or Millennium;

refusals to permit drugs to be imported into or exported from the United States;

restrictions on operations, including costly new manufacturing requirements; and

product recalls or seizures.

The policies of the FDA and other regulatory agencies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of brentuximab vedotin 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 or Millennium might not be permitted to market brentuximab vedotin and our business could suffer.

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 three other clinical-stage programs, SGN-75, ASG-5ME and ASG-22ME, and several preclinical product candidates, including SGN-19A. If a product candidate fails at any stage of development or we otherwise determine to discontinue development of that product candidate, we will not have the anticipated revenues from that product candidate to fund our operations, and we may not receive any return on our investment in that product candidate. In this regard, we recently announced that we discontinued the development of dacetuzumab and SGN-70 to focus our efforts on our pipeline of ADC product candidates, and we previously determined to discontinue our lintuzumab development program following negative clinical trial results. As a result of the uncertain and time-consuming clinical development and regulatory approval process, we may not successfully develop any of our product candidates and it is possible that none of our product candidates will ever become commercial products. In addition, 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.

Table of Contents

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 later in the third quarter 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.

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 trials of SGN-75, ASG-5ME and ASG-22ME. 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 approximately 100 patients and we believe that any clinical trial designed to test the efficacy of SGN-75, ASG-5ME or ASG-22ME, 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.

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 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 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 some of our clinical trials in compliance with Good Clinical Practice, or GCP, and to the extent they fail to enroll patients for our clinical trials, fail to conduct our trials in accordance with GCP, 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.

Table of Contents

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 cGMP 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, GCP 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;

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

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

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 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 that granted Millennium rights to develop and commercialize brentuximab vedotin outside of the United States and Canada. We also have ADC collaborations with Abbott, Bayer, Celldex, Daiichi Sankyo, GSK, Genentech, Millennium, Pfizer and Progenics, and ADC co-development agreements with Agensys and Genmab.

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. If we had decided to continue the development of dacetuzumab, we would have been responsible for funding any further dacetuzumab development and clinical trial activities. 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,

Table of Contents

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, we may not be able to effectively commercialize brentuximab vedotin if approved for commercial sale.*

We recently established a sales and marketing organization, but we may not be able to successfully develop adequate sales and marketing capabilities. For example, if we receive approval for commercial sale, we intend to market brentuximab vedotin in the United States and Canada with a sales force of approximately 60 sales representatives. Although we have hired the number of employees that we believe are required to market brentuximab vedotin, this number may turn out to be incorrect and we may not be able to effectively commercialize brentuximab vedotin with such force. If we are unable to establish adequate sales and marketing capabilities and successful distribution relationships with logistics companies and wholesalers, we may fail to realize the full sales potential of brentuximab vedotin. Even if we are able to establish distribution relationships 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 brentuximab vedotin, and if they fail to devote sufficient time and resources to the marketing and distribution of brentuximab vedotin, or if their performance is substandard, it will adversely affect the sale of brentuximab vedotin.

We are subject to various state and federal healthcare related laws and regulations that may impact the commercialization of our product candidates and could subject us to significant fines and penalties.*

Our operations may be directly or indirectly subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act. These laws may impact, among other things, the sales, marketing and education programs for any of our product candidates that may be approved for commercial sale, including brentuximab vedotin.

The federal Anti-Kickback Statute prohibits persons from knowingly and willingly soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Suits filed under the False Claims Act, known as qui tam actions, can be brought by any individual on behalf of the government and such individuals, commonly known as whistleblowers, may share in any amounts paid by the entity to the government in fines or settlement. The filing of qui tam actions has caused a number of pharmaceutical, medical device and other healthcare companies to have to defend a False Claims Act action. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Various states have also enacted laws modeled after the federal False Claims Act.

Although we take our obligation to maintain our compliance with these various laws and regulations seriously and have enacted a compliance program aimed at preventing the violation of these laws and regulation, if we are found to be in violation of any of the laws and regulations described above or other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and the curtailment or restructuring of our operations, all of which could have a material adverse effect on our business and results of operations.

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

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

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 negatively 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.

Table of Contents

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

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

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

We do not currently have the internal ability to manufacture the drug products that we need to conduct our clinical trials or for potential commercial sale 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 with Piramal Healthcare to perform conjugation of our drug-linker to the antibody used in brentuximab vedotin, and we have also 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 AMRI 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, AMRI, Baxter, Lonza Sales AG, Laureate Pharma, and SAFC. In addition, we rely on other third parties to perform additional steps in the manufacturing process, including shipping 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 and for potential commercial sale. If our contract manufacturers or other third parties fail to deliver our product candidates for clinical use or sale 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, production and sale 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 have entered into agreements necessary for our commercial scale supply chain for brentuximab vedotin, 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, a shortfall in available product candidates or the inability to sell our products in the U.S. or abroad.

Our contract manufacturers are required to produce our clinical and commercial product candidates under cGMP 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 pre-approval inspections and periodic unannounced inspections by the FDA and corresponding state and foreign authorities to ensure strict compliance with cGMP 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 and 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

Table of Contents

of any recently manufactured product candidate compared to the product candidate used in prior clinical trials. If we are unable to demonstrate comparability, the FDA could require us to conduct additional clinical trials, which would be expensive and may significantly delay our clinical progress and the possible commercialization of such product candidates. Similarly, if we believe there may be comparability issues with any one of our product candidates, we may postpone or suspend manufacture of the product candidate to conduct further process development of such product candidate in order to alleviate such product comparability concerns, which may significantly delay the clinical progress of such product candidate or increase its manufacturing costs.

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

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

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

Our ADC technology, utilizing proprietary stable linkers and potent cell-killing synthetic drugs, has not been incorporated into a commercial product. This ADC technology is used in our brentuximab vedotin, SGN-75, ASG-5ME, ASG-22ME and SGN-19A product candidates and is the basis of our collaborations with Abbott, Agensys, Bayer, Celldex, Daiichi Sankyo, Genentech, Genmab, GSK, Millennium, Pfizer 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 in patients with Hodgkin lymphoma and our phase II trial in patients with sALCL for which we are requesting approval for those two indications from the FDA, we may not receive any approvals and 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 June 30, 2011, we had an accumulated deficit of approximately \$546.2 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 may need to raise 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 related to brentuximab vedotin are expected to be shared with Millennium, we may need to raise 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 uncertainty, which, along with current economic conditions, may make it more difficult for us to raise equity and debt financing when we need it. 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 when we need them, 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 timing of potential receipt of regulatory approval of brentuximab vedotin and its potential commercialization;

the scope, number, rate of progress and cost of the confirmatory studies that we may be required to conduct as a condition to any grant by the FDA of accelerated approval of brentuximab vedotin;

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

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

Table of Contents

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

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

progress with clinical trials;

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

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

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

the potential costs associated with state and federal taxes;

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

competing technological and market developments.

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

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

We have entered into agreements with third-party commercial and academic institutions to license technology for use in our product candidates and ADC technology. Currently, we have license agreements with Bristol-Myers Squibb, Arizona State University, CLB-Research and Development, 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, linker and drug-based technologies. Our rights to these patents and patent applications are derived in part from worldwide licenses from Bristol-Myers Squibb and Arizona State University, among others. In addition, we have licensed our U.S. and foreign patents and patent applications to third parties.

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

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.

Table of Contents

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. For example, we are currently involved in a pending patent opposition proceeding against our European patent, EP Patent No. 1347730, which covers the use of certain CD30 antibodies and conjugates, including brentuximab vedotin, for the treatment of Hodgkin lymphoma. 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 and may allow third parties to use our proprietary technologies without a license from us or our collaborators. For example, the possible invalidation of our European patent or amendment of its granted claims could adversely affect our ability to restrict third party products from competing with brentuximab vedotin, if approved for commercial sale in the European Union. 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.

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 have been required to expand our workforce, particularly in the areas of manufacturing, clinical trials management, regulatory affairs, business development, sales and marketing. These activities required the addition of new personnel, including sales and marketing management, and the development of additional expertise by existing management personnel. We continue to 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 retain these individuals on favorable terms or attract any additional personnel that may be required, 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, GSK, Genzyme, Gilead, ImmunoGen, Merck, Millennium, Micromet, Novartis, Pfizer, and Pharmacyclics 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

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

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;

Table of Contents

develop less costly products;

obtain quicker regulatory approval;

have access to more manufacturing capacity;

form more advantageous strategic alliances; or

establish superior proprietary positions.

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

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

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

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

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

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 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.

Table of Contents

Legislative actions and potential new accounting pronouncements 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 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-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 ARS, pose risks arising from liquidity and credit concerns. As of June 30, 2011 we held ARS valued at \$13.1 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 will not occur. In addition, Standard & Poor's Financial Services LLC, or S&P, recently announced that it had revised its outlook on the long-term credit rating of the United States to negative. S&P and other ratings agencies have also raised the possibility of a downgrade to the sovereign credit rating of the United States, which could impact the stability of future U.S. treasury auctions and affect the trading market for U.S. government securities. While the U.S. congress recently approved increases to the federal debt ceiling, uncertainty surrounding the credit ratings of U.S. government securities could impact the market for these securities. These factors could impact the liquidity or valuation of our available-for-sale securities, 96% of which were invested in U.S. treasury securities as of June 30, 2011. 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 second quarter of 2011, our closing stock price fluctuated between \$15.00 and \$21.34 per share. As a result of fluctuations in the price of our common stock, you may be unable to sell your shares at or above the price you paid for them. The market price of our common stock may be subject to substantial volatility in response to many risk factors listed in this section, and others beyond our control, including:

announcements concerning our two BLAs that were accepted for filing by the FDA for brentuximab vedotin or any other regulatory submissions we may in the future plan or determine to make, including with respect to the number and scope of the confirmatory studies required as a condition to any grant by the FDA of accelerated approval for brentuximab vedotin;

announcements of FDA approval or non-approval of brentuximab vedotin, or specific label indications for or restrictions, warnings or limitations in its use, or delays in the FDA review process;

announcements regarding the results of discovery efforts and preclinical and clinical activities by us or our competitors;

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, or the termination or completion of any collaborations or other arrangements, by us or our competitors;

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

our ability to raise additional capital when we need it and the terms upon which we may raise any additional 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

Table of Contents

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 our development and 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 49.7 percent of our voting power as of August 1, 2011. As a result, these stockholders, acting together, may be able to control our management and affairs and matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as mergers, consolidations or the sale of substantially all of our assets. Consequently, this concentration of ownership may have the effect of delaying, deferring or preventing a change in control, including a merger, consolidation, takeover or other business combination involving us or discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control, which might affect the market price of our common stock.

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

Our Board of Directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the price, rights, preferences, privileges and restrictions, including voting rights, of those shares without any further vote or action by the stockholders, 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**

Number	Description
3.1(1)	Fourth Amended and Restated Certificate of Incorporation of Seattle Genetics, Inc.
3.2(2)	Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation of Seattle Genetics, Inc.
3.3(3)	Amended and Restated Bylaws of Seattle Genetics, Inc.
4.1(4)	Specimen Stock Certificate.
4.2(5)	Form of Common Stock Warrant.
4.3(1)	Investor Rights Agreement dated July 8, 2003 among Seattle Genetics, Inc. and certain of its stockholders.
10.1+	Office Lease dated May 9, 2011 between Seattle Genetics, Inc. and WCM Highlands II, LLC.
10.2+	Third Amendment to Lease dated May 9, 2011 between Seattle Genetics, Inc. and B&N 141-302, LLC
10.3+	Amended and Restated 2000 Employee Stock Purchase Plan, effective May 20, 2011.
10.4+	Form of Notice of Stock Option Grant and Stock Option Agreement for non-employee directors under the Amended and Restated 2007 Equity Incentive Plan.
31.1+	Certification of Chief Executive Officer pursuant to Rule 13a-14(a).
31.2+	Certification of Chief Financial Officer pursuant to Rule 13a-14(a).
32.1+	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.
32.2+	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350.
101.INS+(6)	XBRL Instance Document
101.SCH+(6)	XBRL Taxonomy Extension Schema Document.
101.CAL+(6)	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF+(6)	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB+(6)	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE+(6)	XBRL Taxonomy Extension Presentation Linkbase Document.

- (1) Previously filed as an exhibit to the Registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2008 filed with the Commission on November 7, 2008 (File No. 000-32405) and incorporated herein by reference.
- (2) Previously filed as an exhibit to the Registrant's current report on Form 8-K filed with the Commission on May 26, 2011 (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 filed with the Commission on August 12, 2003 (File No. 333-50266) and incorporated herein by reference.
- (4) Previously filed as an exhibit to the Registrant's registration statement on Form S-1 (File No. 333-50266) originally filed with the Commission on November 20, 2000, as subsequently amended, and incorporated herein by reference.
- (5) Previously filed as an exhibit to the Registrant's current report on Form 8-K filed with the Commission on May 15, 2003 (File No. 333-50266) and incorporated herein by reference.
- (6) Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal

Table of Contents

securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fails to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act, are deemed not filed for purposes of section 18 of the Exchange Act and otherwise are not subject to liability under these sections.

+ Filed herewith.

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

Table of Contents

SIGNATURES

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

SEATTLE GENETICS, INC.

By: **/s/ TODD E. SIMPSON**
Todd E. Simpson
Duly Authorized and Chief Financial Officer
Date: August 5, 2011

Table of Contents**EXHIBIT INDEX**

Number	Description
3.1(1)	Fourth Amended and Restated Certificate of Incorporation of Seattle Genetics, Inc.
3.2(2)	Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation of Seattle Genetics, Inc.
3.3(3)	Amended and Restated Bylaws of Seattle Genetics, Inc.
4.1(4)	Specimen Stock Certificate.
4.2(5)	Form of Common Stock Warrant.
4.3(1)	Investor Rights Agreement dated July 8, 2003 among Seattle Genetics, Inc. and certain of its stockholders.
10.1+	Office Lease dated May 9, 2011 between Seattle Genetics, Inc. and WCM Highlands II, LLC.
10.2+	Third Amendment to Lease dated May 9, 2011 between Seattle Genetics, Inc. and B&N 141-302, LLC
10.3+	Amended and Restated 2000 Employee Stock Purchase Plan, effective May 20, 2011.
10.4+	Form of Notice of Stock Option Grant and Stock Option Agreement for non-employee directors under the Amended and Restated 2007 Equity Incentive Plan.
31.1+	Certification of Chief Executive Officer pursuant to Rule 13a-14(a).
31.2+	Certification of Chief Financial Officer pursuant to Rule 13a-14(a).
32.1+	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.
32.2+	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350.
101.INS+(6)	XBRL Instance Document
101.SCH+(6)	XBRL Taxonomy Extension Schema Document.
101.CAL+(6)	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF+(6)	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB+(6)	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE+(6)	XBRL Taxonomy Extension Presentation Linkbase Document.

- (1) Previously filed as an exhibit to the Registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2008 filed with the Commission on November 7, 2008 (File No. 000-32405) and incorporated herein by reference.
- (2) Previously filed as an exhibit to the Registrant's current report on Form 8-K filed with the Commission on May 26, 2011 (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 filed with the Commission on August 12, 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

- (6) Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fails to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act, are deemed not filed for purposes of section 18 of the Exchange Act and otherwise are not subject to liability under these sections.
- + Filed herewith.
- Pursuant to a request for confidential treatment, portions of this Exhibit have been redacted from the publicly filed document and have been furnished separately to the Securities and Exchange Commission as required by Rule 24b-2 under the Securities Exchange Act of 1934.