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 discounted cash flow analysis. This analysis relies upon significant unobservable inputs referred to as level 3 inputs within the fair value hierarchy, as described in Note 6 to the condensed consolidated financial statements, including the probability-weighted term to an orderly liquidation and the discount rate applied to future cash flows. The discount rate used to determine fair value is based on the observed comparable yield of securities with similar characteristics, adjusted for illiquidity, credit risk and other factors. Investments valued based on level 3 inputs consisted of auction rate securities and accounted for 5% of total investment securities measured at fair value as of September 30, 2011 and December 31, 2010. 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 September 30, 2011, we had $361.7 million held in cash reserves or debt securities scheduled to mature within the next twelve months.

At our currently planned spending rate we believe that our financial resources, together with 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 expectation does not take into consideration cash received from sales of ADCETRIS, which may extend the sufficiency of our financial resources. However, changes in our spending rate may occur that would consume available capital resources sooner, such as increased development, manufacturing and clinical trial expenses, including in connection with required post-approval confirmatory studies and additional studies to potentially expand the use of ADCETRIS, and the increases in our sales and marketing expenses in connection with the commercialization of ADCETRIS. Additionally, we may not receive the payments that we currently expect under our existing collaboration agreements, including the ADCETRIS 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 ADCETRIS collaboration agreement with Millennium, we would not receive development cost sharing payments, nor would we receive milestone payments or royalties for the development or sales of ADCETRIS in Millennium s territories.

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 for our product candidates, as well as position ADCETRIS, for potential additional regulatory approvals, 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.

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Commitments

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

	Total	Remainder of 2011	2012	2013	2014	2015	Thereafter
Operating leases	$ 28,422	$ 706	$ 3,676	$ 4,071	$ 4,208	$ 4,348	$ 11,413
Manufacturing, license & collaboration agreements	153,073	33,242	28,451	11,784	10,482	10,482	58,632
Tenant improvements	4,131	4,131					
Total	$ 185,626	$ 38,079	$ 32,127	$ 15,855	$ 14,690	$ 14,830	$ 70,045

We have entered into leases for our office and laboratory facilities expiring in 2018 that contain rate escalations and options for us to extend the leases. In May 2011, we 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. Operating lease obligations in the table above do not assume the exercise by us of any termination or extension options. Tenant improvement obligations primarily relate to improvements to the 81,000 square foot facility that are currently in process.

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 commercial operations in the case of ADCETRIS. 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. Some of our licensing agreements obligate us to pay a royalty on net sales of products utilizing licensed technology. Such royalties are dependent on future product sales and are not provided for in the table above as they are not estimable. The above table also excludes up to approximately $13.4 million in potential future milestone payments to third parties under license and collaboration agreements for ADCETRIS and our current development programs, which generally become due and payable only upon the achievement of certain developmental, clinical, regulatory and/or commercial milestones. Milestone payments under these agreements through September 30, 2011 have totaled $9.1 million. These contingent payments have not been included in the above table and will not be included until the event triggering such payment or obligation has occurred.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

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

	September 30, 2011	December 31, 2010
Short-term investments	$ 249,592	$ 260,682
Long-term investments	12,791	13,031
Other non-current assets	304	303
Total	$ 262,687	$ 274,016

As more fully described in Note 6 to the condensed consolidated financial statements, included in long-term investments as of September 30, 2011 are 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. No assurance can be made that further downgrades, losses, failed auctions or other significant deterioration in the fair value of our cash equivalents, short-term or long-term investments will not occur. If any such further downgrades, losses, failed auctions or other significant deteriorations occur, it may negatively impact or impair our current portfolio of cash equivalents, short-term and long-term investments and our ability to fund our planned operations.

We have estimated the effect on our investment portfolio of a hypothetical increase in interest rates by one percent to be a reduction of $1.0 million in the fair value of our investments as of September 30, 2011. In addition, a hypothetical decrease of 10% in the effective yield of our investments would reduce our expected investment income by approximately $0.1 million over the next twelve months based on our investment balance at September 30, 2011.

Foreign Currency Risk

All of our revenues and most of our expenses are denominated in U.S. dollars and as a result, we have not experienced significant foreign currency transaction gains and losses to date. We have conducted some transactions in foreign currencies during the nine months ended September 30, 2011, primarily related to contract manufacturing and ex-U.S. clinical trial activities, and we

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expect to continue to do so. Our primary exposure is to fluctuations in the Euro and British Pound. We do not anticipate that foreign currency transaction gains or losses will be significant at our current level of operations. However, transaction gains or losses may become significant in the future as we continue to expand our operations internationally. We have not engaged in foreign currency hedging to date; however, we may do so in the future.

Item 4. Controls and Procedures

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

(b) *Changes in internal control over financial reporting.* There were no changes in our internal control over financial reporting during the quarter ended September 30, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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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 ADCETRIS. If we are unable to successfully commercialize ADCETRIS for the treatment of patients in its approved indications, our ability to generate significant revenue or achieve profitability will be adversely affected. **

On August 19, 2011, we obtained accelerated approval from the United States Food and Drug Administration, or FDA, for ADCETRIS (brentuximab vedotin) for two indications: (1) 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 (2) 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. ADCETRIS is our only product approved for marketing by the FDA and our ability to generate revenue from product sales and achieve profitability is substantially dependent on our ability to successfully commercialize ADCETRIS for the treatment of patients in its two approved indications. We may not be able to successfully commercialize ADCETRIS for a number of reasons, including:

- we may not be able to establish or demonstrate in the medical community the safety and efficacy of ADCETRIS and its potential advantages over and side effects compared to existing therapeutics and products currently in clinical development;
- physicians may be reluctant to prescribe ADCETRIS until results from our required post-approval studies are available or other long term efficacy and safety data exists;
- results from our required post-approval studies may fail to verify the clinical benefit of ADCETRIS in either or both of its approved indications, which could result in the withdrawal of ADCETRIS from the market;
- our limited experience in marketing, selling and distributing ADCETRIS;
- reimbursement and coverage policies of government and private payers such as Medicare, Medicaid, insurance companies, health maintenance organizations and other plan administrators;
- the relative price of ADCETRIS as compared to alternative treatment options;

the relatively low incidence and prevalence of patients in ADCETRIS two approved indications, including the reliability of our estimates;

changed or increased regulatory restrictions;

changes to the label for ADCETRIS that further restrict how we market and sell ADCETRIS, including as a result of data collected from required post-approval studies or as the result of adverse events observed in these or other studies;

we may not have adequate financial or other resources to successfully commercialize ADCETRIS; and

we may not be able to obtain adequate commercial supplies of ADCETRIS to meet demand or at an acceptable cost.

If we are unable to successfully commercialize ADCETRIS in its two approved indications, our ability to generate revenue from product sales and achieve profitability will be adversely affected and our stock price would likely decline.

In December 2009, we entered into an agreement with Millennium to develop and commercialize ADCETRIS, 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

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world. The success of this collaboration and the activities of Millennium will significantly impact the potential commercialization of ADCETRIS in countries other than the United States and in Canada, and although Millennium has submitted a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA, seeking approval to market ADCETRIS in the European Union, ADCETRIS has not to date been approved for marketing in any jurisdiction other than the United States. We are also planning to develop ADCETRIS for use as a single agent and in combination therapy regimens in a range of hematologic malignancies and solid tumor indications, but there can be no assurance that we and/or Millennium will obtain and maintain the necessary regulatory approvals to market ADCETRIS for any additional indications or to market ADCETRIS at all in any other jurisdictions. Even if we and Millennium receive the required regulatory approvals to market ADCETRIS for any additional indications or in any other jurisdictions, we and Millennium may not be able to successfully commercialize ADCETRIS, including for the reasons set forth above.

Our operating results are unpredictable and may fluctuate. If our operating results are below the expectations of securities analysts or investors, the trading price of our stock could decline. *

Our operating results are difficult to predict and will likely fluctuate from quarter to quarter and year to year. Due to the recent approval by the FDA of ADCETRIS in its two indications and the lack of historical sales data, ADCETRIS sales will be difficult to predict from period to period and as a result, you should not rely on ADCETRIS sales results in any period as being indicative of future performance and sales of ADCETRIS may be below the expectation of securities analysts or investors in the future. We believe that our quarterly and annual results of operations may be affected by a variety of factors, including:

- the level of demand for ADCETRIS;
- the extent to which coverage and reimbursement for ADCETRIS is available from government and health administration authorities, private health insurers, managed care programs and other third-party payers;
- the timing, cost and level of investment in our sales and marketing efforts to support ADCETRIS sales;
- the timing, cost and level of investment in our research and development activities involving ADCETRIS and our product candidates; and
- expenditures we will or may incur to conduct required post-approval studies for ADCETRIS and acquire or develop additional technologies, product candidates and products.

In addition, from time to time, we enter into collaboration agreements with other companies that include development funding and significant upfront and milestone payments, and we expect that amounts earned from our collaboration agreements will continue to be an important source of our revenues. Accordingly, our revenues will also depend on development funding and the achievement of development and clinical milestones under our existing collaboration and license agreements, including, in particular, our ADCETRIS collaboration with Millennium, as well as entering into new collaboration and license agreements. These upfront and milestone payments may vary significantly from quarter to quarter and any such variance could cause a significant fluctuation in our operating results from one quarter to the next. Further, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award, and recognize the cost as an expense over the employee s requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price, the magnitude of the expense that we must recognize may vary significantly.

For these and other reasons, it is difficult for us to accurately forecast future profits or losses. As a result, it is possible that in some quarters our operating results could be below the expectations of securities analysts or investors, which could cause the trading price of our common stock to decline, perhaps substantially.

Because the target patient population for ADCETRIS is small and has not been definitively determined, we must be able to successfully identify patients in ADCETRIS two approved indications and achieve a significant market share in order to achieve profitability.*

The incidence and prevalence of patients in ADCETRIS two approved indications has not been definitively determined, but the number of patients in ADCETRIS two approved indications is relatively low. There can be no guarantee that we will be effective at identifying patients in ADCETRIS two approved indications and the number of such patients in the United States may turn out to be lower than expected or may not be otherwise amenable to treatment with ADCETRIS, all of which would adversely affect our results of operations and our ability to achieve profitability. Initial sales of ADCETRIS may deplete the prevalence pool of patients in the two approved indications more quickly than expected, which would have a negative impact on sales of ADCETRIS in the future and would adversely affect our results of operations and our ability to achieve profitability.

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***Even though we have obtained accelerated approval to market ADCETRIS in the United States in two indications, we are subject to ongoing regulatory obligations and review, including post-approval requirements that could result in the withdrawal of ADCETRIS from the market.* ***

ADCETRIS was approved for treating patients in two indications under the FDA s accelerated approval regulations, which allows the FDA to approve products for cancer or other life threatening diseases based on initial positive clinical data. Under these provisions, we are subject to certain post-approval requirements pursuant to which we have agreed to conduct additional confirmatory phase III trials to verify and describe the clinical benefit of ADCETRIS in its two approved indications. Our failure to conduct these required post-approval studies, or to confirm a clinical benefit during these post-approval studies, could result in the FDA withdrawing ADCETRIS from the market, which would seriously harm our business. In addition, we are subject to extensive ongoing obligations and continued regulatory review from the FDA and other applicable regulatory agencies, such as continued adverse event reporting requirements and the requirement to have our promotional materials pre-cleared by the FDA. There may also be additional FDA post-marketing obligations, all of which may result in significant expense and limit our ability to commercialize ADCETRIS in the United States or potentially other jurisdictions.

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

- issuance of Form 483 notices or Warning Letters by the FDA or other regulatory agencies;
- imposition of fines and other civil penalties;
- criminal prosecutions;
- injunctions, suspensions or revocations of regulatory approvals;
- suspension of any ongoing clinical trials;
- total or partial suspension of manufacturing;
- delays in commercialization;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or Millennium;
- refusals to permit drugs to be imported into or exported from the United States;

restrictions on operations, including costly new manufacturing requirements; and

product recalls or seizures.

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The policies of the FDA and other regulatory agencies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of ADCETRIS in other indications or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we or Millennium might not be permitted to market ADCETRIS and our business would suffer.

We have only very limited experience in commercializing products on our own and we may not be able to effectively commercialize ADCETRIS.*

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. We recently established a sales and marketing organization in anticipation of the commercial launch of ADCETRIS, but we may not be able to successfully maintain adequate sales and marketing capabilities or scale our sales and marketing capabilities to effectively commercialize ADCETRIS. For example, we market ADCETRIS in the United States with a sales force of approximately 60 sales representatives, which is a relatively small number of sales representatives compared with the number of sales representatives of most other pharmaceutical companies with marketed products. Although we have hired the number of employees that we believe are required to market ADCETRIS, this number may turn out to be incorrect and we may not be able to effectively commercialize ADCETRIS with our sales force. We also have to compete with other pharmaceutical and life sciences companies to recruit, hire, train and retain sales and marketing personnel, and turnover in our sales force and marketing personnel could negatively affect sales of ADCETRIS. If we are unable to maintain adequate sales and marketing capabilities and successful distribution relationships with logistics companies and wholesalers, we may fail to realize the full sales potential of ADCETRIS. Although we have established relationships with such companies, we generally do not have control over the resources or degree of effort that any of these third parties may devote to ADCETRIS, and if they fail to devote sufficient time and resources to the distribution of ADCETRIS, or if their performance is substandard, this will adversely affect sales of ADCETRIS.

The status of coverage and reimbursement from third-party payers for newly approved prescription drug products is uncertain and failure to obtain adequate coverage and reimbursement could limit our ability to generate revenue. *

Our ability to successfully commercialize ADCETRIS for its approved indications or for other future indications will depend, in part, on the extent to which coverage and reimbursement for ADCETRIS is available from government and health administration authorities, private health insurers, managed care programs and other third-party payers. Significant uncertainty exists as to the coverage and reimbursement of newly approved prescription drug products.

Healthcare providers and third-party payers use coding systems to identify diagnoses, procedures, services, drugs, pharmaceutical devices, equipment and other health-related items and services. Proper coding is an integral component to receiving appropriate reimbursement for the administration of ADCETRIS and related services. The majority of payers use nationally recognized code sets to report medical conditions, services and drugs. Although we are in the process of applying for permanent reimbursement codes for ADCETRIS, healthcare providers prescribing ADCETRIS will initially be required to submit claims for reimbursement using temporary miscellaneous codes, which may result in payment delays or incorrect payment levels. We cannot predict at this time whether our customers will receive adequate reimbursement for ADCETRIS, nor can we predict when ADCETRIS will receive permanent reimbursement codes in the future.

Government and other third-party payers increasingly are attempting to contain health care costs by limiting both coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide coverage for uses of approved products for indications for which the FDA has not granted approval. Third-party insurance coverage may not be available to patients for ADCETRIS. If government and other third-party payers do not provide adequate coverage and reimbursement levels for ADCETRIS, market acceptance of ADCETRIS would be adversely affected.

If our competitors develop and market products that are more effective than ADCETRIS, our commercial opportunity will be reduced or eliminated. *

Even though we have obtained approval in the United Stated to market ADCETRIS in two indications, our commercial opportunity will be reduced or eliminated if our competitors develop and market products that are more effective, have fewer side effects or are less expensive than ADCETRIS for its two approved indications or any other potential indication. Our competitors include large, fully-integrated pharmaceutical companies and more established biotechnology companies, both of which have significant resources and expertise in research and development, manufacturing, testing, obtaining regulatory approvals and marketing. 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 competitors will succeed in developing technologies that are more effective than those used in ADCETRIS and in our product candidates or being developed by us, or that would render our technology obsolete or noncompetitive.

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

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

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

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

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

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. We have incurred these losses principally from costs incurred in our research and development programs and from our selling, general and administrative expenses. We expect to continue to spend substantial amounts on research and development, including amounts on conducting required post-approval and other clinical trials of, and seeking additional regulatory approvals for, ADCETRIS as well as commercializing ADCETRIS for the treatment of patients in its two approved indications. In addition, 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. Although we have recently begun to commercialize ADCETRIS and we continue to earn amounts under our collaboration agreements, our revenue and profit potential is unproven and our limited operating history makes our future operating results difficult to predict. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.

Our current product candidates are at an early stage of development, and it is possible that none of our product candidates will ever become commercial products. *

Our current product candidates are in relatively early stages of development. These product candidates will require significant further development, financial resources and personnel to obtain regulatory approval and develop into commercially viable products, if at all. Currently, we have three clinical-stage programs, SGN-75, ASG-5ME and ASG-22ME, and several preclinical product candidates, including SGN-CD19A. If a product candidate fails at any stage of development or we otherwise determine to discontinue development of that product candidate, we will not have the anticipated revenues from that product candidate to fund our operations, and we may not receive any return on our investment in that product candidate. In this regard, we recently announced that we discontinued the development of dacetuzumab and SGN-70 to focus our efforts on our pipeline of ADC product candidates, and we previously determined to discontinue our lintuzumab development program following negative clinical trial results. As a result of the

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uncertain and time-consuming clinical development and regulatory approval process, we may not successfully develop any of our product candidates and it is possible that none of our current product candidates will ever become commercial products. In addition, we expect that much of our effort and many of our expenditures over the next few years will be devoted to required post-approval studies and commitments and commercialization activities associated with ADCETRIS, which may restrict or delay our ability to develop our clinical and preclinical product candidates.

Our ability to commercialize any of our product candidates 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. Even though ADCETRIS has received required regulatory approval in the United States, commercial success for ADCETRIS outside of the United States and Canada will depend on Millennium s commercialization efforts. The degree of commercial success of any of our product candidates that may be approved for commercial sale will depend on a number of factors, including:

- establishment and demonstration of clinical efficacy and safety;
- cost-effectiveness of the product;
- the product s potential advantage over alternative treatment methods;
- whether the product can be produced in commercial quantities at acceptable costs; and
- marketing and distribution support for the product.

If we and/or our collaborators are unable to develop, obtain regulatory approval for, and commercialize any of our product candidates, if development is delayed or if sales revenue from any product candidate that receives marketing approval is insufficient, we may never reach sustained profitability.

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

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate, through extensive preclinical studies and clinical trials, that the product candidate is safe and effective in humans. Ongoing and future clinical trials of our product candidates may not show sufficient safety or efficacy to obtain requisite regulatory approvals. Moreover, we still only have limited data from our phase I trials of SGN-75, ASG-5ME and ASG-22ME. Phase I and phase II clinical trials generally are not designed to test the efficacy of a product candidate but rather are designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the product candidate s side effects at various doses and dosing schedules. Furthermore, success in preclinical and early clinical trials does not ensure that later large-scale trials will be successful nor does it predict final results. Acceptable results in early trials may not be repeated in later trials. The pivotal trials of ADCETRIS required the enrollment of approximately 160 patients, and we believe that any clinical trial designed to test the efficacy of SGN-75, ASG-5ME or ASG-22ME, whether phase II or phase III, will likely involve a larger number of patients to achieve statistical significance, will be expensive and will take a substantial amount of time to complete. As a result, we may conduct lengthy and expensive clinical trials of our product candidates, only to learn that the product candidate is not an effective treatment or is not superior to existing approved therapies, or has an unacceptable safety profile, which could prevent or significantly delay regulatory approval for such product candidate.

Clinical trials 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 ADCETRIS and our other clinical product candidates, and we plan to commence additional trials of ADCETRIS and our 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 ADCETRIS 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 required for phase III studies of ADCETRIS that we are required to conduct to satisfy the FDA s post-approval requirements. We depend on medical institutions and clinical research organizations, or CROs, to conduct some of our clinical trials in compliance with Good Clinical Practice, or GCP, and to the extent they fail to enroll patients for our clinical trials, fail to conduct our trials in accordance with GCP, or are delayed for a significant time in achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business. In addition, we conduct clinical trials in foreign countries which may subject us to further delays and expenses as a result of increased drug shipment costs, additional regulatory requirements and the engagement

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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 cGMP and other requirements in foreign countries, and may require large numbers of test patients. We, the FDA or other foreign governmental agencies could delay, suspend or halt our clinical trials of ADCETRIS or any of our product candidates for numerous reasons, including:

- deficiencies in the conduct of the clinical trial, including failure to conduct the clinical trial in accordance with regulatory requirements, GCP or clinical protocols;
- deficiencies in the clinical trial operations or trial sites resulting in the imposition of a clinical hold;
- ADCETRIS or 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 ADCETRIS or the product candidate is effective may be longer than expected;
- fatalities or other adverse events arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;
- ADCETRIS or the product candidate may not appear to be more effective than current therapies;
- the quality or stability of ADCETRIS or the product candidate may fall below acceptable standards;
- our inability to produce or obtain sufficient quantities of ADCETRIS or 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, we recently announced that, based on a phase I trial combining ADCETRIS with ABVD chemotherapy, ADCETRIS should not be combined with bleomycin, one of the drugs in ABVD chemotherapy, due to increased incidence of pulmonary toxicity in the combination arm of the trial. 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 ADCETRIS or our product candidates, during a clinical trial could cause it to be redone or terminated or negatively affect our ability to market ADCETRIS or expand into other indications. 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 ADCETRIS and 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 ADCETRIS and 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. In addition, we entered into a collaboration agreement with Millennium in December 2009 that granted Millennium rights to develop and commercialize ADCETRIS 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, Genmab, and Oxford BioTherapeutics.

Under certain conditions, our collaborators may terminate their agreements with us and discontinue use of our technologies. For example, in December 2009, Genentech notified us that it had elected to terminate our collaboration agreement for dacetuzumab. If we had decided to continue the development of dacetuzumab, we would have been responsible for funding any further dacetuzumab development and clinical trial activities. In addition, we cannot control the amount and timing of resources our collaborators may

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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 ADCETRIS collaboration, we would not receive milestone payments, co-funded development payments or royalties for the sale of ADCETRIS outside the United States and Canada. As a result of such termination, we may have to engage another collaborator to complete the ADCETRIS development process and to commercialize ADCETRIS outside the United States and Canada, or to complete the development process and undertake commercializing ADCETRIS outside the United States and Canada ourselves, either of which could significantly delay the continued development and commercialization of ADCETRIS 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 ADCETRIS, 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.

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 negatively impact our business and operations, including those relating to the approvability of biosimilar products, the increased use of comparative effectiveness research on healthcare products, changes to enrollment in federal healthcare programs, reimbursement changes and fraud and abuse provisions, all of which will impact existing government healthcare programs and will result in the development of new programs. Many of the implementing regulations of the Healthcare Reform Act are currently being drafted by federal agencies, including FDA, and while it is too early to predict specifically what effect the recently enacted Healthcare Reform Act and its implementation or any future legislation or policies will have on our business, they may have a material adverse effect on our business and financial condition.

To date, we have depended on a small number of collaborators for most of our revenue. The loss of any one of these collaborators or our inability to generate sufficient sales revenue 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 although we have begun commercializing ADCETRIS, we expect that substantial amounts of revenue will continue to come from corporate collaborations. Even if a product candidate is approved for commercial sale, we may still be highly dependent on the activities of a collaborator to derive revenue from the approved product. For example, even though ADCETRIS received regulatory approval in the United States, our revenues will still depend in part on Millennium s ability and willingness to market the approved product outside of the United States and Canada. The loss of our collaborators, especially Millennium, or the failure of our collaborators to perform their obligations under their agreements with us, including paying license or technology fees, milestone payments, royalties or reimbursements, could have a material adverse effect on our financial performance. Payments under our existing and future collaboration agreements are also subject to significant fluctuations in both timing and amount, which could cause our revenue to fall below the expectations of securities analysts and investors and cause a decrease in our stock price.

We are dependent upon a small number of distributors for a significant portion of our net sales, and the loss of, or significant reduction or cancellation in sales to, any one of these distributors could adversely affect our operations and financial condition.

In the United States, we sell ADCETRIS to a small number of distributors who in turn sell to health care providers. We do not promote ADCETRIS to these distributors and they do not set or determine demand for ADCETRIS. Our ability to successfully commercialize ADCETRIS will depend, in part, on the performance of these distributors. Although we believe we can find alternative distributors on a relatively short notice, the loss of a major distributor could materially and adversely affect our results of operations and financial condition.

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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 continued development and commercialization of ADCETRIS and the continued development of our product candidates. *

We do not currently have the internal ability to manufacture the drug products that we sell or need to conduct our clinical trials and we rely upon a limited number of manufacturers to supply such drug products. For the monoclonal antibody used in ADCETRIS, we have contracted with Abbott Laboratories for clinical and commercial supplies and with Piramal Healthcare to perform conjugation of our drug-linker to the antibody used in ADCETRIS, 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 ADCETRIS. For ADCETRIS 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 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 ADCETRIS and 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 ADCETRIS and our product candidates for use in our clinical trials and for commercial sale. If our contract manufacturers or other third parties fail to deliver ADCETRIS or our product candidates for clinical use or sale on a timely basis, with sufficient quality, and at commercially reasonable prices, and we fail to find replacement manufacturers or to develop our own manufacturing capabilities, we may be required to delay or suspend clinical trials or otherwise discontinue development, production and sale of ADCETRIS or our product candidates. In addition, we depend on outside vendors for the supply of raw materials used to produce ADCETRIS and 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 ADCETRIS and our product candidates manufactured to meet commercial and clinical requirements would be adversely affected.

Although we have entered into agreements necessary for our commercial scale supply chain for ADCETRIS, we may not be able to maintain sufficient commercial manufacturing arrangements on commercially reasonable terms. In addition, we have committed to provide Millennium with their needs of ADCETRIS for a limited period of time, which may require us to arrange for additional manufacturing supply. Securing commercial quantities of ADCETRIS and our product candidates from contract manufacturers has and will continue to 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 ADCETRIS and 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 ADCETRIS or our product candidates, or the inability to sell our products in the U.S. or abroad.

Our contract manufacturers are required to produce ADCETRIS and our clinical and commercial product candidates under cGMP in order to meet acceptable standards for use in our clinical trials and for commercial sale, as applicable. If such standards change, the ability of contract manufacturers to produce ADCETRIS and our product candidates on the schedule we require for our clinical trials or to meet commercial requirements 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 clinical and commercial supplies of ADCETRIS and our product candidates. We and our contract manufacturers are subject to pre-approval inspections and periodic unannounced inspections by the FDA and corresponding state and foreign authorities to ensure strict compliance with cGMP and other applicable government regulations and corresponding foreign standards. We do not have control over a third-party manufacturer s compliance with these regulations and standards. Any difficulties or delays in our contractors manufacturing and supply of ADCETRIS and our 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 ADCETRIS and our product candidates, or cause ADCETRIS and any of our product candidates 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 or product candidates manufactured by different organizations. Because we have used and intend to use multiple sources to manufacture ADCETRIS and 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 or product candidate compared to the product or 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 or impede our clinical progress and the commercialization of ADCETRIS or such product candidates. Similarly, if we believe there may be comparability issues with ADCETRIS or any one of our product candidates, we may postpone or suspend manufacture of ADCETRIS or the product candidate to conduct further process development of ADCETRIS or such product candidate in order to alleviate such product comparability concerns, which may significantly delay the clinical progress of such product candidate, increase its manufacturing costs or result in insufficient commercial supply.

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

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

Any failures or setbacks in our ADC development program would negatively affect our business and financial position. *

ADCETRIS and our SGN-75, ASG-5ME, ASG-22ME and SGN-CD19A product candidates are based on our ADC technology, which utilizes proprietary stable linkers and potent cell-killing synthetic drugs. Our ADC technology is also the basis of our collaborations with Abbott, Agensys, Bayer, Celldex, Daiichi Sankyo, Genentech, Genmab, GSK, Millennium, Oxford BioTherapeutics, Pfizer and Progenics. Although ADCETRIS has received marketing approval in the United States, ADCETRIS is our first and only ADC product that has been approved for commercial sale in any jurisdiction. Any failures or setbacks in our ADC development program, including adverse effects resulting from the use of this technology in human clinical trials, could have a detrimental impact on the continued commercialization of ADCETRIS and our internal product candidate pipeline, as well as our ability to maintain and/or enter into new corporate collaborations regarding our ADC technology, which would negatively affect our business and financial position.

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 commercialize ADCETRIS and position our product candidates for potential regulatory approval and commercial sale. Although some of these expenditures related to ADCETRIS 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 level of sales and market acceptance of ADCETRIS;
- the rate of progress and cost of the confirmatory studies that we are required to conduct as a condition to the FDA s accelerated approval of ADCETRIS;
- the time and costs involved in obtaining regulatory approvals of ADCETRIS in other countries and in additional indications, including the preparation for additional commercialization in these countries and indications;
- the size, complexity, timing, and number of our clinical programs;
- our receipt of milestone-based payments or other revenue from our collaborations or license arrangements;

- the cost of establishing and maintaining clinical and commercial supplies of ADCETRIS, our product candidates and any future products that we and/or our collaborators may develop;
- progress with clinical trials;
- the costs associated with acquisitions or licenses of additional products, including licenses we may need to commercialize our products;
- the terms and timing of any future collaborative, licensing and other arrangements that we may establish;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- the potential costs associated with state and federal taxes;
- the timing and cost of milestone payment obligations as our product candidates progress towards commercialization; and
- competing technological and market developments.

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

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

We have entered into agreements with third-party commercial and academic institutions to license technology for use in ADCETRIS, our product candidates and our ADC technology. Currently, we have license agreements with Bristol-Myers Squibb, Arizona State University, CLB-Research and Development, and the University of Miami, among others. Some of these license agreements contain diligence and milestone-based termination provisions, in which case our failure to meet any agreed upon diligence requirements or milestones may allow the licensor to terminate the agreement. Many of our license agreements grant us exclusive licenses to the underlying technologies. If our licensors terminate our license agreements or if we are unable to maintain the exclusivity of our exclusive license agreements, we may be unable to continue to develop and commercialize ADCETRIS or our product candidates. In addition, continued development and commercialization of ADCETRIS and continued development 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 ADCETRIS and 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 the University of Miami, 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. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent Office is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act will not become effective until one year or 18 months after its enactment. Accordingly, it is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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 continue to commercialize ADCETRIS or any product candidates that are approved for commercial sale as a result of litigation or other proceedings relating to patent and other intellectual property rights, and we may be required to obtain patent and other intellectual property rights from others. *

We may face potential lawsuits by companies alleging infringement of their intellectual property. Because patent applications can take a few years to publish, there may be currently pending applications of which we are unaware that may later result in issued patents that adversely affect the continued commercialization of ADCETRIS and 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 enforceability in order to continue commercializing ADCETRIS or any of our other product candidates that may be approved for commercial sale.

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

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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 in ADCETRIS, 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, which may also result in loss of future royalty payments. 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 ADCETRIS, if approved for commercial sale in the European Union. Furthermore, if such challenges to our rights are not resolved promptly in our favor, our existing business relationships may be jeopardized and we could be delayed or prevented from entering into new collaborations or from commercializing potential products, which could adversely affect our business and results of operations. In addition, we may challenge the patent or other intellectual property rights of third parties and if we are unsuccessful in actions we bring against the rights of such parties, through litigation or otherwise, and it is determined that we infringe the intellectual property rights of such parties, we may be prevented from commercializing potential products in the relevant jurisdiction, or may be required to obtain licenses to those rights or develop or obtain alternative technologies, any of which could harm our business.

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

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

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

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

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

- develop safer or more effective products;
- implement more effective approaches to sales and marketing;
- develop less costly products;

obtain quicker regulatory approval;

have access to more manufacturing capacity;

form more advantageous strategic alliances; or

establish superior proprietary positions.

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.

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Product liability and product recalls could harm our business, and we may not be able to obtain adequate insurance to protect us against product liability losses.*

The current and future use of ADCETRIS and our product candidates by us and our corporate collaborators in clinical trials, and the sale of ADCETRIS and any approved products in the future, expose us to product 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 expanded our insurance coverage to include the sale of commercial products upon approval of ADCETRIS. 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.

Product recalls may be issued at our discretion or at the discretion of our suppliers, government agencies and other entities that have regulatory authority for pharmaceutical sales. Any recall of ADCETRIS could materially adversely affect our business by rendering us unable to sell ADCETRIS for some time and by adversely affecting our reputation.

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.

Legislative actions and potential new accounting pronouncements are likely to impact our future financial position or results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to 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

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reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from science and business activities to compliance activities.

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

Our cash, cash equivalents and investments are held in interest-bearing instruments and subject to investment guidelines allowing for investments in United States government and agency securities, high-grade corporate bonds, taxable municipal bonds, mortgage-backed securities, auction rate securities, or ARS, commercial paper and money market accounts. As a result of the uncertain global credit and financial market conditions, investments in some financial instruments, such as ARS, pose risks arising from liquidity and credit concerns. As of September 30, 2011 we held ARS valued at $12.8 million that have failed at auction and are currently illiquid. Given that future deterioration in the global credit and financial markets is a possibility, no assurance can be made that losses, failed auctions or other significant deterioration in the fair value of our cash equivalents, short-term or long-term investments will not occur. In addition, Standard & Poor s Financial Services LLC, or S&P, recently announced that it had revised its credit rating of the United States to AA+. The long term impact of this credit rating change is not currently known. However, this could impact the liquidity or valuation of our available-for-sale securities, 92% of which were invested in U.S. treasury securities as of September 30, 2011. If any such losses, failed auctions or other significant deteriorations occur, it may negatively impact or impair our current portfolio of cash equivalents, short-term and long-term investments and our ability to fund our planned operations. Further, unless and until the current global credit and financial market crisis has been sufficiently resolved, it may be difficult for us to liquidate our investments prior to their maturity without incurring a loss.

Risks Related to Our Stock

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

The market price of our stock has in the past been, and is likely to continue in the future to be, very volatile. During the third quarter of 2011, our closing stock price fluctuated between $21.08 and $12.67 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:

- the level of ADCETRIS sales in the United States;
- announcements regarding the results of discovery efforts and preclinical and clinical activities by us, including the clinical results of any of our current product candidates, or our competitors;
- announcements regarding the results of the confirmatory studies of ADCETRIS that we are required to conduct as a condition to the FDA s grant of accelerated approval for ADCETRIS, as well as the results of any other clinical trials that we are or may in the future conduct for ADCETRIS;
- issuance of new or changed analysts reports and recommendations regarding us or our competitors;
- announcements of FDA approval or non-approval of our product candidates, or specific label indications for or restrictions, warnings or limitations in its use, or delays in the FDA review process;
- termination of or changes in our existing collaborations or licensing arrangements, especially our ADCETRIS 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;

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

changes in government regulations; and

economic or other external factors.

The stock markets in general, and the markets for biotechnology stocks in particular, have experienced significant volatility that has often been unrelated to the operating performance of particular companies. The financial markets continue to face significant uncertainty, resulting in a decline in investor confidence and concerns about the proper functioning of the securities markets, which decline in general investor confidence resulted in depressed stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. These broad market fluctuations may adversely affect the

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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 60.6 percent of our voting power as of October 31, 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On July 15, 2011, we issued 173,327 shares of our common stock pursuant to the net exercise of warrants originally issued to investors in our Series A preferred stock financing in 2003. These warrants were exercisable for an aggregate of 250,000 shares of common stock and had an exercise price of $6.25 per share. The number of shares issued upon the exercise of these warrants was reduced by an aggregate of 76,673 shares to effect the net exercise of the warrant in accordance with its terms. In issuing the above-mentioned shares, we relied on the exemption provided by Section 4(2) of the Securities Act of 1933, as amended, and/or Regulation D promulgated thereunder as a transaction by an issuer not involving a public offering.

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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+	Commercial Supply Agreement dated December 1, 2010 between Seattle Genetics, Inc. and SAFC, an operating division of Sigma-Aldrich, Inc.
10.2(6)	Development and Supply Agreement dated February 23, 2004 between Seattle Genetics, Inc. and Abbott Laboratories.
10.3(7)	First Amendment to Development and Supply Agreement dated April 17, 2008 between Seattle Genetics, Inc. and Abbott Laboratories, Inc.
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10.8+	Sixth Amendment to Development and Supply Agreement dated November 18, 2010 between Seattle Genetics, Inc. and Abbott Laboratories, Inc.
10.9(8)	Form of Stock Unit Grant Notice and Stock Unit Agreement under Seattle Genetics, Inc. Amended and Restated 2007 Equity Incentive Plan.
31.1+	Certification of Chief Executive Officer pursuant to Rule 13a-14(a).
31.2+	Certification of Chief Financial Officer pursuant to Rule 13a-14(a).
32.1+	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.
32.2+	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350.
101.INS+(9)	XBRL Instance Document
101.SCH+(9)	XBRL Taxonomy Extension Schema Document.
101.CAL+(9)	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF+(9)	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB+(9)	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE+(9)	XBRL Taxonomy Extension Presentation Linkbase Document.

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

(2) Previously filed as an exhibit to the Registrant s current report on Form 8-K filed with the Commission on May 26, 2011 (File No. 000-32405) and incorporated herein by reference.

(3) Previously filed as an exhibit to the Registrant s quarterly report on Form 10-Q for the quarter ended September 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.

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(9) Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fails to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act, are deemed not filed for purposes of section 18 of the Exchange Act and otherwise are not subject to liability under these sections.

+ Filed herewith.

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SIGNATURES

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

SEATTLE GENETICS, INC.

By: **/s/ TODD E. SIMPSON**
Todd E. Simpson
Duly Authorized and Chief Financial Officer
Date: November 4, 2011

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