

SEATTLE GENETICS INC /WA
Form 10-Q
May 06, 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 March 31, 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 May 3, 2011, there were 113,776,331 shares of the registrant's common stock outstanding.

Table of Contents

Seattle Genetics, Inc.

Quarterly Report on Form 10-Q

For the quarter ended March 31, 2011

INDEX

	Page
PART I. FINANCIAL INFORMATION (Unaudited)	
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>	19
PART II. OTHER INFORMATION	
Item 1A. <u>Risk Factors</u>	20
Item 6. <u>Exhibits</u>	33
<u>SIGNATURES</u>	34
<u>EXHIBIT INDEX</u>	35

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

	March 31, 2011	December 31, 2010
Assets		
Current assets		
Cash and cash equivalents	\$ 61,469	\$ 21,127
Short-term investments	381,128	260,682
Interest receivable	1,228	782
Accounts receivable	8,621	19,279
Prepaid expenses and other current assets	2,673	2,246
Total current assets	455,119	304,116
Property and equipment, net	11,739	12,311
Long-term investments	13,256	13,031
Other non-current assets	479	478
Total assets	\$ 480,593	\$ 329,936
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued liabilities	\$ 25,393	\$ 25,783
Current portion of deferred revenue	34,424	29,038
Total current liabilities	59,817	54,821
Long-term liabilities		
Deferred revenue, less current portion	112,962	110,630
Deferred rent and other long-term liabilities	2,985	2,967
Total long-term liabilities	115,947	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, 150,000 shares authorized; 113,511 shares issued and outstanding at March 31, 2011 and 101,607 shares issued and outstanding at December 31, 2010	114	102
Additional paid-in capital	800,523	624,759
Accumulated other comprehensive loss	(1,164)	(1,373)
Accumulated deficit	(494,644)	(461,970)
Total stockholders' equity	304,829	161,518

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

Total liabilities and stockholders' equity	\$ 480,593	\$ 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 March 31,	
	2011	2010
Revenues from collaboration and license agreements	\$ 12,171	\$ 46,455
Operating expenses		
Research and development	32,434	30,316
General and administrative	12,713	5,231
Total operating expenses	45,147	35,547
Income (loss) from operations	(32,976)	10,908
Investment income, net	302	552
Net income (loss)	\$ (32,674)	\$ 11,460
Net income (loss) per share - basic	\$ (0.30)	\$ 0.11
Net income (loss) per share - diluted	\$ (0.30)	\$ 0.11
Weighted-average shares used in computing:		
Net income (loss) per share - basic	108,513	100,622
Net income (loss) per share - diluted	108,513	103,036

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)

	Three months ended March 31,	
	2011	2010
Operating activities		
Net income (loss)	\$ (32,674)	\$ 11,460
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities		
Share-based compensation expense	4,268	3,184
Depreciation and amortization	875	816
Amortization and accretion on investments	827	1,398
Deferred rent and other long-term liabilities	18	28
Changes in operating assets and liabilities		
Interest receivable	(446)	(1,042)
Accounts receivable	10,658	66,307
Prepaid expenses and other current assets	(427)	(1,226)
Other non-current assets	(1)	29
Accounts payable and accrued liabilities	(390)	(4,572)
Deferred revenue	7,718	(31,807)
Net cash provided by (used in) operating activities	(9,574)	44,575
Investing activities		
Purchases of securities available for sale	(238,899)	(146,107)
Proceeds from maturities of securities available for sale	117,610	101,391
Purchases of property and equipment	(303)	(1,053)
Net cash used in investing activities	(121,592)	(45,769)
Financing activities		
Net proceeds from issuance of common stock	168,118	0
Proceeds from exercise of stock options and employee stock purchase plan	3,390	1,040
Net cash provided by financing activities	171,508	1,040
Net increase (decrease) in cash and cash equivalents	40,342	(154)
Cash and cash equivalents, at beginning of period	21,127	18,486
Cash and cash equivalents, at end of period	\$ 61,469	\$ 18,332

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-month period ended March 31, 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 2 to 8 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 March 31,	
	2011	2010
Numerator		
Net income (loss)	\$ (32,674)	\$ 11,460
Denominator		
Weighted average shares outstanding - basic	108,513	100,622
Dilutive effect of common shares from stock options and warrants	0	2,414
Weighted average shares outstanding - diluted	108,513	103,036
Basic net income (loss) per share	\$ (0.30)	\$ 0.11
Diluted net income (loss) per share	\$ (0.30)	\$ 0.11

Due to the net loss incurred for the three-month period ended March 31, 2011, the Company excluded all warrants and options to purchase common stock from the calculation of diluted net loss per share as such securities were antidilutive. For the period ended March 31, 2010, the Company excluded certain options to purchase common stock from the calculation of diluted net 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 March 31,	
	2011	2010
Warrants to purchase common stock	1,113	0
Options to purchase common stock	12,799	4,825
Total	13,912	4,825

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 March 31,	
	2011	2010
Net income (loss)	\$ (32,674)	\$ 11,460
Unrealized gain on securities available-for-sale	209	244
Comprehensive income (loss)	\$ (32,465)	\$ 11,704

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 \$168.1 million, after deducting underwriting discounts and commissions and other offering expenses.

5. Investments

Short-term and long-term investments consist of U.S. treasury securities, corporate notes 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
March 31, 2011				
U.S. treasury securities	\$ 381,402	\$ 41	\$ (11)	\$ 381,432
Auction rate securities	14,450	0	(1,194)	13,256
Total	\$ 395,852	\$ 41	\$ (1,205)	\$ 394,688
Contractual Maturities				
Due in one year or less	\$ 381,402			\$ 381,432
Due in 2017	14,450			13,256
Total	\$ 395,852			\$ 394,688
Reported as:				
Short-term investments				\$ 381,128
Long-term investments				13,256
Other non-current assets				304
Total				\$ 394,688

	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
March 31, 2011				
U.S. treasury securities	\$ 110,549	\$ (11)	\$ NA	\$ NA
Auction rate securities	NA	NA	13,256	(1,194)
Total	\$ 110,549	\$ (11)	\$ 13,256	\$ (1,194)
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 bonds 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 three month period ended March 31, 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):

	Fair value measurement using:			Total
	Quoted prices in active markets for identical assets (Level 1)	Other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
As of March 31, 2011:				
Cash equivalents:				
Money market funds	\$ 23,399	\$ 0	\$ 0	\$ 23,399
U.S. treasury securities	10,006	0	0	10,006
Short-term investments - U.S. treasury securities	381,128	0	0	381,128
Long-term investments - auction rate securities	0	0	13,256	13,256
Other non-current assets - U.S. treasury note	304	0	0	304
Total	\$ 414,837	\$ 0	\$ 13,256	\$ 428,093

	Fair value measurement using:			Total
	Quoted prices in active markets for identical assets (Level 1)	Other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
As of December 31, 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 March 31, 2011, the Company held auction rate securities valued at \$13.3 million that have failed at auction and are currently illiquid. Liquidity of these investments is subject to a successful auction process, redemption of the investment, a sale of the security in a secondary market or a negotiated or adjudicated resolution. Each of the securities continues to pay interest according to the stated terms on a monthly basis. The interest rate on these auction rate securities is no longer established based on an auction process but is established according to the terms of the issue. As of March 31, 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

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

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 loss	225
Balance as of March 31, 2011	\$ 13,256

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 clinical stage biotechnology company focused on the development and commercialization of monoclonal antibody-based therapies for cancer and autoimmune diseases. Our lead product candidate, 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. In May 2011, we announced that the U.S. Food and Drug Administration, or FDA, accepted for filing two biologics license applications, or BLAs, for brentuximab vedotin seeking approval for the treatment of relapsed or refractory Hodgkin lymphoma and relapsed or refractory sALCL. In addition, the FDA granted a six-month priority review for both BLAs, and has established an action date of August 30, 2011 for both BLAs under the Prescription Drug User Fee Act, or PDUFA. 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 that had relapsed following an autologous stem cell transplant 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 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, and the median duration of response was 29 weeks as assessed by independent central review and 47 weeks as assessed by investigators. 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. The median duration of response for the phase II sALCL trial had not yet been reached at a median follow up on study of approximately six months. Fifty-three 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 highly potent synthetic drugs and stable linkers for attaching the drugs to monoclonal antibodies. In addition, we have four other clinical-stage programs, which consist of SGN-75, ASG-5ME, dacetuzumab (SGN-40) and SGN-70, as well as an investigational new drug candidate planned for 2012, 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 all 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. 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.

Although the FDA recently accepted for filing our two BLAs for brentuximab vedotin we cannot predict with certainty when, or whether, regulatory approval will be received or the timing or success of its potential commercialization, and we do not currently have any commercial products for sale. Our other product candidates are in relatively early stages of development. As of March 31, 2011, we had an accumulated deficit of \$494.6 million. Over the next several years, we expect that we will incur substantial expenses, primarily as a result of activities related to the potential regulatory approval and commercialization of brentuximab vedotin, including commercial manufacturing. We will also continue to invest in research, development and manufacturing of our product

Table of Contents

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 also likely increase as a result of such activities. In addition, we may incur significant milestone payment obligations as our product candidates progress through clinical trials towards potential commercialization.

We expect that 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 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.

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 three months ended March 31, 2011, revenues decreased to \$12.2 million, compared to \$46.5 million for the same period in 2010. This decrease was primarily due to revenue earned in the first half of 2010 related to our former dacetuzumab collaboration with Genentech that ended in June 2010. For the three months ended March 31, 2011, total operating expenses increased 27% to \$45.1 million, compared to \$35.6 million for the same period in 2010 primarily due to increased general and administrative costs related to pre-commercialization activities. As of March 31, 2011, we had \$455.9 million in cash, cash equivalents and short-term and long-term investments, and \$304.8 million in total stockholders' equity.

*Results of operations***Three months ended March 31, 2011***Revenues.*

Revenues by collaborator are summarized as follows:

Collaboration and license agreement revenue by collaborator (\$ in thousands)	Three months ended		
	2011	March 31, 2010	% Change
Millennium	\$ 7,227	\$ 2,784	160%
Genentech	1,419	41,839	(97%)
Pfizer	1,000	0	N/A (1)
Other	2,525	1,832	38%
Total	\$ 12,171	\$ 46,455	(74%)

(1) No amount in comparable period.

Millennium revenues increased 160% to \$7.2 million for the first three months of 2011 compared to the comparable period 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 first quarter ended March 31, 2011 compared to the corresponding period in 2010. Revenues in 2011 also reflect 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 97% to \$1.4 million for the first three months of 2011 compared to the comparable period in 2010. Genentech revenues reflect amounts earned under our ADC collaboration agreement during 2011 and under our ADC collaboration and former dacetuzumab collaboration agreements during 2010. The decrease in Genentech revenues for the three month period ended March 31, 2011 was

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

attributable to our former dacetuzumab collaboration agreement which ended in June 2010 and generated no revenue during the three month period ended March 31, 2011.

Pfizer revenues for the three month period ended March 31, 2011 reflect the earned portion of an \$8 million upfront payment under our ADC collaboration agreement that we entered into in December 2010.

Table of Contents

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 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 ADC product candidates through the development process. 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 level of support we provide to our collaborators, the timing of milestones achieved, and our ability to enter into additional collaboration agreements. We expect revenues related to Millennium will increase as a result of the recognition of amounts earned as we fulfill our performance obligations 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		
	2011	March 31, 2010	% Change
Research	\$ 3,487	\$ 3,427	2%
Development and contract manufacturing	10,792	9,816	10%
Clinical	15,863	15,141	5%
Share-based compensation expense	2,292	1,932	19%
Total research and development expenses	\$ 32,434	\$ 30,316	7%

Development and contract manufacturing expenses increased 10% to \$10.8 million in the first three months of 2011 from the comparable period of 2010. The increase reflects higher contract manufacturing costs for our SGN-75 clinical program and our SGN-19A preclinical program, in addition to continued brentuximab vedotin activities. Clinical expenses increased 5% to \$15.9 million in the first three months of 2011 from the comparable period in 2010 primarily due to increased staffing levels in support of our clinical trials and our BLA submissions for brentuximab vedotin. Clinical trial expenses for dacetuzumab and lintuzumab decreased during the three month period ended March 31, 2011 as these trials have been completed. Share-based compensation expense increased 19% during the first three months of 2011 from the comparable period 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.

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:

Table of Contents

Product candidates (\$ in thousands)	Three months ended March 31,		Five years ended March 31,
	2011	2010	2011
Brentuximab vedotin (SGN-35)	\$ 8,889	\$ 10,594	\$ 114,701
SGN-19A	1,053	9	2,586
SGN-75	841	375	10,972
ASG-5ME	392	516	4,827
Other third party costs	455	2,893	106,761
Total third party costs	11,630	14,387	239,847
Other costs and overhead	18,512	13,997	232,728
Share-based compensation expense	2,292	1,932	32,065
Total research and development	\$ 32,434	\$ 30,316	\$ 504,640

Our third-party costs for brentuximab vedotin decreased during the three months ended March 31, 2011 from the comparable period in 2010 primarily due to lower manufacturing costs in 2011 as we manufactured less drug supply in the first quarter of 2011. Our third party costs for SGN-19A increased during the three months ended March 31, 2011 from the comparable period in 2010 due to a higher level of manufacturing activities in preparation for potential clinical trials. Third party costs for SGN-75 increased during the three month period ended March 31, 2011 related to manufacturing costs incurred for additional material to support our phase I clinical trial. Our third party costs for ASG-5ME decreased during the three months ended March 31, 2011 compared to 2010 as a result of lower manufacturing costs in the 2011 period.

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 anticipate that our total research and development expenses will increase in the foreseeable future as we continue to seek regulatory approval for and prepare for the potential commercialization of brentuximab vedotin, as well as continue our preclinical and clinical activities for our other product candidates. In particular, we expect that development costs for brentuximab vedotin, SGN-75, ASG-5ME and SGN-19A will increase in 2011 compared to 2010. We expect our development costs for dacetuzumab and lintuzumab to decrease in 2011 compared to 2010. The lintuzumab program has been discontinued and we are focusing our development efforts on our ADC programs. Expenses will fluctuate based upon many factors including the degree of collaborative activities, timing of manufacturing campaigns, numbers of patients enrolled in our clinical trials and the outcome of each clinical trial event.

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

Table of Contents**General and administrative.**

General and administrative (\$ in thousands)	Three months ended		
	2011	March 31, 2010	% Change
General and administrative, excluding share-based compensation expense	\$ 10,737	\$ 3,979	170%
Share-based compensation expense	1,976	1,252	58%
Total general and administrative expenses	\$ 12,713	\$ 5,231	143%

General and administrative expenses, excluding share-based compensation expense, increased during the three months ended March 31, 2011 from the comparable period in 2010. The increase resulted primarily from increased staffing levels and contracted activities in preparation for the potential commercial launch of brentuximab vedotin as we continue to establish our commercial infrastructure. Share-based compensation expense increased during the three months ended March 31, 2011 from the comparable period in 2010. This resulted from a larger number of optioned shares subject to expense recognition during the three months ended March 31, 2011 as a result of increased staffing levels and a higher average value per optioned share primarily attributable to increases in our stock price.

Investment income, net.

Investment income, net decreased 45% to \$0.3 million in the first three months of 2011 from the comparable period of 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)	March 31,	December 31,
	2011	2010
Cash, cash equivalents and investments	\$ 455,853	\$ 294,840
Working capital	395,302	249,295
Stockholders' equity	304,829	161,518

	Three months ended	
	March 31, 2011	March 31, 2010
Cash provided by (used in):		
Operating activities	\$ (9,574)	\$ 44,575
Investing activities	(121,592)	(45,769)
Financing activities	171,508	1,040

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 \$455.9 million at March 31, 2011, compared to \$294.8 million at December 31, 2010 and our working capital was \$395.3 million at March 31, 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 \$168.1 million in February 2011. During the first three months of 2011, we used \$9.6 million of cash in our operating activities compared to \$44.6 million generated from operating activities during the first three 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 three month periods ended March 31, 2011 and 2010, respectively. We have structured our investment portfolio to provide working capital as needed. Our cash, cash equivalents and investments are held in a variety of interest-bearing instruments and subject to investment guidelines allowing for holdings in U.S. government and agency securities, corporate bonds, taxable municipal bonds, auction rate securities, commercial paper and money market accounts. As of March 31, 2011, we held auction rate securities valued at \$13.3 million that have failed at auction and are currently illiquid. Liquidity of these investments is subject to a

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

successful auction process, redemption of the investment, a sale of the security in a secondary market or a negotiated or adjudicated resolution. Each of the securities continues to pay interest according to the stated terms on a monthly basis. The interest rate on these auction rate securities is no longer established based on an auction process but is established according to the terms of the issue. As of March 31, 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 rate securities has been determined based on a probability-weighted discounted cash flow analysis. This analysis relies upon significant

Table of Contents

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 3% and 5% of total investment securities measured at fair value as of March 31, 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 March 31, 2011, we had \$442.6 million held in cash reserves or debt securities scheduled to mature within the next twelve months.

Included in net cash used in investing activities in 2011 are capital expenditures related to the purchase of laboratory equipment in support of our research and development activities and for computer hardware equipment to support the growth in our infrastructure. We expect that our 2011 capital expenditures will increase compared to 2010 as we expand our facilities to accommodate our growth.

At our currently planned spending rate, we believe that our financial resources, including the \$168.1 million in net proceeds received from our recently completed public offering of our common stock, 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 at least 2013. This forecast does not take into account revenues from potential sales of brentuximab vedotin, which we expect may extend the sufficiency of our financial resources. Although the FDA recently accepted for filing our two BLAs for brentuximab vedotin, we cannot predict with certainty when, or whether, regulatory approval will be received or the timing or success of its potential commercialization. In addition, changes in our spending rate may occur that would consume available capital resources sooner, such as increased development, manufacturing and clinical trial expenses and the expansion of our sales and marketing organization preceding the potential commercialization of brentuximab vedotin. Additionally, we may not receive the payments that we currently expect under our existing collaboration and license agreements, including the brentuximab vedotin collaboration agreement with Millennium, which may shorten the timeframe through which we are able to fund operations. For example, in the event of a termination of the brentuximab vedotin collaboration agreement with Millennium, we would not receive 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.

Commitments

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

Table of Contents

The following table reflects our future minimum contractual commitments as of March 31, 2011 (in thousands):

	Total	Remainder of 2011	2012	2013	2014	2015	Thereafter
Operating leases	\$ 22,138	\$ 2,104	\$ 2,836	\$ 2,917	\$ 3,014	\$ 3,113	\$ 8,154
Manufacturing, license & collaboration agreements	36,513	33,590	1,749	1,174	0	0	0
Total	\$ 58,651	\$ 35,694	\$ 4,585	\$ 4,091	\$ 3,014	\$ 3,113	\$ 8,154

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 \$20.6 million in potential future milestone payments to third parties under license and collaboration agreements for our current development programs, which generally become due and payable only upon achievement of certain developmental, clinical, regulatory and/or commercial milestones. Milestone payments under these agreements to date have totaled \$6.0 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 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 three months ended March 31, 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):

	March 31, 2011	December 31, 2010
Short-term investments	\$ 381,128	\$ 260,682
Long-term investments	13,256	13,031
Other non-current assets	304	303
Total	\$ 394,688	\$ 274,016

As more fully described in note 6 to the condensed consolidated financial statements, included in long-term investments as of March 31, 2011 are auction rate securities valued at \$13.3 million that have failed at auction and are currently illiquid. Liquidity of these investments is subject to a successful auction process, redemption of the investment, a sale of the security in a secondary market or a negotiated or adjudicated resolution. No assurance can be made that further downgrades, losses or other significant deterioration in the fair value of our cash equivalents, short-term or long-term investments will not occur. If any such further downgrades, losses, or other significant deteriorations occur, it may negatively impact or impair our current portfolio of cash equivalents, short-term and long-term investments.

We have estimated the effect on our investment portfolio of a hypothetical increase in interest rates by one percent to be a reduction of \$1.8 million in the fair value of our investments as of March 31, 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 March 31, 2011.

Foreign Currency Risk

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

All of our revenues and the majority of our expenses are denominated in U.S. dollars and as a result, we have not experienced significant foreign currency transaction gains and losses to date. We have conducted some transactions in foreign currencies during the three months ended March 31, 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.

Table of Contents

Item 4. Controls and Procedures

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

(b) *Changes in internal control over financial reporting.* There were no changes in our internal control over financial reporting during the quarter ended March 31, 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, 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, for which the U.S. Food and Drug Administration, or FDA, recently accepted for filing our two biologics license applications, or BLAs, seeking approval of brentuximab vedotin in two indications. 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. In the fall of 2010 we announced positive data from both the pivotal clinical trial of brentuximab vedotin for patients with relapsed or refractory Hodgkin lymphoma and the phase II clinical trial of brentuximab vedotin for patients with relapsed or refractory sALCL. However, the design of these trials or data collected from either of these trials may not be adequate to demonstrate the safety and efficacy of brentuximab vedotin for the treatment of patients with either relapsed or refractory Hodgkin lymphoma or relapsed or refractory sALCL, or otherwise may not be sufficient to support FDA or any foreign regulatory approval for either or both of these indications. For example, the FDA may disagree with our interpretation of the results of the trials and determine that the data from the trials are not sufficient to support approval. If we fail to obtain regulatory approval for brentuximab vedotin, we will be unable to market and sell brentuximab vedotin and therefore will not generate any revenue from product sales in the near term, if at all.

Even if we and Millennium receive the required regulatory approvals to market brentuximab vedotin, we may not be able to successfully commercialize brentuximab vedotin. In December 2009, we entered into an agreement with Millennium to develop and commercialize brentuximab vedotin, under which we have commercial rights in the United States and its territories and Canada, and Millennium has commercial rights in the rest of the world. The success of this collaboration and the activities of Millennium will significantly impact the potential commercialization of brentuximab vedotin in countries other than the United States and Canada. Brentuximab vedotin is not expected to be commercially available for any indication until at the earliest the second half of 2011, if at all. Further, if it is approved for commercial sale, the commercial success of brentuximab vedotin will depend upon its acceptance by physicians, patients, third party payors and other key decision-makers as a therapeutic alternative to currently available products. In addition, the indications that we and Millennium are pursuing for brentuximab vedotin have relatively low incidence rates, including relapsed or refractory Hodgkin lymphoma and relapsed or refractory sALCL, which may limit the revenue potential of brentuximab vedotin. If we and Millennium are unable to successfully obtain regulatory approval for and commercialize brentuximab vedotin for the treatment of relapsed or refractory Hodgkin lymphoma and relapsed or refractory sALCL in a timely manner or at all, our ability to generate revenue from product sales would be significantly delayed and our business would be materially affected, and we may not be able to earn sufficient revenues to continue as a going concern.

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

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

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

BLA, and provides an agreement that the study design, including trial size, clinical endpoints and/or data analyses are acceptable to the FDA. Reaching agreement with the FDA on an SPA is not an indication of approvability. Even though we believe that the data from the pivotal trial are supportive, our SPA with the FDA is not a guarantee or indication of approval for the

Table of Contents

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

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

Although we reported positive results from our pivotal trial and our phase II clinical trial of brentuximab vedotin in relapsed or refractory Hodgkin lymphoma and relapsed or refractory sALCL, respectively, and we believe that the data from these trials are supportive of approval, we might never receive any regulatory approvals for brentuximab vedotin. Regulatory agencies, including the FDA, or their advisors, may disagree with our interpretations of data from preclinical studies and clinical trials of brentuximab vedotin. The FDA has substantial discretion in the approval process, and when or whether regulatory approval will be obtained for brentuximab vedotin or any other drug we develop. For example, even though our Hodgkin lymphoma pivotal trial was conducted under an SPA with the FDA, there is no guarantee that the data generated from this trial will be adequate to support FDA approval. The FDA's Oncologic Drugs Advisory Committee, if reviewing brentuximab vedotin, may recommend against approval of either or both of our brentuximab vedotin BLAs, may recommend that we conduct one or more additional clinical trials to support potential approval, or may recommend more narrow or restricted labeling or distribution under risk evaluation and mitigation strategies, or REMS. The FDA may also require that either or both of our BLAs be approved under accelerated approval regulations that would require us to provide confirmatory evidence of clinical benefit post-approval and would require us to have all our product promotional materials pre-cleared by the FDA until such accelerated approval restrictions are lifted. Regulatory agencies also may approve brentuximab vedotin for fewer conditions than requested or may grant approval subject to the performance of post-marketing studies or 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.

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 post-approval studies. Any unforeseen problems with an approved brentuximab vedotin product or any violation of regulations could result in restrictions on the approved product, including its withdrawal from the market. Any delay in or failure to receive or maintain regulatory approval for brentuximab vedotin could harm our business and prevent us from ever achieving profitability.

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

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

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

approved product will depend on a number of factors, including:

Table of Contents

establishment and demonstration of clinical efficacy and safety;

cost-effectiveness of the product;

the product's potential advantage over alternative treatment methods;

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

marketing and distribution support for the product.

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

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

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

In addition, changes in 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 the Prescription Drug User Fee Act, or 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 one of our product candidates, including brentuximab vedotin, the development and commercialization of the product candidate could be delayed. Likewise, regulatory changes may require us to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to institutional review boards, or IRBs, for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Due to these and other factors, our current product candidates or any of our other future product candidates could take a significantly longer time to gain regulatory approval than we expect or may never gain regulatory approval, which could delay or eliminate any potential product revenue by delaying or terminating the potential commercialization of our product candidates.

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

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

subject to civil and criminal penalties, we may not be permitted to market our products and our business could suffer. Any delay in or failure to receive or maintain regulatory approval for any of our product candidates could harm our business and prevent us from ever generating any revenues from product sales or achieving profitability. We and our collaborators will need to obtain regulatory approval from authorities in foreign countries to market our product candidates in those countries. Neither we nor our collaborative partners have filed for regulatory approval to market our product candidates in any foreign jurisdictions. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. If we or our collaborative partners fail to obtain approvals from foreign jurisdictions, the geographic market for our product candidates would be limited.

Table of Contents

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

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate, through extensive preclinical studies and clinical trials, that the product candidate is safe and effective in humans. Ongoing and future clinical trials of our product candidates may not show sufficient safety or efficacy to obtain requisite regulatory approvals. Moreover, we still only have limited data from our phase I and phase II clinical trials of dacetuzumab, and our phase I trials of SGN-75, ASG-5ME, and SGN-70. Phase I and phase II clinical trials generally are not designed to test the efficacy of a product candidate but rather are designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the product candidate's side effects at various doses and dosing schedules. Furthermore, success in preclinical and early clinical trials does not ensure that later large-scale trials will be successful nor does it predict final results. Acceptable results in early trials may not be repeated in later trials. The pivotal trial of brentuximab vedotin required the enrollment of approximately 100 patients and we believe that any clinical trial designed to test the efficacy of SGN-75, ASG-5ME, dacetuzumab or SGN-70, whether phase II or phase III, will likely involve a larger number of patients to achieve statistical significance, will be expensive and will take a substantial amount of time to complete. As a result, we may conduct lengthy and expensive clinical trials of our product candidates, only to learn that the product candidate is not an effective treatment or is not superior to existing approved therapies, or has an unacceptable safety profile, which could prevent or significantly delay regulatory approval for such product candidate. For example, in September 2010, we announced that our phase IIb clinical trial of lintuzumab in combination with low-dose cytarabine chemotherapy in older patients with acute myeloid leukemia did not meet its primary endpoint of extending overall survival. As a result of the outcome of this trial, we have discontinued our lintuzumab development program and we will not receive any return on our investment in that product candidate.

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

We are currently conducting multiple clinical trials for our clinical product candidates, and we expect to commence additional trials of brentuximab vedotin and our other product candidates in the future. Each of our clinical trials requires the investment of substantial expense and 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 our clinical trials in compliance with Good Clinical Practice and to the extent they fail to enroll patients for our clinical trials or are delayed for a significant time in achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business. In addition, we conduct clinical trials in foreign countries which may subject us to further delays and expenses as a result of increased drug shipment costs, additional regulatory requirements and the engagement of foreign CROs, as well as expose us to risks associated with less experienced clinical investigators who are unknown to the FDA, different standards of medical care, and foreign currency transactions insofar as changes in the relative value of the United States dollar to the foreign currency where the trial is being conducted may impact our actual costs.

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

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

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

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

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;

Table of Contents

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

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

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

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

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

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

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

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

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

In addition, we may experience significant setbacks in advanced clinical trials, even after promising results in earlier trials, such as unexpected adverse events that occur when our product candidates are combined with other therapies, which often occurs in later-stage clinical trials. For example, in 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 and, as a result, we will not receive any additional milestone payments, cost reimbursements or royalties for the development or sale of dacetuzumab from Genentech. If we decide to continue the development of dacetuzumab, we will be responsible for and will be required to solely fund any new dacetuzumab

development and clinical trial activities, which will increase our costs and could result in a significant delay in the dacetuzumab development process. If we determine instead to discontinue the development of dacetuzumab, we will not receive any future return on our investment from that product candidate. In addition, we cannot control the amount and timing of resources our collaborators may devote to products incorporating our technology. Moreover, our relationships with our collaborators divert significant time and effort of our scientific staff and management team and require effective allocation of our resources to multiple internal and collaborative projects. Our collaborators may separately pursue competing products, therapeutic approaches or technologies to develop treatments for the diseases targeted by us or our collaborators. Even if our collaborators continue their contributions to the collaborative arrangements, they may nevertheless determine not to actively pursue the development or commercialization of any resulting products. Our collaborators may fail to perform their obligations under the collaboration agreements or may be slow in performing their obligations. If any of our collaborators terminate or breach our agreements with them, or otherwise fail to complete their obligations in a timely manner, it may have a detrimental effect on our financial position by reducing or eliminating the potential for us to receive technology access and license fees, milestones and royalties, reimbursement of development costs, as well as possibly requiring us to devote additional efforts and incur costs associated with pursuing internal development of product candidates. In particular, if Millennium were to terminate the brentuximab vedotin collaboration, we would not receive milestone payments, co-funded development payments or royalties for the sale of brentuximab vedotin outside the United States and Canada. As a result of such termination, we may have to engage another collaborator to

Table of Contents

complete the brentuximab vedotin development process or complete the process ourselves internally, either of which could significantly delay the development process and increase our costs. In turn, this could significantly harm our financial position, adversely affect our stock price and require us to incur all the costs of developing and commercializing brentuximab vedotin, which are now being co-funded by Millennium. Furthermore, if our collaborators do not prioritize and commit substantial resources to programs associated with our product candidates, we may be unable to commercialize our product candidates, which would limit our ability to generate revenue and become profitable. In the future, we may not be able to locate third-party collaborators to develop and market our product candidates and we may lack the capital and resources necessary to develop all our product candidates alone.

We have no experience in commercializing products on our own and, to the extent we do not successfully develop this ability or contract with a third party to assist us, we may not be able to successfully commercialize our product candidates that may be approved for commercial sale.

We are still in the process of establishing a sales and marketing organization and 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 50 to 75 sales representatives, and we will need to commit significant additional management and other resources to the growth of our sales and marketing organization before the commercial launch of brentuximab vedotin. We may not be able to achieve the necessary growth in a cost-effective manner or realize a positive return on our investment. We will also have to compete with other pharmaceutical and life sciences companies to recruit, hire, train and retain the sales and marketing personnel that we anticipate we will need. If we are unable to establish adequate sales and marketing capabilities, we will need to enter into sales and marketing agreements to market any of our product candidates that may be approved for commercial sale. If we are unable to establish adequate sales and marketing capabilities or successful distribution relationships with logistics, wholesalers, biotechnology or pharmaceutical companies, we may fail to realize the full sales potential of some of our product candidates. Even if we are able to establish distribution agreements with such companies, we generally would not have control over the resources or degree of effort that any of these third parties may devote to our product candidates, and if they fail to devote sufficient time and resources to the marketing of such product candidates, or if their performance is substandard, it will adversely affect the sale of our product candidates.

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

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

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

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.

Table of Contents

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

We do not currently have the internal ability to manufacture the drug products that we need to conduct our clinical trials and we rely upon a limited number of manufacturers to supply our drug products. For the monoclonal antibody used in brentuximab vedotin, we have contracted with Abbott Laboratories for clinical and potential future commercial supplies and 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. If our contract manufacturers or other third parties fail to deliver our product candidates for clinical use on a timely basis, with sufficient quality, and at commercially reasonable prices, and we fail to find replacement manufacturers or to develop our own manufacturing capabilities, we may be required to delay or suspend clinical trials or otherwise discontinue development and production of our product candidates. In addition, we depend on outside vendors for the supply of raw materials used to produce our product candidates. If the third-party suppliers were to cease production or otherwise fail to supply us with quality raw materials and we were unable to contract on acceptable terms for these raw materials with alternative suppliers, our ability to have our product candidates manufactured and to conduct preclinical testing and clinical trials of our product candidates would be adversely affected.

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

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

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

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

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

Table of Contents

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

Our ADC technology, utilizing proprietary stable linkers and highly potent cell-killing drugs, has not been incorporated into a commercial product. This ADC technology is used in our brentuximab vedotin, SGN-75, ASG-5ME and SGN-19A product candidates and is the basis of our collaborations with 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 March 31, 2011, we had an accumulated deficit of approximately \$494.6 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 time and costs involved in obtaining regulatory approvals, including the preparation for product commercialization;

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

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

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

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

progress with clinical trials;

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

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

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

the potential costs associated with state and federal taxes;

Table of Contents

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, Mabtech, and the University of Miami, among others. Some of these license agreements contain diligence and milestone-based termination provisions, in which case our failure to meet any agreed upon diligence requirements or milestones may allow the licensor to terminate the agreement. Many of our license agreements grant us exclusive licenses to the underlying technologies. If our licensors terminate our license agreements or if we are unable to maintain the exclusivity of our exclusive license agreements, we may be unable to continue to develop and commercialize our product candidates. In addition, continued development and commercialization of our product candidates will likely require us to secure licenses to additional technologies. We may not be able to secure these licenses on commercially reasonable terms, if at all.

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

Our success depends, in part, on obtaining and maintaining patent protection and successfully enforcing these patents and defending them against third-party challenges in the United States and other countries. We own multiple U.S. and foreign patents and pending patent applications for our technologies. We also have rights to issued U.S. patents, patent applications, and their foreign counterparts, relating to our monoclonal antibody, 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.

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.

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.

Table of Contents

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 will be required to expand our workforce, particularly in the areas of manufacturing, clinical trials management, regulatory affairs, business development, sales and marketing. These activities will require the addition of new personnel, including management, and the development of additional expertise by existing management personnel. We face intense competition for qualified individuals from numerous pharmaceutical and biotechnology companies, as well as academic and other research institutions. To the extent we are not able to attract and retain these individuals on favorable terms, our business may be harmed.

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

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

develop safer or more effective products;

implement more effective approaches to sales and marketing;

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

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

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

Our cash, cash equivalents and investments are held in a variety of interest-bearing instruments and subject to investment guidelines allowing for investments in United States government and agency securities, high-grade corporate bonds, taxable municipal bonds, mortgage-backed securities, auction rate securities, or ARS, commercial paper and money market accounts. As a result of the uncertain global credit and financial market conditions, investments in some financial instruments, such as mortgage-backed securities and ARS, pose risks arising from liquidity and credit concerns. For example, as of March 31, 2011 we held ARS valued at \$13.3 million that have failed at auction and are currently illiquid. Given that future deterioration in the global credit and financial markets is a possibility, no assurance can be made that losses, failed auctions or other significant deterioration in the fair value of our cash equivalents, short-term or long-term investments or ARS will not occur. If any such losses, failed auctions or other significant deteriorations occur, it may negatively impact or impair our current portfolio of cash equivalents, short-term and long-term investments and our ability to fund our planned operations. Further, unless and until the current global credit and financial market crisis has been sufficiently resolved, it may be difficult for us to liquidate our investments prior to their maturity without incurring a loss.

In addition, Standard & Poor's recently announced that it had revised its outlook on the long-term credit rating of the United States to negative, which could impact the stability of future U.S. treasury auctions and affect the trading market for U.S. government securities. Uncertainty surrounding U.S. congressional approval of increases to the federal debt ceiling similarly could impact the trading market for U.S. government securities. These factors could impact the liquidity or valuation of our available-for-sale securities, 97% of which were invested in U.S. treasury securities as of March 31, 2011.

Risks Related to Our Stock

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

The market price of our stock has in the past been, and is likely to continue in the future to be, very volatile. During the first quarter of 2011, our closing stock price fluctuated between \$13.95 and \$17.23 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 recently accepted for filing by the FDA for brentuximab vedotin or any other regulatory submissions we may in the future plan or determine to make;

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

announcements regarding the review, evaluation and recommendations of potential approval by the FDA's Oncologic Drugs Advisory Committee regarding brentuximab vedotin;

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

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

Table of Contents

economic or other external factors.

The stock markets in general, and the markets for biotechnology stocks in particular, have experienced significant volatility that has often been unrelated to the operating performance of particular companies. The financial markets continue to face significant uncertainty, resulting in a decline in investor confidence and concerns about the proper functioning of the securities markets, which decline in general investor confidence resulted in depressed stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. These broad market fluctuations may adversely affect the trading price of our common stock. In the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs, which would hurt our financial condition and results of operations and divert management's attention and resources, which could result in delays of our clinical trials or 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 45 percent of our voting power as of May 3, 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(6)	Amended and Restated 2000 Employee Stock Purchase Plan, effective February 1, 2011.
10.2(6)	2011 Compensation Information for Executive Officers and Directors.
10.3(7)	Seattle Genetics, Inc. 2011 Senior Executive Annual Bonus 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	XBRL Instance Document(8)
101.SCH	XBRL Taxonomy Extension Schema Document(8)
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document(8)
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document(8)
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document(8)
(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 quarterly report on Form 10-Q for the quarter ended June 30, 2008 filed with the Commission on August 8, 2008 (File No. 000-32405) and incorporated herein by reference.
(3)	Previously filed as an exhibit to the Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2003 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)	Previously filed as an exhibit to the Registrant's annual report on Form 10-K for the year ended December 31, 2010 filed with the Commission on February 28, 2011 (File No. 000-32405) and incorporated herein by reference.
(7)	Previously filed as an exhibit to the Registrant's current report on Form 8-K filed with the Commission on February 16, 2011 (File No. 000-32405) and incorporated herein by reference.
(8)	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.

Table of Contents

SIGNATURES

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

SEATTLE GENETICS, INC.

By: /s/ **TODD E. SIMPSON**
 Todd E. Simpson
 Duly Authorized and Chief Financial Officer
Date: May 6, 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(6)	Amended and Restated 2000 Employee Stock Purchase Plan, effective February 1, 2011.
10.2(6)	2011 Compensation Information for Executive Officers and Directors.
10.3(7)	Seattle Genetics, Inc. 2011 Senior Executive Annual Bonus 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	XBRL Instance Document(8)
101.SCH	XBRL Taxonomy Extension Schema Document(8)
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document(8)
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document(8)
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document(8)
(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 quarterly report on Form 10-Q for the quarter ended June 30, 2008 filed with the Commission on August 8, 2008 (File No. 000-32405) and incorporated herein by reference.
(3)	Previously filed as an exhibit to the Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2003 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)	Previously filed as an exhibit to the Registrant's annual report on Form 10-K for the year ended December 31, 2010 filed with the Commission on February 28, 2011 (File No. 000-32405) and incorporated herein by reference.
(7)	Previously filed as an exhibit to the Registrant's current report on Form 8-K filed with the Commission on February 16, 2011 (File No. 000-32405) and incorporated herein by reference.
(8)	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.

