SEATTLE GENETICS INC /WA
Form 10-Q
November 04, 2011
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2011

OR

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

For the transition period from to

Commission file number 0-32405

SEATTLE GENETICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**91-1874389**
(State or other jurisdiction of incorporation or organization)	**(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 x 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 x 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 x	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 x

As of October 31, 2011, there were 115,011,284 shares of the registrant s common stock outstanding.

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Seattle Genetics, Inc.

Quarterly Report on Form 10-Q

For the quarter ended September 30, 2011

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

Seattle Genetics, Inc.

Condensed Consolidated Balance Sheets

(Unaudited)

(In thousands, except par value)

	September 30, 2011	December 31, 2010
Assets		
Current assets		
Cash and cash equivalents	$ 112,105	$ 21,127
Short-term investments	249,592	260,682
Interest receivable	1,014	782
Accounts receivable	15,447	19,279
Inventories	3,428	0
Prepaid expenses and other current assets	5,325	2,246
Total current assets	386,911	304,116
Property and equipment, net	14,638	12,311
Long-term investments	12,791	13,031
Other non-current assets	6,150	478
Total assets	$ 420,490	$ 329,936
Liabilities and Stockholders Equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 38,287	$ 25,783
Current portion of deferred revenue	35,636	29,038
Total current liabilities	73,923	54,821
Long-term liabilities		
Deferred revenue, less current portion	111,836	110,630
Deferred rent and other long-term liabilities	3,487	2,967
Total long-term liabilities	115,323	113,597
Commitments and contingencies		
Stockholders equity		
Preferred stock, $0.001 par value, 5,000 shares authorized; none issued	0	0
Common stock, $0.001 par value, 250,000 shares authorized at September 30, 2011 and 150,000 shares authorized at December 31, 2010; 114,909 shares issued and outstanding at September 30, 2011 and 101,607 shares issued and outstanding at December 31, 2010	115	102
Additional paid-in capital	819,581	624,759
Accumulated other comprehensive loss	(1,617)	(1,373)
Accumulated deficit	(586,835)	(461,970)

Total stockholders equity	231,244	161,518
Total liabilities and stockholders equity	$ 420,490	$ 329,936

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

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Seattle Genetics, Inc.

Condensed Consolidated Statements of Operations

(Unaudited)

(In thousands, except per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2011	2010	2011	2010
Revenues:				
Net product sales	$ 10,047	$ 0	$ 10,047	$ 0
Collaboration and license agreement revenues	10,619	15,991	35,844	99,324
Total revenues	20,666	15,991	45,891	99,324
Costs and expenses:				
Cost of sales	724	0	724	0
Research and development	41,080	44,287	123,157	113,890
Selling, general and administrative	19,795	7,038	47,705	18,736
Total costs and expenses	61,599	51,325	171,586	132,626
Loss from operations	(40,933)	(35,334)	(125,695)	(33,302)
Investment income, net	248	478	830	1,583
Net loss	$ (40,685)	$ (34,856)	$ (124,865)	$ (31,719)
Net loss per share - basic and diluted	$ (0.35)	$ (0.34)	$ (1.11)	$ (0.31)
Weighted-average shares used in computing net loss per share - basic and diluted	114,727	101,221	112,435	100,922

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

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Seattle Genetics, Inc.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(In thousands)

	Nine months ended September 30,	
	2011	**2010**
Operating activities		
Net loss	$ (124,865)	$ (31,719)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities		
Share-based compensation expense	14,020	10,098
Depreciation and amortization	2,779	2,624
Amortization and accretion on investments	3,206	2,948
Deferred rent and other long-term liabilities	520	141
Changes in operating assets and liabilities		
Interest receivable	(232)	298
Accounts receivable	3,832	64,860
Inventories	(3,428)	0
Prepaid expenses and other current assets	(3,079)	2,861
Accounts payable and accrued liabilities	12,504	7,484
Deferred revenue	7,804	(30,829)
Net cash provided by (used in) operating activities	(86,939)	28,766
Investing activities		
Purchases of securities available for sale	(384,073)	(328,923)
Proceeds from maturities of securities available for sale	391,953	299,981
Proceeds from sale of securities available for sale	0	2,066
Purchases of property and equipment	(5,016)	(3,133)
Change in other non-current assets	(5,762)	31
Net cash used in investing activities	(2,898)	(29,978)
Financing activities		
Net proceeds from issuance of common stock	168,053	0
Proceeds from exercise of stock options and employee stock purchase plan	12,762	5,497
Net cash provided by financing activities	180,815	5,497
Net increase in cash and cash equivalents	90,978	4,285
Cash and cash equivalents, at beginning of period	21,127	18,486
Cash and cash equivalents, at end of period	$ 112,105	$ 22,771

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

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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 and sale of pharmaceutical products on its own behalf or in collaboration with others.

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

These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and accompanying notes included in the Company s Annual Report on Form 10-K for the year ended December 31, 2010, as filed with the SEC.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results could differ from those estimates. The results of the Company s operations for the three and nine month periods ended September 30, 2011 are not necessarily indicative of the results to be expected for the full year.

On August 19, 2011, the U.S. Food and Drug Administration, or FDA, granted accelerated approval of ADCETRIS™, or brentuximab vedotin, for the treatment of patients with Hodgkin lymphoma after failure of autologous stem cell transplant, or ASCT, or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates, and for the treatment of patients with systemic anaplastic large cell lymphoma, or sALCL, after failure of at least one prior multi-agent chemotherapy regimen. There are no data available demonstrating improvement in patient-reported outcomes or survival with ADCETRIS. Following FDA approval of ADCETRIS, the Company began to recognize product sales and cost of sales during the third quarter of 2011.

Inventories

The Company considers regulatory approval of product candidates to be uncertain. Accordingly, it charges manufacturing costs to research and development expense as incurred until such time as a product has received regulatory approval for commercial sale. The Company began capitalizing ADCETRIS production costs into inventory following its approval by the FDA on August 19, 2011. Production costs for the Company s other product candidates continue to be charged to research and development expense as incurred.

The Company values its inventories at the lower of cost or market value. Cost is determined on a specific identification basis and inventory is used in a manner which approximates the first-in, first-out method. Inventory includes the cost of materials, third-party contract manufacturing and overhead associated with the production of ADCETRIS. In the event that the Company identifies excess, obsolete or unsalable inventory, its value is written down to net realizable value.

Revenue recognition

The Company markets ADCETRIS in the United States. The Company has also 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 collaboration and license 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 collectability being reasonably assured.

Net product sales

The Company sells ADCETRIS through a limited number of pharmaceutical distributors. Health care providers order ADCETRIS through these distributors. The Company receives orders from distributors and ships product directly to the health care

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provider. Distributors are invoiced at wholesale acquisition cost, or WAC, and the Company records product sales upon delivery of the product to the health care provider at which time title and risk of loss pass. Product sales are recorded net of estimated government-mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions. Reserves are established for these deductions and actual amounts incurred are offset against the applicable reserves. The Company reflects these reserves as either a reduction in the related account receivable from the distributor, or as an accrued liability depending on the nature of the sales deduction. Sales reserves are based on management s estimates of payer mix in target markets, industry benchmarks, and experience to date. These estimates are periodically reviewed and adjusted as necessary.

Government-mandated rebates and chargebacks: In late September 2011, the Company entered into a Medicaid Drug Rebate Agreement, or MDRA, with the Centers for Medicare & Medicaid Services. This agreement provides for rebates to participating states based on covered purchases of ADCETRIS. Medicaid rebates will be charged to the Company by participating states. The Company will also provide a discount to private entities that qualify for government pricing under the Public Health Services program, or PHS, and to certain other U.S. government purchasers of ADCETRIS under the Federal Supply Schedule, or FSS. As of September 30, 2011, the PHS and FSS agreements had not yet been completed. Once these agreements are effective, distributors will process a chargeback to the Company for the difference between WAC and the discounted price for health care providers entitled to PHS discounts and FSS pricing.

Distribution fees, product returns and other deductions: The Company s distributors charge a fee for distribution services that they perform on behalf of the Company. The Company allows customers to return product that is within 30 days of its expiration date or that is damaged. The Company estimated product returns based on historical industry information of return rates for other specialty pharmaceutical products. In addition, the Company considered its direct-ship distribution model, its belief that product is not held in the distribution channel and the expected rapid use of the product by healthcare providers. In addition, the Company provides financial assistance to qualifying patients that are underinsured or cannot cover the cost of commercial coinsurance amounts through its patient assistance program, SeaGen Secure . SeaGen Secure is available to patients in the U.S. and its territories and who meet various financial need criteria.

Collaboration and license agreement revenue

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

The Company adopted Accounting Standards Update 2009-13 entitled Multiple-Deliverable Revenue Arrangements, a consensus of the FASB Emerging Issues Task Force on a prospective basis in the first quarter of 2011. This standards update broadened the nature of evidence which may be used to determine the relative selling price of separate deliverables to include estimation. Adoption of this standard did not have a material impact on the Company s financial statements.

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2. Net loss per share

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

	Three months ended September 30,		Nine months ended September 30,	
	2011	2010	2011	2010
Warrants to purchase common stock	901	1,113	1,041	1,113
Options to purchase common stock	13,272	11,463	12,855	10,935
Total	14,173	12,576	13,896	12,048

3. Comprehensive loss

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

	Three months ended September 30,		Nine months ended September 30,	
	2011	2010	2011	2010
Net loss	$ (40,685)	$ (34,856)	$ (124,865)	$ (31,719)
Unrealized gain (loss) on securities available-for-sale	(413)	753	(244)	(289)
Comprehensive loss	$ (41,098)	$ (34,103)	$ (125,109)	$ (32,008)

4. Common stock

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 offering expenses.

5. Investments

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.

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

	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
September 30, 2011				
U.S. treasury securities	$ 241,755	$ 50	$ 0	$ 241,805
Corporate obligations	8,099	0	(8)	8,091
Auction rate securities	14,450	0	(1,659)	12,791
Total	$ 264,304	$ 50	$ (1,667)	$ 262,687
Contractual Maturities				
Due in one year or less	$ 249,854			$ 249,896
Due in 2017	14,450			12,791
Total	$ 264,304			$ 262,687
Reported as:				
Short-term investments				$ 249,592
Long-term investments				12,791
Other non-current assets				304
Total				$ 262,687

	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

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The aggregate estimated fair value of the Company s investments with unrealized losses was as follows (in thousands):

	Period of continuous unrealized loss			
	12 months or less		Greater than 12 months	
	Fair value	Gross unrealized losses	Fair value	Gross unrealized losses
September 30, 2011				
Corporate obligations	$ 8,091	$ (8)	$ NA	$ NA
Auction rate securities	NA	NA	12,791	(1,659)
Total	$ 8,091	$ (8)	$ 12,791	$ (1,659)
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)

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6. Fair Value

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

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

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

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

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

Level 1 investments, which include investments that are valued based on quoted market prices in active markets, consisted of U.S. treasury securities. Level 2 investments, which include investments that are valued based on quoted prices in markets that are not active, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency, consisted of high-grade corporate obligations. 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 nine month period ended September 30, 2011.

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

	Quoted prices in active markets for identical assets (Level 1)	Other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
As of September 30, 2011:				
Cash equivalents - money market funds	$ 717	$ 0	$ 0	$ 717
Short-term investments:				
U.S. treasury securities	241,501	0	0	241,501
Corporate obligations	0	8,091	0	8,091
Long-term investments - auction rate securities	0	0	12,791	12,791
Other non-current assets - U.S. treasury note	304	0	0	304
Total	$ 242,522	$ 8,091	$ 12,791	$ 263,404

	Fair value measurement using:			
	Quoted prices in active markets for identical assets (Level 1)	Other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
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 September 30, 2011, the Company held auction rate securities valued at $12.8 million that have failed at auction and are currently illiquid. Liquidity of these investments is subject to a successful auction process, redemption of the investment, a sale of the security in a secondary market or a negotiated or adjudicated resolution. Each of the securities continues to pay interest according to the stated terms on a monthly basis. The interest rate on these auction rate securities is no longer established based on an auction process but is established according to the terms of the issue. As of September 30, 2011, the interest rate of each of the auction rate securities was set at the 30-day London Interbank Offering Rate plus 225 basis points. The Company considers the market for these securities to be inactive and distressed. Accordingly, fair value for the auction rate securities has been determined based on a probability-weighted discounted cash flow analysis. This analysis relies upon certain estimates, including the probability-weighted term to an orderly liquidation and the discount rate applied to future cash flows. The discount rate used to determine fair value is based on the observed comparable yield of securities with similar characteristics, adjusted for illiquidity, credit risk and other factors. Investments in auction rate securities are presented as long-term investments in the accompanying condensed consolidated balance sheets.

The Company believes it is more likely than not that it has the ability to hold, and intends to hold, these investments until recovery of substantially all of the cost basis of the securities. This belief is based on a current assessment of the Company s available cash, expected operating cash requirements, future operating plans and assessment of the individual securities and general market conditions. The Company

periodically assesses this conclusion based on several factors, including the continued failure of future auctions, failure of the investment to be redeemed, further deterioration of the credit rating of the investment, market risk and other factors. Any such future reassessment that results in a conclusion that the unrealized losses on these investments are other than temporary would result in a write down in the fair value of these investments. Such a write down would be recognized in operating results.

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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 loss reflected as a component of other comprehensive income	(240)
Balance as of September 30, 2011	$ 12,791

7. Inventories

The following table presents the Company s inventories of ADCETRIS (in thousands):

	September 30, 2011	December 31, 2010
Raw materials	$ 3,035	$ 0
Work in process	385	0
Finished goods	8	0
Total	$ 3,428	$ 0

The Company began capitalizing ADCETRIS inventory costs following its approval by the FDA on August 19, 2011. Prior to FDA approval, the Company expensed ADCETRIS production costs as a research and development expense. The Company does not capitalize manufacturing costs for any of its product candidates.

8. Commitments

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

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 t 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

Seattle Genetics is a biotechnology company focused on the development and commercialization of monoclonal antibody-based therapies for cancer. On August 19, 2011, the U.S. Food and Drug Administration, or FDA, granted accelerated approval of ADCETRIS™, or brentuximab vedotin, for the treatment of patients with Hodgkin lymphoma after failure of autologous stem cell transplant, or ASCT, or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates, and for the treatment of patients with systemic anaplastic large cell lymphoma, or sALCL, after failure of at least one prior multi-agent chemotherapy regimen. There are no data available demonstrating improvement in patient-reported outcomes or survival with ADCETRIS. Following accelerated approval of ADCETRIS by the FDA, we began to recognize product sales and cost of sales during the third quarter of 2011.

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ADCETRIS is an antibody-drug conjugate, or ADC, comprising an anti-CD30 monoclonal antibody attached by a protease-cleavable linker to a microtubule disrupting agent, monomethyl auristatin E (MMAE), utilizing our proprietary technology. In addition, we have three clinical-stage ADC programs, which consist of SGN-75, ASG-5ME, and ASG-22ME, as well as several preclinical product candidates, including SGN-CD19A.

In December 2009, we entered into a collaboration agreement with Millennium: The Takeda Oncology Company, or Millennium, to develop and commercialize ADCETRIS. Under this collaboration, Seattle Genetics has retained commercial rights for ADCETRIS in the United States and its territories and in Canada, and Millennium has commercial rights in the rest of the world. In June 2011, Millennium s Marketing Authorization Application, or MAA, submission seeking regulatory approval to market ADCETRIS for the treatment of relapsed or refractory Hodgkin lymphoma and relapsed or refractory sALCL in the European Union was accepted by the European Medicines Agency, or EMA, which is currently reviewing the application. We also have collaborations for our ADC technology with a number of biotechnology and pharmaceutical companies, including Abbott Biotechnology Ltd., or Abbott; Bayer Pharmaceuticals Corporation, or Bayer; Celldex Therapeutics, Inc., or Celldex; Daiichi Sankyo Co., Ltd., or Daiichi Sankyo; Genentech, Inc., a member of the Roche Group, or Genentech; GlaxoSmithKline LLC, or GSK; Millennium, Pfizer, Inc., or Pfizer, and PSMA Development Company LLC, a subsidiary of Progenics Pharmaceuticals Inc., or Progenics; as well as ADC co-development agreements with Agensys, Inc., an affiliate of Astellas Pharma, Inc., or Agensys, Genmab A/S, or Genmab, and Oxford BioTherapeutics Ltd., or OBT.

We began commercializing ADCETRIS in August 2011 and the commercial potential of and our ability to successfully commercialize ADCETRIS is unproven. Our success in commercializing ADCETRIS will require, among other things, effective sales, marketing, manufacturing, distribution, information systems and pricing strategies, as well as compliance with applicable laws and regulations. The FDA granted accelerated approval of ADCETRIS which means that we are, among other things, obligated to conduct specific post-approval clinical studies to confirm patient benefit as a condition of that approval. In addition, we intend to explore the use of ADCETRIS earlier in the treatment of Hodgkin lymphoma and sALCL and in other CD30-positive malignancies. In order to do this, we will be required to conduct additional extensive clinical studies and, if successful, we intend to seek additional regulatory approvals. These activities will require substantial amounts of capital and may not ultimately prove successful. Further, our other 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. Accordingly, over the next several years, we expect that we will incur substantial expenses, primarily as a result of activities related to the commercialization and continued development of ADCETRIS. We will also continue to invest in research, development and manufacturing of our other product candidates. Our commitment of resources to the continuing development, regulatory and commercialization activities for ADCETRIS and the research, continued development and manufacturing of our other product candidates may require us to raise substantial amounts of additional capital and our operating expenses will fluctuate as a result of such activities. In addition, we may incur significant milestone payment obligations as our product candidates progress through clinical trials towards potential commercialization.

Although we have begun to recognize revenue from ADCETRIS product sales in the United States, we are very early in the product launch. We expect that our sales revenue may vary significantly from period to period as the launch progresses. We also expect that amounts earned from our collaboration agreements will continue to be an important source of our revenues. These revenues will be impacted by future development funding and the achievement of development and clinical milestones under our existing collaboration and license agreements, including, in particular, our ADCETRIS 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 being indicative of our future performance.

Financial summary

Although we began commercial sales of ADCETRIS in the United States during the third quarter of 2011, our revenues to date have principally come 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 nine months ended September 30, 2011, revenues decreased to $45.9 million, compared to $99.3 million for the same period in 2010. This decrease was due to approximately $70 million of revenue earned in 2010 under our former dacetuzumab collaboration with Genentech that ended in June 2010, partially offset by revenue earned from our other collaboration agreements and product sales of ADCETRIS. For the nine months ended September 30, 2011, total costs and expenses increased 29% to $171.6 million, compared to $132.6 million for the same period in 2010. This reflects increases in sales and marketing expenses and manufacturing activities in advance of the approval and launch of ADCETRIS as well as clinical development activities to explore additional potential applications of ADCETRIS and our activities to continue developing our ADC pipeline programs. As of September 30, 2011, we had $374.5 million in cash, cash equivalents and short-term and long-term investments, and $231.2 million in total stockholders equity.

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Results of operations

Three months and nine months ended September 30, 2011 and 2010

Net product sales

We sell ADCETRIS through a limited number of pharmaceutical distributors. Health care providers order ADCETRIS through these distributors. We receive orders from distributors and ship product directly to the health care provider. Distributors are invoiced at wholesale acquisition cost, or WAC, and we record product sales upon delivery of the product to the health care provider at which time title and risk of loss pass. Product sales are recorded net of estimated government-mandated rebates and chargebacks, distribution fees, product returns and other deductions. Reserves are established for these deductions and actual amounts incurred are offset against applicable reserves. We reflect these reserves as either a reduction in the related account receivable from the distributor, or as an accrued liability depending on the nature of the sales deduction. Sales reserves are based on management s estimates that consider payer mix in target markets, industry benchmarks and experience to date. These estimates are periodically reviewed and adjusted as necessary.

Government-mandated rebates and chargebacks: In late September 2011, we entered into a Medicaid Drug Rebate Agreement, or MDRA, with the Centers for Medicare & Medicaid Services. This agreement provides for rebates to participating states based on covered purchases of ADCETRIS. Medicaid rebates will be charged to us by participating states. In the fourth quarter of 2011, we also expect to provide a discount to private entities that qualify for government pricing under the Public Health Services program, or PHS, and to certain other U.S. government purchasers of ADCETRIS under the Federal Supply Schedule, or FSS. Once these agreements are effective, distributors will process a chargeback to us for the difference between WAC and the discounted price for health care providers entitled to PHS discounts and FSS pricing.

Distribution fees, product returns and other deductions: Our distributors charge a fee for distribution services that they perform on our behalf. We allow for the return of product that is within 30 days of its expiration date or that is damaged. We estimated product returns based on historical industry information of return rates for other specialty pharmaceutical products. In addition, we considered our direct-ship distribution model and our belief that product is not held in the distribution channel, and the expected rapid use of the product by healthcare providers. In addition, we provide financial assistance to qualifying patients that are underinsured or cannot cover the cost of commercial coinsurance amounts through our patient assistance program, SeaGen Secure . SeaGen Secure is available to patients in the U.S. and its territories who meet various financial need criteria.

The following table summarizes the reductions from gross sales for the items discussed above, net of related payments and credits, for the three-month period ended September 30, 2011 (in thousands):

Balance at June 30, 2011	$
Provision related to third quarter sales	326
Payments/credits	(2)
Balance at September 30, 2011	$ 324

We received accelerated approval from the FDA to market ADCETRIS in the United States and its territories on August 19, 2011. We entered into a MDRA in late September 2011. As a result, ADCETRIS sales were subject to government rebates under Medicaid for only a portion of the third quarter. We had not yet finalized our FSS or PHS agreements as of September 30, 2011. Once these agreements are effective, we expect deductions from gross sales to increase as the number of patients eligible for discounted pricing increases.

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Collaboration and license agreement revenues

Collaboration and license agreement revenues by collaborator are summarized as follows:

Collaboration and license agreement revenues by collaborator ($ in thousands)	Three months ended September 30, 2011	2010	% Change	Nine months ended September 30, 2011	2010	% Change
Millennium	$ 5,969	$ 4,705	27%	$ 20,531	$ 11,175	84%
Genentech	824	8,929	(91%)	3,705	81,744	(95%)
Pfizer	1,000		N/A [1]	3,000		N/A [1]
GSK	759	754	1%	2,277	2,256	1%
Abbott	1,069	31	3,348%	2,100	219	859%
Other	998	1,572	(37%)	4,231	3,930	8%
Total	$ 10,619	$ 15,991	(34%)	$ 35,844	$ 99,324	(64%)

(1) No amount in comparable period.

Millennium revenues increased 27% to $6.0 million in the third quarter and 84% to $20.5 million for the first nine months of 2011 compared to the comparable periods in 2010. These revenues reflect amounts earned under our ADCETRIS collaboration agreement and our ADC collaboration agreement with Millennium. Revenues for the three and nine month periods ended September 30, 2011 increased as compared to the prior year due to revenues earned under the ADCETRIS collaboration. Revenues for the nine month period ended September 30, 2011 also increased over comparable periods in 2010 due to the earned portion of a payment received from Millennium upon its exercise of an option to take an exclusive license to a second antigen target under the ADC collaboration.

Genentech revenues decreased 91% to $0.8 million in the third quarter of 2011. Revenues in the third quarter of 2010 and 2011 reflect amounts earned under our ADC collaboration with Genentech, and in 2010 included the earned portion of a payment received from Genentech to expand the collaboration. Genentech revenue decreased during the nine months ended September 30, 2011 as a result of approximately $70 million of revenues earned in the 2010 period under the dacetuzumab collaboration that ended in June 2010.

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

GSK revenues for the three and nine month periods ended September 30, 2011 reflect the earned portion of a $12 million upfront payment and reimbursable support we provided to GSK under our ADC collaboration agreement entered into in December 2009.

Abbott revenues for the three and nine month periods ended September 30, 2011 reflect the earned portion of an $8 million upfront payment and reimbursable support we provided to Abbott under our ADC collaboration agreement that we entered into in March 2011.

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 the upfront license payments, renewal fees, milestones and payments for research and development support that we may provide to our collaborators. These payments are recognized as revenue over the development period of the collaboration.

Our collaboration revenues are impacted by the term and duration of our collaboration agreements and by progress-dependent milestones, annual maintenance fees and reimbursement of materials and support services as our collaborators advance their product candidates through development. Collaboration revenues may vary substantially from year to year and quarter to quarter depending on the progress made by our collaborators with their product candidates, the timing of milestones achieved, our ability to enter into additional collaboration agreements and the level of support we provide to our collaborators. Millennium collaboration revenues to date have exceeded the 2010 full year amounts as a result of the recognition of amounts earned under the ADCETRIS 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.

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Cost of Sales

ADCETRIS cost of sales includes manufacturing costs of product sold, third party royalty costs, amortization of technology license costs and distribution and other costs. We began capitalizing ADCETRIS production costs as inventory following accelerated approval by the FDA in its two approved indications on August 19, 2011. The cost of product manufactured prior to FDA approval was expensed as research and development expense as incurred. Most of this product is available for us to use commercially. We expect that our cost of sales as a percentage of sales will increase in future periods as product manufactured prior to FDA approval, and therefore fully expensed, is consumed.

Research and development.

Our research and development expenses are summarized as follows:

	Three months ended September 30,			Nine months ended September 30,		
Research and development ($ in thousands)	**2011**	**2010**	**% Change**	**2011**	**2010**	**% Change**
Research	$ 3,942	$ 8,652	(54%)	$ 15,771	$ 15,763	0%
Development and contract manufacturing	17,117	20,448	(16%)	50,243	47,551	6%
Clinical	17,431	13,097	33%	50,112	44,690	12%
Share-based compensation expense	2,590	2,090	24%	7,031	5,886	19%
Total research and development expenses	$ 41,080	$ 44,287	(7%)	$ 123,157	$ 113,890	8%

Research expenses decreased 54% to $3.9 million in the third quarter and remained relatively unchanged for the first nine months of 2011 from the comparable periods in 2010. The decrease in research expenses in the third quarter of 2011 is primarily the result of technology access fees paid in the third quarter of 2010.

Development and contract manufacturing expenses decreased 16% to $17.1 million in the third quarter and increased 6% to $50.2 million for the nine month period ended September 30, 2011 from the comparable periods in 2010. The decrease in development and contract manufacturing expenses for the third quarter of 2011 as compared to the prior year period resulted from lower contract manufacturing costs incurred for lintuzumab, the development of which has been discontinued. The increase in contract manufacturing costs for the first nine months of 2011 reflects higher manufacturing costs for ADCETRIS as we prepared for regulatory approval and for our SGN-CD19A preclinical program.

Clinical expenses increased 33% to $17.4 million in the third quarter and 12% to $50.1 million for the nine month period ended September 30, 2011 from the comparable periods in 2010. This increase reflects higher regulatory costs and staffing levels in support of our Biologics License Application submissions to the FDA for ADCETRIS, as well as higher third party clinical trial costs for ADCETRIS, offset by lower third party clinical trial costs for the lintuzumab and dacetuzumab programs, both of which have been discontinued.

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

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The following table shows expenses incurred for research, contract manufacturing of our pre-commercial product candidates and clinical and regulatory services provided by third parties as well as payments for in-licensed technology for ADCETRIS and 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:

ADCETRIS and product candidates ($ in thousands)	Three months ended September 30, 2011	Three months ended September 30, 2010	Nine months ended September 30, 2011	Nine months ended September 30, 2010	Five years ended September 30, 2011
ADCETRIS (brentuximab vedotin)	$ 13,439	$ 15,612	$ 42,945	$ 43,836	$ 148,229
SGN-CD19A	2,869	338	4,934	368	6,467
ASG-22ME	603		4,712		4,712
ASG-5ME	1,417	248	2,750	2,241	10,246
SGN-75	457	1,738	2,101	2,696	12,205
	18,785	17,936	57,442	49,141	181,859
Other costs and overhead	19,705	24,261	58,684	58,863	358,371
Share-based compensation expense	2,590	2,090	7,031	5,886	35,329
Total research and development	$ 41,080	$ 44,287	$ 123,157	$ 113,890	$ 575,559

Our third-party costs for ADCETRIS decreased during the three and nine months ended September 30, 2011 from the comparable periods in 2010 primarily due to technology access fees paid in the third quarter of 2010, offset by increases in contract manufacturing costs as we prepared for the launch of ADCETRIS in 2011. We began capitalizing ADCETRIS production costs as inventory following accelerated approval of ADCETRIS by the FDA on August 19, 2011. Our third party costs for SGN-CD19A increased during the three and nine months ended September 30, 2011 from the comparable periods in 2010 reflecting increased contract manufacturing activities in preparation for potential clinical trials. In June 2011, we exercised an option under our agreement with Agensys to co-develop ASG-22ME. In addition to the payment of an option fee, we now co-fund fifty percent of the development costs of this program. Our third party costs for ASG-5ME increased during the three and nine months ended September 30, 2011 compared to the 2010 periods as a result of higher clinical trial costs related to ongoing phase I trials. Third party costs for SGN-75 decreased during the three and nine month periods ended September 30, 2011 compared to 2010 as a result of higher manufacturing costs in the 2010 periods.

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

- the number of patients who participate in the trials;
- the length of time required to enroll trial participants;
- the number and location of sites included in the trials;
- the costs of producing supplies of the product candidates needed for clinical trials and regulatory submissions;
- the safety and efficacy profile of the product candidate;

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

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

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

We expect that aggregate development costs for our product candidates will increase in 2011 compared to 2010. However, due to the approval of ADCETRIS for commercial sale by the FDA, the costs associated with manufacturing ADCETRIS will be recorded as inventory instead of research and development expenses, resulting in a potential decrease in research and development expenses for ADCETRIS. Expenses will fluctuate based upon many factors including timing of potential regulatory approvals, degree of collaborative activities, timing of manufacturing campaigns, numbers of patients enrolled in our clinical trials and the outcome of each clinical trial.

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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 our product candidates.

Selling, general and administrative

	Three months ended September 30,			Nine months ended September 30,		
Selling, general and administrative ($ in thousands)	**2011**	**2010**	**% Change**	**2011**	**2010**	**% Change**
Selling, general and administrative, excluding share-based compensation expense	$ 16,895	$ 5,392	213%	$ 40,716	$ 14,524	180%
Share-based compensation expense	2,900	1,646	76%	6,989	4,212	66%
Total selling, general and administrative expenses	$ 19,795	$ 7,038	181%	$ 47,705	$ 18,736	155%

Selling, general and administrative expenses, excluding share-based compensation expense, increased during the three and nine months ended September 30, 2011 from the comparable periods in 2010. The increases resulted primarily from increased staffing levels and outside agency services to support the commercial launch of ADCETRIS. Share-based compensation expense increased during the three and nine months ended September 30, 2011 from the comparable periods in 2010. This resulted from a higher average value per optioned share primarily attributable to increases in our stock price and a larger number of optioned shares subject to expense recognition as a result of increased staffing levels.

Investment income, net

Investment income, net decreased 48% to $0.2 million in the third quarter and 48% to $0.8 million for the first nine months of 2011 from the comparable periods in 2010. The decrease resulted from lower yields on investments during 2011, partially offset by higher average balances of investments.

Liquidity and capital resources

Selected balance sheet and cashflow data ($ in thousands)	**September 30, 2011**	**December 31, 2010**
Cash, cash equivalents and investments	$ 374,488	$ 294,840
Working capital	312,988	249,295
Stockholders equity	231,244	161,518

	Nine months ended September 30,	
	2011	**2010**
Cash provided by (used in):		
Operating activities	$ (86,939)	$ 28,766
Investing activities	(2,898)	(29,978)
Financing activities	180,815	5,497

We have financed the majority of our operations through the issuance of equity securities and by amounts received pursuant to our product 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 $374.5 million at September 30, 2011, compared to $294.8 million at December 31, 2010 and our working capital was $313.0 million at September 30, 2011, compared to $249.3 million at December 31, 2010. These increases reflect net proceeds from the sale of common stock in an underwritten public offering totaling $168.1 million in February 2011 and collaboration payments received of $58.8 million. During the first nine months of 2011, we used $86.9 million of cash in our operating activities compared to $28.8 million generated from operating activities during the first nine months of 2010. Our cash provided by (used in) operating activities included upfront payments under new collaboration agreements of $16.0 million and $84.0 million during the nine month

periods ended September 30, 2011 and 2010, respectively and also reflects increases in our operating expenses in 2011.

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We have structured our investment portfolio to provide working capital as needed to fund our operations. Our cash, cash equivalents and investments are held in a variety of non-interest bearing bank accounts and interest-bearing instruments and subject to investment guidelines allowing for holdings in U.S. government and agency securities, corporate securities, taxable municipal bonds, auction rate securities, commercial paper and money market accounts. As of September 30, 2011, we held auction rate securities valued at $12.8 million that have failed at auction and are currently illiquid. Liquidity of these investments is subject to a successful auction process, redemption of the investment, a sale of the security in a secondary market or a negotiated or adjudicated resolution. Each of the securities continues to pay interest according to the stated terms on a monthly basis. The interest rate on these auction rate securities is no longer established based on an auction process but is established according to the terms of the issue. As of September 30, 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 dis