SEATTLE GENETICS INC /WA
Form 10-Q
November 07, 2012
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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, 2012

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 November 1, 2012, there were 119,093,407 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, 2012

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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, 2012	December 31, 2011
Assets		
Current assets		
Cash and cash equivalents	$ 54,931	$ 87,634
Short-term investments	259,003	243,062
Interest receivable	1,496	641
Accounts receivable, net	35,156	54,955
Inventories	34,296	9,469
Prepaid expenses and other current assets	4,696	3,820
Total current assets	389,578	399,581
Property and equipment, net	20,348	19,652
Other non-current assets	5,404	5,983
Total assets	$ 415,330	$ 425,216
Liabilities and Stockholders Equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 42,525	$ 53,048
Current portion of deferred revenue	32,011	38,092
Total current liabilities	74,536	91,140
Long-term liabilities		
Deferred revenue, less current portion	113,179	110,013
Deferred rent and other long-term liabilities	5,039	5,214
Total long-term liabilities	118,218	115,227
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; 119,014 shares issued and outstanding at September 30, 2012 and 116,023 shares issued and outstanding at December 31, 2011	119	116
Additional paid-in capital	879,630	832,713
Accumulated other comprehensive income	13	20
Accumulated deficit	(657,186)	(614,000)
Total stockholders equity	222,576	218,849

Total liabilities and stockholders equity	$ 415,330	$ 425,216

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

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Seattle Genetics, Inc.

Condensed Consolidated Statements of Comprehensive Loss

(Unaudited)

(In thousands, except per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Revenues				
Net product sales	$ 33,658	$ 10,047	$ 102,845	$ 10,047
Collaboration and license agreement revenues	14,476	10,619	41,119	35,844
Royalty revenues	1,698	0	2,936	0
Total revenues	49,832	20,666	146,900	45,891
Costs and expenses				
Cost of sales	2,742	724	8,808	724
Cost of royalty revenues	613	0	1,115	0
Research and development	41,392	41,080	122,634	123,157
Selling, general and administrative	18,842	19,795	60,889	47,705
Total costs and expenses	63,589	61,599	193,446	171,586
Loss from operations	(13,757)	(40,933)	(46,546)	(125,695)
Investment and other income, net	105	248	3,360	830
Net loss	$ (13,652)	$ (40,685)	$ (43,186)	$ (124,865)
Net loss per share basic and diluted	$ (0.12)	$ (0.35)	$ (0.37)	$ (1.11)
Shares used in computation of net loss per share basic and diluted	118,471	114,727	117,361	112,435
Comprehensive loss:				
Net loss	$ (13,652)	$ (40,685)	$ (43,186)	$ (124,865)
Other comprehensive gain (loss) unrealized gain (loss) on securities available for sale	50	(413)	(7)	(244)
Comprehensive loss	$ (13,602)	$ (41,098)	$ (43,193)	$ (125,109)

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,	
	2012	2011
Operating activities		
Net loss	$ (43,186)	$ (124,865)
Adjustments to reconcile net loss to net cash used in operating activities		
Share-based compensation expense	17,909	14,020
Depreciation and amortization	4,562	2,779
Amortization of premiums, accretion of discounts and gain on investments	1,770	3,206
Deferred rent and other long-term liabilities	(175)	520
Changes in operating assets and liabilities		
Interest receivable	(855)	(232)
Accounts receivable	19,799	3,832
Inventories	(24,827)	(3,428)
Prepaid expenses and other current assets	(876)	(3,079)
Accounts payable and accrued liabilities	(10,523)	12,504
Deferred revenue	(2,915)	7,804
Net cash used in operating activities	(39,317)	(86,939)
Investing activities		
Purchases of securities available for sale	(346,394)	(384,073)
Proceeds from maturities of securities available for sale	317,851	391,953
Proceeds from sales of securities available-for-sale	10,825	0
Purchases of property and equipment	(4,679)	(5,016)
Purchases of other non-current assets	0	(5,762)
Net cash used in investing activities	(22,397)	(2,898)
Financing activities		
Net proceeds from issuance of common stock	0	168,053
Proceeds from exercise of stock options and employee stock purchase plan	29,011	12,762
Net cash provided by financing activities	29,011	180,815
Net increase (decrease) in cash and cash equivalents	(32,703)	90,978
Cash and cash equivalents at beginning of period	87,634	21,127
Cash and cash equivalents at end of period	$ 54,931	$ 112,105

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, 2011 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, 2011, 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, 2012 are not necessarily indicative of the results to be expected for the full year.

Revenue recognition

The Company s revenues are comprised of ADCETRIS net product sales, amounts earned under its collaboration and licensing agreements and royalties. Revenue recognition is predicated upon persuasive evidence of an agreement existing, delivery of products or services being rendered, amounts payable being fixed or determinable, and collectibility being reasonably assured.

Net product sales

In August 2011, the U.S. Food and Drug Administration, or FDA, granted accelerated approval of ADCETRIS®, or brentuximab vedotin, in two indications. The Company sells ADCETRIS in the United States through a limited number of pharmaceutical distributors. Healthcare providers order ADCETRIS through these distributors. The Company receives orders from distributors and primarily ships product directly to the healthcare provider. The Company records product sales upon delivery of the product to the healthcare 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 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 that consider payer mix in target markets, industry benchmarks and experience to date. These estimates involve a high degree of judgment and are periodically reviewed and adjusted as necessary.

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Government-mandated rebates and chargebacks: The Company has entered into a Medicaid Drug Rebate Agreement, or MDRA, with the Centers for Medicare & Medicaid Services. This agreement provides for a rebate to participating states based on covered purchases of ADCETRIS. Medicaid rebates are invoiced to the Company by participating states. The Company estimated Medicaid rebates based on a third party study of the payer mix for ADCETRIS and information on utilization by Medicaid-eligible patients who received assistance through SeaGen Secure . These estimates are compared to historical experience and adjusted as necessary. The Company has also completed an interim Federal Supply Schedule, or FSS, agreement under which certain U.S. government purchasers receive a discount on their purchases of ADCETRIS. The Company has entered into a Pharmaceutical Pricing Agreement, or PPA, with the Secretary of Health and Human Services, which enables certain private entities that qualify for government pricing under the Public Health Services Act, or PHS, to receive discounts on their qualified purchases of ADCETRIS. Under these agreements, distributors process a chargeback to the Company for the difference between wholesale acquisition cost and the discounted price for healthcare providers entitled to FSS discounts and PHS pricing. As a result of the Company s direct-ship distribution model, it can determine the entities purchasing ADCETRIS and this information enables the Company to estimate expected chargebacks for FSS and PHS purchases based on each entity s eligibility for the FSS and PHS programs. The Company also reviews actual chargeback information to further refine these estimates.

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 is able to calculate the amount due for each distributor based on the amount of sales to each distributor. The Company allows for the return of 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 typically not held in the distribution channel, and the expected rapid use of the product by healthcare providers. 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 who meet various financial need criteria. Estimated contributions for commercial coinsurance are deducted from gross sales. These contributions are based on an analysis of expected plan utilization and are adjusted as necessary to reflect our actual experience.

Collaboration and license agreement revenues

The Company uses a time-based proportional performance model to recognize revenue over the Company s performance period and has adopted ASU 2009-13 entitled Multiple-Deliverable Revenue Arrangements, a consensus of the FASB Emerging Issues Task Force. Under this standard, payments received by the Company are recognized as revenue over the performance period of the collaboration. Collaboration and license agreements are evaluated to determine whether the multiple elements and 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, including any upfront payments, maintenance fees, milestone payments and reimbursement payments, are recognized as revenue over the performance obligation periods of each agreement, which range from two to fourteen years for the Company s current agreements. Following the completion of the performance obligation period, such amounts will be recognized as revenue when collectibility is reasonably assured. 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 believes that the period used in each agreement is a reasonable estimate of the performance obligation period of such agreement. ASU 2010-17, entitled Milestone Method of Revenue Recognition , was available as an accounting policy election beginning in the first quarter of 2011. The Company elected not to apply this optional guidance.

The Company s collaboration and license agreements include contractual milestones. Generally, the milestone events contained in the Company s collaboration and license agreements coincide with the progression of the collaborators product candidates from development, to regulatory approval and then to commercialization and fall into the following categories.

Development milestones in the Company s collaborations may include the following types of events:

Designation of a product candidate or initiation of preclinical studies. The Company s collaborators must undertake significant preclinical research and studies to make a determination of a product candidate and the time from those studies or designation to initiation of a clinical trial may take several years.

Initiation of a phase I clinical trial. Generally, phase I clinical trials take one to two years to complete.

Initiation or completion of a phase II clinical trial. Generally, phase II clinical trials take one to three years to complete.

Initiation or completion of a phase III clinical trial. Generally, phase III clinical trials take two to six years to complete.

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Regulatory milestones in the Company s collaborations may include the following types of events:

- Filing of regulatory applications for marketing approval such as a Biologics License Application in the United States or a Marketing Authorization Application in Europe. Generally, it takes up to twelve months to prepare and submit regulatory filings.

- Receiving marketing approval in a major market, such as in the United States, Europe or Japan. Generally it takes up to three years after a marketing application is submitted to obtain full approval for marketing and pricing from the applicable regulatory agency.

Commercialization milestones in the Company s collaborations may include the following types of events:

- First commercial sale in a particular market, such as in the United States or Europe.

- Product sales in excess of a pre-specified threshold, such as annual sales exceeding $1 billion. The amount of time to achieve this type of milestone depends on several factors, including, but not limited to, the dollar amount of the threshold, the pricing of the product, market penetration of the product and the rate at which customers begin using the product.

The Company has developed a proprietary technology for linking cytotoxic agents to monoclonal antibodies called antibody-drug conjugates, or ADCs. This proprietary technology is the basis of ADC collaborations that the Company has entered into in the ordinary course of its business with a number of biotechnology and pharmaceutical companies. Under these ADC collaboration agreements, the Company grants its collaborators research and commercial licenses to the Company s technology and provides technology transfer services, technical advice, supplies and services for a period of time of between two and fourteen years. The Company s ADC collaborators are solely responsible for the development of their product candidates and the achievement of milestones in any of the categories identified above is based solely on the collaborators efforts.

In the case of the Company s other collaboration and license agreements, such as the Company s ADCETRIS collaboration with Millennium: The Takeda Oncology Company, or Millennium, or its co-development agreement with Agensys, Inc., an affiliate of Astellas Pharma, Inc., or Agensys, the Company s proprietary products or product candidates may be covered by the collaboration or the Company may be involved in certain development activities; however, the achievement of milestone events under these agreements is based on activities undertaken by the collaborator.

The process of successfully developing a product candidate, obtaining regulatory approval and ultimately commercializing a product candidate is highly uncertain and the attainment of any milestones is therefore uncertain and difficult to predict. In addition, since the Company does not take a substantive role or control the research, development or commercialization of any products generated by its ADC collaborators, the Company is not able to reasonably estimate when, if at all, any milestone payments or royalties may be payable to the Company by its ADC collaborators. As such, the milestone payments associated with its ADC collaborations involve a substantial degree of uncertainty and risk that they may never be received. Similarly, even in those collaborations where the Company may have an active role in the development of the product candidate, such as the Company s ADCETRIS collaboration with Millennium, the attainment of a milestone is based on the collaborator s activities and is generally outside the direction and control of the Company.

The Company generally invoices its collaborators on a monthly or quarterly basis, or upon the completion of the effort or achievement of a milestone, based on the terms of each agreement. Deferred revenue arises from amounts received in advance of the culmination of the earnings process and is recognized as revenue in future periods when the applicable revenue recognition criteria have been met. Deferred revenue expected to be recognized within the next twelve months is classified as a current liability.

Royalty revenues and cost of royalty revenues

Royalty revenues reflect amounts earned under the ADCETRIS collaboration with Millennium. Royalties are based on a percentage of Millennium s net sales in its territory at rates that range from the mid-teens to the mid-twenties based on sales volume. Royalty revenues also include the portion of royalties owed to the Company s third party licensors on Millennium s sales of ADCETRIS, which is paid by Millennium. Cost of royalty revenues reflects amounts owed to the Company s third party licensors related to the sale of ADCETRIS in Millennium s territory. Millennium is responsible for paying such royalties on sales of ADCETRIS. These amounts are recognized in the quarter in which Millennium

reports its sales activity to the Company, which is the quarter following the related sales.

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 restricted stock units, warrants and options to purchase common stock from the calculation of diluted net loss per share as such securities are anti-dilutive for all periods presented.

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The following table presents the weighted-average shares that have been excluded from the number of shares used to calculate basic and diluted net loss per share (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Warrants to purchase common stock	0	901	0	1,041
Options to purchase common stock and restricted stock units	13,104	13,272	13,513	12,855
Total	13,104	14,173	13,513	13,896

3. 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 income in stockholders equity. Investments in securities with a maturity of less than one year, or where management s intent is to use the investments to fund current operations, or to make them available for current operations, are classified as short-term investments.

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

	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
September 30, 2012				
U.S. Treasury securities	$ 259,294	$ 14	$ (1)	$ 259,307
Contractual Maturities				
Due in one year or less	$ 259,294			$ 259,307

	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
December 31, 2011				
U.S. Treasury securities	$ 228,001	$ 24	$ (3)	$ 228,022
Corporate obligations	9,565	0	(1)	9,564
Auction rate securities	5,780	0	0	5,780
Total	$ 243,346	$ 24	$ (4)	$ 243,366
Contractual Maturities				
Due in one year or less	$ 237,566			$ 237,586
Due in 2017	5,780			5,780
Total	$ 243,346			$ 243,366

Investments are presented in the accompanying consolidated balance sheets as follows (in thousands):

	September 30, 2012	December 31, 2011
Short-term investments	$ 259,003	$ 243,062
Other non-current assets	304	304
Total	$ 259,307	$ 243,366

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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
As of September 30, 2012				
U.S. Treasury securities	$ 24,153	$ (1)	$ NA	$ NA
As of December 31, 2011				
U.S. Treasury securities	$ 80,234	$ (3)	$ NA	$ NA
Corporate obligations	4,571	(1)	NA	NA
Total	$ 84,805	$ (4)	$ NA	$ NA

4. Fair Value

The Company holds short-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 at December 31, 2011. Level 3 investments consisted of auction rate securities at December 31, 2011 that were sold in March 2012. The Company did not hold any level 2 or 3 investments as of September 30, 2012 and did not transfer any investments into or out of Levels 1, 2 and 3 during the nine month period ended September 30, 2012.

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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):

	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 September 30, 2012				
Short-term investments U.S. Treasury securities	$ 259,003	$ 0	$ 0	$ 259,003
Other non-current assets U.S. Treasury securities	304	0	0	304
Total	$ 259,307	$ 0	$ 0	$ 259,307

	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, 2011				
Cash equivalents money market funds	$ 66	$ 0	$ 0	$ 66
Short-term investments:				
U.S. Treasury securities	227,718	0	0	227,718
Corporate obligations	0	9,564	0	9,564
Auction rate securities	0	0	5,780	5,780
Other non-current assets U.S. Treasury securities	304	0	0	304
Total	$ 228,088	$ 9,564	$ 5,780	$ 243,432

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

	Fair Value
Balance as of December 31, 2011	$ 5,780
Sale of auction rate securities	(5,825)
Realized gain on auction rate securities	45
Balance as of September 30, 2012	$ 0

5. Inventories

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

	September 30, 2012	December 31, 2011
Raw materials	$ 28,865	$ 9,275

Work in process	5,002	173
Finished goods	429	21
Total	$ 34,296	$ 9,469

The Company began capitalizing ADCETRIS inventory costs following accelerated approval by the FDA in August 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 other product candidates. ADCETRIS inventory that is deployed into clinical, research or development use is charged to research and development expense when it is no longer available for use in commercial sales.

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6. Subsequent Events

On October 31, 2012, Millennium announced that it had received conditional marketing authorization for ADCETRIS from the European Commission for two indications: (1) the treatment of adult patients with relapsed or refractory CD30-positive Hodgkin lymphoma following autologous stem cell transplant, or ASCT, or following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option, and (2) the treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma. The conditional marketing authorization triggered two milestone payments to the Company under the ADCETRIS collaboration with Millennium totaling $25 million.

In October 2012, the Company expanded its ADC collaboration agreement with Abbott Laboratories, or Abbott. Under the terms of the multi-year agreement, the Company received a $25 million upfront fee for rights to utilize the Company s ADC technology with antibodies to additional oncology targets.

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 these or other 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, uncertainties and other factors. 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. In August 2011, the U.S. Food and Drug Administration, or FDA, granted accelerated approval of ADCETRIS®, or brentuximab vedotin, in 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 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. We have a broad development strategy for ADCETRIS evaluating its potential application in earlier lines of therapy for patients with Hodgkin lymphoma and mature T-cell lymphoma, or MTCL, and in other CD30-positive malignancies. 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 and SGN-CD33A.

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. We are in the process of seeking regulatory approval to market ADCETRIS in Canada for relapsed Hodgkin lymphoma and sALCL and we anticipate a review decision by Health Canada in early 2013. On October 31, 2012, Millennium announced that it had received conditional marketing authorization for ADCETRIS from the European Commission for two indications: (1) the treatment of adult patients with relapsed or refractory CD30-positive Hodgkin lymphoma following ASCT or following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option, and (2) the treatment of adult patients with relapsed or refractory sALCL. Conditional marketing authorization by the European Commission includes obligations to provide

additional clinical data at a later stage to

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confirm the positive benefit-risk balance. We also have collaborations for our ADC technology with a number of biotechnology and pharmaceutical companies, including Abbott Laboratories, 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 ADCETRIS and our ability to realize that potential remains uncertain. 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 these studies are successful, we intend to seek additional regulatory approvals. We and Millennium have initiated two phase III clinical trials of ADCETRIS, one in relapsed cutaneous T-cell lymphoma, or CTCL, and one in front-line advanced stage Hodgkin lymphoma. In addition, we and Millennium plan to conduct another phase III clinical trial of ADCETRIS in front-line mature T-cell lymphoma, or MTCL, including sALCL, which is planned to start by late 2012 or early 2013. The FDA has agreed to special protocol assessments, or SPAs, for all three of these current and planned phase III clinical trials. An SPA is an agreement with the FDA regarding the design of the clinical trial, including size and clinical endpoints, to support an efficacy claim in a biologics license application submission to the FDA. We have an agreement with Ventana Medical Systems, Inc., a member of the Roche Group, or Ventana, under which Ventana will develop, manufacture and commercialize a molecular companion diagnostic test with the goal of identifying patients who might respond to treatment with ADCETRIS based on CD30 expression levels in their tissue specimens. A molecular companion diagnostic is not required for the current approved indications for ADCETRIS; however, we expect that a molecular companion diagnostic may be required by regulatory authorities to support regulatory approval of ADCETRIS in other CD30-positive malignancies. All of 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 have only limited experience commercializing ADCETRIS and our future ADCETRIS product sales will be difficult to predict from period to period. Our product sales revenue may vary significantly from period to period. We also expect that amounts earned from our collaboration agreements will continue to be an important source of our revenues and cash flows. These revenues will be impacted by future development funding and the achievement of development and clinical milestones by our collaborators 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 should not be relied upon as being indicative of our future performance.

Financial summary

Our revenues are generated from a combination of ADCETRIS sales, which we began in the United States during August 2011, collaboration and license agreements and royalties. Collaboration 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. Under our ADCETRIS collaboration with Millennium, we are entitled to receive royalties based on a percentage of Millennium s net sales in its territories ranging from the mid-teens to the mid-twenties based on sales volume. For the nine months ended September 30, 2012, total revenues increased to $146.9 million, compared to $45.9 million for the same period in 2011. This increase primarily reflects our product sales of ADCETRIS during the 2012 period. For the nine months ended September 30, 2012, total costs and expenses increased 13% to $193.4 million, compared to $171.6 million for the same period in 2011. This reflects increases in sales and marketing expenses, development costs associated with advancing our ADC product candidates and cost of sales. As of September 30, 2012, we had $313.9 million in cash, cash equivalents and short-term investments, and $222.6 million in total stockholders equity.

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Results of operations

Three months and nine months ended September 30, 2012 and 2011

Net product sales

Net product sales were $33.7 million and $102.8 million for the three and nine months ended September 30, 2012 and $10.0 million for the three and nine month periods ended September 30, 2011. We began selling ADCETRIS in the United States in August 2011.

We sell ADCETRIS in the United States through a limited number of pharmaceutical distributors. Healthcare providers order ADCETRIS through these distributors. We receive orders from distributors and primarily ship product directly to the healthcare provider. We record product sales upon delivery of the product to the healthcare 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 involve a high degree of judgment and are periodically reviewed and adjusted as necessary.

Government-mandated rebates and chargebacks: We have entered into a Medicaid Drug Rebate Agreement, or MDRA, with the Centers for Medicare & Medicaid Services. This agreement provides for a rebate to participating states based on covered purchases of ADCETRIS. Medicaid rebates are invoiced to us by participating states. We estimated Medicaid rebates based on a third party study of the payer mix for ADCETRIS and information on utilization by Medicaid-eligible patients who received assistance through SeaGen Secure, our patient assistance program. We compare these estimates to our historical experience and adjust as necessary. We also completed our interim Federal Supply Schedule, or FSS, agreement under which certain U.S. government purchasers receive a discount on their purchases of ADCETRIS. We have entered into a Pharmaceutical Pricing Agreement, or PPA, with the Secretary of Health and Human Services which enables certain private entities that qualify for government pricing under the Public Health Services Act, or PHS, to receive discounts on their qualified purchases of ADCETRIS. Under these agreements, distributors process a chargeback to us for the difference between wholesale acquisition cost and the discounted price for healthcare providers entitled to FSS discounts or PHS pricing. As a result of our direct-ship distribution model, we can identify the entities purchasing ADCETRIS and this information enables us to estimate expected chargebacks for FSS and PHS purchases based on each entity s eligibility for the FSS and PHS programs. We also review actual chargeback information to further refine these estimates.

Distribution fees, product returns and other deductions: Our distributors charge a fee for distribution services that they perform on our behalf. We are able to calculate the amount due for each distributor based on the amount of sales to each distributor and the negotiated fee. 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, our belief that product is typically not held in the distribution channel, and the expected rapid use of the product by healthcare providers. We provide reimbursement and financial assistance to qualifying patients in the U.S. and its territories who meet various financial need criteria and are underinsured or cannot cover the cost of commercial coinsurance amounts through SeaGen Secure. Estimated contributions for commercial coinsurance are deducted from gross sales. These contributions are based on an analysis of expected plan utilization and are adjusted as necessary to reflect our actual experience.

The following table summarizes the reductions from gross sales for the items discussed above, net of related payments and credits, for the nine month period ended September 30, 2012 (in thousands):

	Rebates and chargebacks	Distribution fees, product returns and other	Total
Balance as of December 31, 2011	$ 895	$ 1,036	$ 1,931
Provision related to current period sales	11,130	2,890	14,020
Adjustment for prior period sales	(240)	0	(240)
Payments/credits for current period sales	(7,363)	(1,701)	(9,064)
Payments/credits for prior period sales	(132)	(709)	(841)
Balance as of September 30, 2012	$ 4,290	$ 1,516	$ 5,806

Deductions from gross sales increased in 2012 compared to 2011 as a result of the timing of government discount programs becoming effective. We expect modest fluctuations in future gross to net discounts as a result of variability in product use and the amount of government mandated discounts.

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Collaboration and license agreement revenues

We use a time-based proportional performance model to recognize revenue over our performance obligation period and have adopted ASU 2009-13 entitled Multiple-Deliverable Revenue Arrangements, a consensus of the FASB Emerging Issues Task Force. Under this standard, payments received by us are recognized as revenue over the performance period of the collaboration. Collaboration and license agreements are evaluated to determine whether the multiple elements and associated deliverables can be considered separate units of accounting. To date, the deliverables under our collaboration and license agreements have not qualified as separate units of accounting. Accordingly, all amounts received or due, including any upfront payments, maintenance fees, milestone payments and reimbursement payments, are recognized as revenue over the performance obligation periods of each agreement, which range from two to fourteen years for our current agreements. Following the completion of the performance obligation period, such amounts received or due will be recognized as revenue when collectibility is reasonably assured. 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. We believe that the period used in each agreement is a reasonable estimate of the performance obligation period of such agreement. ASU 2010-17, entitled Milestone Method of Revenue Recognition , was available as an accounting policy election beginning in the first quarter of 2011. We elected not to apply this optional guidance.

Our collaboration and license agreements include contractual milestones. Generally, the milestone events contained in our collaboration and license agreements coincide with the progression of the collaborators product candidates from development, to regulatory approval and then to commercialization and fall into the following categories.

Development milestones in our collaborations may include the following types of events:

- Designation of a product candidate or initiation of preclinical studies. Our collaborators must undertake significant preclinical research and studies to make a determination of a product candidate and the time from those studies or designation to initiation of a clinical trial may take several years.
- Initiation of a phase I clinical trial. Generally, phase I clinical trials take one to two years to complete.
- Initiation or completion of a phase II clinical trial. Generally, phase II clinical trials take one to three years to complete.
- Initiation or completion of a phase III clinical trial. Generally, phase III clinical trials take two to six years to complete.

Regulatory milestones in our collaborations may include the following types of events:

- Filing of regulatory applications for marketing approval such as a Biologics License Application in the United States or a Marketing Authorization Application in Europe. Generally, it takes up to twelve months to prepare and submit regulatory filings.
- Receiving marketing approval in a major market, such as in the United States, Europe or Japan. Generally it takes up to three years after a marketing application is submitted to obtain full approval for marketing and pricing from the applicable regulatory agency.

Commercialization milestones in our collaborations may include the following types of events:

- First commercial sale in a particular market, such as in the United States or Europe.

Product sales in excess of a pre-specified threshold, such as annual sales exceeding $1 billion. The amount of time to achieve this type of milestone depends on several factors, including, but not limited to, the dollar amount of the threshold, the pricing of the product, market penetration of the product and the rate at which customers begin using the product.

Our proprietary ADC technology is the basis of our ADC collaborations that we have entered into in the ordinary course of our business with a number of biotechnology and pharmaceutical companies. Under our ADC collaboration agreements, we grant our collaborators research and commercial licenses to our technology and provide technology transfer services, technical advice, supplies and services for time periods ranging from two to fourteen years. Our ADC collaborators are solely responsible for the development of their product candidates and the achievement of a milestone in any of the categories identified above is based solely on the collaborators efforts. In the case of our other collaboration and license agreements, such as our ADCETRIS collaboration with Millennium or our co-development agreement with Agensys, our proprietary products or product candidates may be covered by the collaboration or we may be involved in certain development activities; however, the achievement of milestone events under these agreements is based on activities undertaken by the collaborator.

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The process of successfully developing a product candidate, obtaining regulatory approval and ultimately commercializing a product candidate is highly uncertain and the attainment of any milestones is therefore uncertain and difficult to predict. In addition, since we do not take a substantive role or control the research, development or commercialization of any products generated by our ADC collaborators, we are not able to reasonably estimate when, if at all, any milestone payments or royalties may be payable to us by our ADC collaborators. As such, the milestone payments we may receive from our ADC collaborators involve a substantial degree of uncertainty and risk that they may never be received. Similarly, even in those collaborations where we may have an active role in the development of the product candidate, such as our ADCETRIS collaboration with Millennium, the attainment of a milestone is based on the collaborator s activities and is generally outside our direction and control.

We generally invoice our collaborators on a monthly or quarterly basis, or upon completion of the effort or achievement of a milestone, based on the terms of each agreement. Amounts due, but not billed to a collaborator, if any, are included in accounts receivable in our consolidated balance sheets. Deferred revenue arises from amounts received in advance of the culmination of the earnings process and is recognized as revenue in future periods when the applicable revenue recognition criteria have been met. Deferred revenue expected to be recognized within the next twelve months is classified as a current liability.

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

	Three months ended September 30,			Nine months ended September 30,		
Collaboration and license agreement revenue by collaborator ($ in thousands)	**2012**	**2011**	**% Change**	**2012**	**2011**	**% Change**
Millennium	$ 7,030	$ 5,969	18%	$ 20,623	$ 20,531	0%
Genentech	3,045	824	270%	5,264	3,705	42%
Agensys	738	502	47%	4,096	1,507	172%
Abbott	1,265	1,069	18%	3,866	2,100	84%
Pfizer	1,126	1,000	13%	3,379	3,000	13%
Other	1,272	1,255	1%	3,891	5,001	(22%)
Total	$ 14,476	$ 10,619	36%	$ 41,119	$ 35,844	15%

Millennium ADCETRIS and ADC collaborations

Revenues earned under our ADCETRIS and ADC collaborations with Millennium represented 49% and 56% of our collaboration and license agreement revenues during the three months ended September 30, 2012 and 2011, respectively, and 50% and 57% during the nine months ended September 30, 2012 and 2011, respectively. The increase in revenues from Millennium during the three months ended September 30, 2012 from the comparable period in 2011 primarily reflects higher revenue from our ADCETRIS collaboration agreement during the 2012 period as a result of our increased reimbursable costs. Millennium revenues for the nine months ended September 30, 2012 were comparable to the same period in 2011.

Under the ADCETRIS collaboration, we are entitled to receive progress- and sales-dependent milestone payments based on Millennium s achievement of certain events related to ADCETRIS for which Millennium is responsible. We are also entitled to tiered royalties at percentages starting in the mid-teens and escalating to the mid-twenties based on net sales of ADCETRIS within Millennium s licensed territories, subject to partial offsets for third party royalties paid by Millennium. Total potential milestone payments to us under the ADCETRIS collaboration could total approximately $235 million, $30 million of which has been achieved. Of the remaining amount, up to approximately $7 million relates to the achievement of development milestones, up to approximately $133 million relates to the achievement of regulatory milestones and up to approximately $65 million relates to the achievement of commercial milestones. We recognize as collaboration revenue the $60 million upfront collaboration payment, milestone payments and development cost reimbursement payments to us over the ten-year development period of the collaboration. We receive reimbursement funding from Millennium equal to one-half of the cost of joint development activities that are performed by us under the collaboration. To the extent that Millennium performs development activities under the collaboration, our development cost reimbursement payments from Millennium are reduced by half of those costs.

Collaboration and Co-Development Agreement with Agensys

Under this collaboration and co-development agreement, Agensys is conducting preclinical studies aimed at identifying ADC product candidates for multiple designated antigens. We are currently co-developing ASG-5ME and ASG-22ME, and we have the right to exercise a co-development option for one additional ADC product candidate upon Agensys submission of an investigational new drug application, or IND, to the FDA. Agensys has the right to develop and commercialize the other ADC product candidates on

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its own, subject to paying us fees, milestones, royalties and support fees for research and development services and material provided under the agreement. Either party may opt out of co-development and profit-sharing in return for receiving milestones and royalties from the continuing party. Amounts received for product candidates being developed solely by Agensys will be recognized as revenue over the development term of the collaboration agreement using a time-based approach. Revenues attributable to the Agensys agreement increased during both the three and nine months ended September 30, 2012 from the comparable period in 2011 due to a payment made to us in 2012 to exercise an exclusive license for an ADC product candidate.

ADC collaboration agreements

We have active ADC collaborations with nine companies to allow them to use our proprietary ADC technology. Under our ADC collaborations, which we enter into in the ordinary course of business, we receive or are entitled to receive upfront cash payments, progress-dependent milestones and royalties on net sales of products incorporating our ADC technology, as well as annual maintenance fees and support fees for research and development services and materials provided under the agreements. As of September 30, 2012, our ADC collaborations had generated over $175 million, primarily in the form of upfront payments. Total milestone payments to us under our current ADC collaborations could approximate up to $3.2 billion if all potential product candidates achieved all of the milestone events under all of our current ADC collaborations. Of this amount, approximately $0.7 billion relates to the achievement of development milestones, approximately $1.5 billion relates to the achievement of regulatory milestones and approximately $1 billion relates to the achievement of commercial milestones. Our ADC collaborators are responsible for development, manufacturing and commercialization of any ADC product candidates that result from the collaborations and are solely responsible for the achievement of any of the potential milestones under these collaborations. Since we do not control the research, development or commercialization of any products generated by our ADC collaborators, we are not able to reasonably estimate when, if at all, any milestone payments or royalties may be payable by our ADC collaborators. In addition, our current ADC collaborations are at early stages of development. We have not received and do not expect to receive material milestone payments from any of our current ADC collaborators unless and until a product that incorporates our ADC technology enters late-stage clinical development and/or receives marketing approval from the FDA, if at all. Successfully developing a product candidate, obtaining regulatory approval and ultimately commercializing it is a significantly lengthy and highly uncertain process which entails a significant risk of failure. In addition, business combinations, changes in an ADC collaborator s business strategy and financial difficulties or other factors could result in an ADC collaborator abandoning or delaying development of its ADC product candidates. As such, the milestone payments associated with our ADC collaborations involve a substantial degree of risk to achieve and may never be received. Accordingly, we do not expect, and investors should not assume, that we will receive all of the potential milestone payments provided for under our ADC collaborations and it is possible that we may never receive any significant milestone payments under our ADC collaborations.

Genentech revenues increased 270% to $3.0 million during the three month period ended September 30, 2012 and 42% to $5.3 million during the nine months ended September 30, 2012 from the comparable periods in 2011 primarily as a result of the earned portion of development milestone payments received in the third quarter of 2012.

Abbott revenues for the three and nine month periods ended September 30, 2012 reflect the earned portion of an $8.0 million upfront payment, a milestone payment made in late 2011 and reimbursable support we provided to Abbott under our ADC collaboration agreement that we entered into in March 2011.

Pfizer revenues increased 13% during both the three and nine months ended September 30, 2012, from the comparable periods in 2011 as a result of revenue recognition attributable to a milestone payment made to us in late 2011.

Our collaboration revenues are impacted by the term and duration of our collaboration and co-development agreements and by progress-dependent milestones, annual maintenance fees and reimbursement of materials and support services as our collaborators advance their ADC product candidates through the development process. Collaboration revenues may vary substantially from year to year and quarter to quarter depending on the progress made by our collaborators with their product candidates, the level of support we provide to our collaborators, the timing of milestones achieved, and our ability to enter into additional collaboration and co-development agreements. We expect our collaboration and license agreement revenues to increase in 2012 compared to 2011, primarily as a result of our ADCETRIS collaboration with Millennium. 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.

Royalty Revenues and Cost of Royalty Revenues

We are entitled to receive a royalty on sales of ADCETRIS by Millennium in its territory, which is worldwide outside of the U.S. and its territories and Canada. Royalties payable to us are based on a percentage of Millennium s net sales in its territories at rates that range from the mid-teens to the mid-twenties, based on Millennium s sales volume. Royalty revenues also include the portion of royalties owed to our third

party licensors on Millennium s sales of ADCETRIS, which are paid by Millennium. We recognize royalties as revenue when Millennium reports its sales activity to us, which is the quarter following the related sales. Royalty revenues

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recognized in 2012 relate to ADCETRIS sales by Millennium under its international named patient program. Cost of royalty revenues reflects amounts owed to our third party licensors related to Millennium s sale of ADCETRIS in its territory. Millennium is responsible for paying such royalties on sales of ADCETRIS. In October 2012, Millennium received conditional marketing authorization from the European Commission for ADCETRIS in two indications. Millennium has indicated that they intend to begin launching ADCETRIS in the European Union beginning in the fourth quarter of 2012. We expect that royalty revenues and cost of royalty revenues will increase as a result of this European Commission approval.

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 manufacturing costs as inventory following the accelerated approval by the FDA in its two approved indications in August 2011. The cost of product manufactured prior to FDA approval was expensed as research and development expense as incurred and was combined with other research and development expenses. While we track the quantities of individual ADCETRIS product lots, we did not track pre-FDA approval manufacturing costs in our inventory system and therefore the manufacturing cost of ADCETRIS produced prior to FDA approval is not reasonably determinable. Most of the product produced prior to FDA approval is expected to be 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. This cost benefit will vary based on when the components of the specific drug lots sold were produced and is expected to continue for at least the next twelve months; however, the time period over which this reduced-cost inventory is consumed will depend on a number of factors, including the amount of future ADCETRIS sales, the ultimate use of this inventory in either commercial sales, clinical development or other research activities, and the ability to utilize inventory prior to its expiration date. We expect, as this reduced-cost inventory is used, the percentage of total costs of sales for sales of ADCETRIS will increase into the teens.

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)	**2012**	**2011**	**% Change**	**2012**	**2011**	**% Change**
Research	$ 4,710	$ 3,942	19%	$ 12,158	$ 15,771	(23%)
Development and contract manufacturing	15,046	17,117	(12%)	42,307	50,243	(16%)
Clinical	18,684	17,431	7%	59,791	50,112	19%
Share-based compensation expense	2,952	2,590	14%	8,378	7,031	19%
Total research and development expenses	$ 41,392	$ 41,080	1%	$ 122,634	$ 123,157	0%

Research expenses increased 19% to $4.7 million in the third quarter and decreased 23% to $12.2 million for the nine month period ended September 30, 2012 from the comparable periods in 2011. The changes in both periods primarily resulted from the timing of technology access fees.

Development and contract manufacturing expenses decreased 12% to $15.0 million in the third quarter and 16% to $42.3 million for the nine month period ended September 30, 2012 from the comparable periods in 2011. The decreases resulted primarily from lower ADCETRIS manufacturing costs which were expensed to research and development expense prior to FDA approval in August 2011 and capitalized as inventory thereafter.

Clinical expenses increased 7% to $18.7 million in the third quarter and 19% to $59.8 million for the nine month period ended September 30, 2012 from the comparable periods in 2011. These increases reflect costs to develop a companion diagnostic test for identifying CD-30-positive diseases that might respond to treatment with ADCETRIS and higher compensation costs due to an increase in our staffing levels.

Share-based compensation expense increased during the both the three and nine month periods ended September 30, 2012 from the comparable periods in 2011 due to a higher average value per share for our more recent equity grants primarily attributable to an increase in our stock price.

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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 these development programs as well as costs of our earlier-stage development programs:

	Three months ended September 30,		Nine months ended September 30,		Five years ended September 30, 2012
Development program ($ in thousands)	**2012**	**2011**	**2012**	**2011**	
ADCETRIS (brentuximab vedotin)	$ 9,601	$ 13,439	$ 29,954	$ 42,945	$ 185,916
ASG-22ME	882	603	5,160	4,712	11,599
SGN-CD19A	422	2,869	3,411	4,934	14,691
SGN-CD33A	3,464	0	7,277	160	7,773
SGN-75	185	457	569	2,101	12,708
ASG-5ME	270	1,417	626	2,750	11,132
Total third party costs	14,824	18,785	46,997	57,602	243,819
Other costs and overhead	23,616	19,705	67,259	58,524	397,171
Share-based compensation expense	2,952	2,590	8,378	7,031	41,642
Total research and development	$ 41,392	$ 41,080	$ 122,634	$ 123,157	$ 682,632

Third-party costs for ADCETRIS decreased during both the three and nine months ended September 30, 2012 from the comparable periods in 2011, primarily as a result of manufacturing costs which were expensed to research and development in the 2011 periods and capitalized as inventory in 2012. We began capitalizing ADCETRIS production costs as inventory following accelerated approval of ADCETRIS by the FDA in August 2011. However, ADCETRIS inventory that is deployed into clinical, research or development use is charged to research and development expense when it is no longer available for commercial use.

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. ASG-22ME costs in the 2012 periods reflect our share of development costs incurred during the period.

Third party costs for SGN-CD19A decreased for both the three and nine month periods ended September 30, 2012 from the comparable periods in 2011. These decreases reflect the timing of contract manufacturing and other activities in preparation for an IND that was submitted to the FDA earlier in 2012 and potential clinical trials.

Third party costs for SGN-CD33A increased for both the three and nine month periods ended September 30, 2012 from the comparable periods in 2011 as we initiated a contract manufacturing campaign in 2012 in anticipation of a planned IND submission to the FDA in 2013.

Third party costs for both SGN-75 and ASG-5ME decreased during both the three and nine months ended September 30, 2012 compared to the comparable periods in 2011 primarily as a result of higher manufacturing and clinical trial costs in the 2011 periods.

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

- the number of patients required in our clinical 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.

Reports of adverse events or safety concerns involving ADCETRIS and our product candidates could interrupt, delay or halt clinical trials of ADCETRIS and our product candidates, including the FDA-required ADCETRIS post-approval confirmatory studies as well as the post-approval confirmatory studies that Millennium is required to conduct as a condition to the conditional marketing authorization of ADCETRIS by the European Commission.

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Our strategy has included entering into collaborations with third parties. In these situations, the preclinical development or clinical trial process for a product candidate and the estimated completion date are largely 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.

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

Selling, general and administrative ($ in thousands)	Three months ended September 30, 2012	2011	% Change	Nine months ended September 30, 2012	2011	% Change
Selling, general and administrative, excluding share-based compensation expense	$ 15,522	$ 16,895	(8%)	$ 51,358	$ 40,716	26%
Share-based compensation expense	3,320	2,900	14%	9,531	6,989	36%
Total selling, general and administrative expenses	$ 18,842	$ 19,795	(5%)	$ 60,889	$ 47,705	28%

Selling, general and administrative expenses, excluding share-based compensation expense, decreased during the three months ended September 30, 2012 and increased during the nine months ended September 30, 2012 from the comparable periods in 2011. The decrease for the three month period resulted from additional activities around the launch of ADCETRIS in 2011. The increase for the nine month period resulted primarily from the costs of our commercial organization which was established during 2011 but was in place for the entire 2012 period. Share-based compensation expense increased during both the three and nine months ended September 30, 2012 from the comparable periods in 2011 due to a higher average value per share for our more recent equity grants primarily attributable to an increase in our stock price.

Investment and other income, net

Investment and other income, net decreased to $0.1 million in the third quarter and increased to $3.4 million for the nine months ended September 30, 2012 from the comparable periods in 2011. The increase for the nine months ended September 30, 2012 primarily reflects a recovery from a former investment advisor in settlement of claims against the advisor concerning our previous holdings in auction rate securities.

Liquidity and capital resources

Selected balance sheet and cash flow data ($ in thousands)	September 30, 2012	December 31, 2011
Cash, cash equivalents and investments	$ 313,934	$ 330,696
Working capital	315,042	308,441
Stockholders equity	222,576	218,849

	Nine months ended September 30, 2012	2011
Cash provided by (used in):		
Operating activities	$ (39,317)	$ (86,939)
Investing activities	(22,397)	(2,898)
Financing activities	29,011	180,815

We have financed the majority of our operations through the issuance of equity securities and by amounts received pursuant to our sales of ADCETRIS, 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 decreased to $313.9 million at September 30, 2012, compared to $330.7 million at December 31, 2011, and our working capital was $315.0 million at September 30, 2012, compared to $308.4 million at December 31, 2011. During the first nine months of 2012, we used $39.3 million of cash in our operating activities compared to $86.9 million used during the first nine months of 2011. The decrease in cash used in operating activities during the nine months

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ended September 30, 2012 primarily reflects our reduced net operating loss and collections of accounts receivable from the sale of ADCETRIS in the 2012 period. The changes in investing and financing activities primarily resulted from a public offering of our common stock completed in the first quarter of 2011 and the investment of our cash in short term securities.

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 subject to investment guidelines allowing for holdings in U.S. government and agency securities, corporate securities, taxable municipal bonds, commercial paper and money market accounts.

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, 2012, we had $313.9 million held in cash reserves or debt securities scheduled to mature within the next twelve months.

At our currently planned spending rate we believe that our financial resources, together with product revenue from sales of ADCETRIS and the fees, milestone payments and reimbursements we expect to receive under our existing collaboration and license agreements, will be sufficient to fund our operations for at least the next twelve months. Changes in our spending rate may occur that would consume available capital resources sooner, such as increased development, manufacturing and clinical trial expenses in connection with required post-approval studies and additional studies to potentially expand the use of ADCETRIS or to advance our other ADC pipeline programs. Additionally, we may not receive the payments that we currently expect under our existing collaboration agreements, including the ADCETRIS collaboration agreement with Millennium or our ADC collaborations, which may shorten the timeframe through which we are able to fund operations. Further, 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. Any of these factors could lead to a need for us to raise additional capital.

We are required by the FDA to conduct additional confirmatory phase III post-approval studies of ADCETRIS as part of our accelerated approval. These studies will be large studies conducted over a lengthy period of time and although we are in the process of commencing these studies, based on the expected length of these studies and the inherent uncertainty of clinical trial costs, we may be required to raise additional capital in order to complete the studies. In this regard, whether we have sufficient funding to complete these studies will be partially dependent upon cash received from sales of ADCETRIS, which may not be sufficient to complete these studies. Our inability to obtain funds sufficient to complete these studies and establish confirmatory evidence of efficacy for ADCETRIS may have material adverse consequences to us, including the loss of marketing approval for ADCETRIS. These required post-approval studies will also significantly increase our clinical trial expenses, which could increase our losses and/or negatively impact our ability to achieve or maintain profitability.

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, including the post-approval studies we must conduct for ADCETRIS, 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.

Commitments

The following table reflects our future minimum contractual commitments as of September 30, 2012 (in thousands):

	Total	Remainder of 2012	2013	2014	2015	2016	Thereafter
Operating leases	$ 25,038	$ 998	$ 4,071	$ 4,208	$ 4,348	$ 4,495	$ 6,918
Tenant improvements	6,196	6,196					
Manufacturing, license & collaboration agreements	130,033	20,405	15,842	15,656	12,150	11,878	54,102

Total	$ 161,267	$ 27,599	$ 19,913	$ 19,864	$ 16,498	$ 16,373	$ 61,020

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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. Operating lease obligations in the table above do not assume the exercise by us of any termination or extension options.

A substantial portion of the minimum payments under manufacturing, license and collaboration agreements represents contractual obligations related to manufacturing our product candidates for use in our clinical trials and for 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 royalties 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 $32.8 million in potential future milestone payments to third parties under license and collaboration agreements for ADCETRIS and our other later-stage 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, 2012 have totaled $11.7 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, 2012 has not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2011 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. Treasury securities. Our investment securities consisted of the following (in thousands):

	September 30, 2012	December 31, 2011
Short-term investments	$ 259,003	$ 243,062
Other non-current assets	304	304
Total	$ 259,307	$ 243,366

We have estimated the effect on our investment portfolio of a hypothetical increase in interest rates by one percent to be a reduction of $0.9 million in the fair value of our investments as of September 30, 2012. In addition, a hypothetical decrease of 10% in the effective yield of our investments would reduce our expected investment income by less than $0.1 million over the next twelve months based on our investment balance at September 30, 2012.

Foreign Currency Risk

Most of our revenues and 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, 2012, primarily related to contract manufacturing and ex-U.S. clinical trial activities, and we expect to continue to do so. Our primary exposure is to fluctuations in the Euro and British Pound. We do not anticipate that foreign currency transaction gains or losses will be significant at our current level of operations. However, transaction gains or losses may become significant in the future as we continue to expand our operations internationally. We have not engaged in foreign currency hedging to date; however, we may do so in the future.

Item 4. Controls and Procedures

(a) *Evaluation of disclosure controls and procedures.* Our management, with the participation of 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, our Chief Executive Officer and our Chief Financial Officer 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, 2012 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, 2011, filed with the SEC.

Risks Related to Our Business

Our near-term prospects are substantially dependent on ADCETRIS. If we and/or Millennium 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.*

In August 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:

- the market penetration rate of ADCETRIS may be lower, or the duration of therapy in patients in ADCETRIS two approved indications may be shorter, than our projections;
- 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;
- the estimated incidence and prevalence of patients in ADCETRIS two approved indications is limited and may be lower than our projections;
- 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;
- we have limited experience in marketing, selling and distributing ADCETRIS;

ADCETRIS may receive adverse reimbursement and coverage policies from government and private payers such as Medicare, Medicaid, insurance companies, health maintenance organizations and other plan administrators;

the relative price of ADCETRIS may be higher than alternative treatment options;

there may be changed or increased regulatory restrictions;

there may be additional changes to the label for ADCETRIS, including the boxed warning, 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 or our estimates of the incidence and prevalence of patients in such indications is incorrect, 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 world. The success of this collaboration and the activities of Millennium will significantly impact the potential commercialization of

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ADCETRIS in countries other than the United States and in Canada. On October 31, 2012, Millennium announced that it had received conditional marketing authorization for ADCETRIS from the European Commission for two indications: (1) the treatment of adult patients with relapsed or refractory CD30-positive Hodgkin lymphoma following ASCT or following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option, and (2) the treatment of adult patients with relapsed or refractory sALCL. Conditional marketing authorization by the European Commission includes obligations to provide additional clinical data at a later stage to confirm the positive benefit-risk balance. Although Millennium received conditional marketing authorization from the European Commission, we cannot control the amount and timing of resources that Millennium dedicates to the commercialization of ADCETRIS, or to its marketing and distribution, and our ability to generate revenues from ADCETRIS product sales by Millennium depends on Millennium s ability to achieve market acceptance of, and to otherwise effectively market, ADCETRIS for its approved indications in its territory.

We are also planning to develop ADCETRIS for potential use as a single agent and in combination therapy regimens earlier in the treatment of Hodgkin lymphoma and mature T-cell lymphoma, or MTCL, and in a range of CD30-positive 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 jurisdictions other than the United States and the European Union. We and Millennium also recently announced that we formed a collaboration with Ventana Medical Systems, Inc., or Ventana, under which Ventana will develop, manufacture and commercialize a molecular companion diagnostic test with the goal of identifying patients who might respond to treatment with ADCETRIS based on CD30 expression levels in their tissue specimens. However, Ventana may not be able to successfully develop a molecular companion diagnostic that may be required by regulatory authorities to support regulatory approval of ADCETRIS in other CD30-positive malignancies in a timely manner or at all. Even if we and Millennium receive the required regulatory approvals to market ADCETRIS for any additional indications or in additional jurisdictions, we and Millennium may not be able to successfully commercialize ADCETRIS, including for the reasons set forth above.

Our operating results are difficult to predict 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 may fluctuate significantly from quarter to quarter and year to year. Due to the recent approval by the FDA of ADCETRIS in its two indications and the limited amount 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. As a result, although we may provide sales guidance from time to time, such guidance is based on assumptions that may be incorrect or that may change from quarter to quarter. Sales of ADCETRIS have in the past been below the expectations of securities analysts and investors, and sales of ADCETRIS in the future may be below prior period sales, our own guidance and/or the expectations of securities analysts and investors. To the extent that we do not meet our guidance or the expectations of analysts or investors, our stock price may be adversely impacted, perhaps significantly. We believe that our quarterly and annual results of operations may be affected by a variety of factors, including:

- the level of demand and duration of therapy 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;
- changes in the amount of deductions from gross sales, including government-mandated rebates, chargebacks and discounts that can vary due to different levels of utilization by entities entitled to government rebates and discounts and changes in patient demographics;
- changes in our cost of sales, including but not limited to an increase in our cost of sales as a percentage of sales in future periods as product manufactured prior to FDA approval, and therefore fully expensed, is consumed;
- 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

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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 sales of ADCETRIS, collaboration and license agreement revenues, royalty revenues, or future profits or losses. As a result, our operating results in future periods could be below our guidance or the expectations of securities analysts or investors, which could cause the trading price of our common stock to decline, perhaps substantially.

Reports of adverse events or safety concerns involving ADCETRIS or our product candidates could delay or prevent us from obtaining or maintaining regulatory approval, or could negatively impact sales of ADCETRIS.*

Reports of adverse events or safety concerns involving ADCETRIS and our product candidates could interrupt, delay or halt clinical trials of ADCETRIS and our product candidates, including the FDA-required ADCETRIS post-approval confirmatory studies as well as the post-approval confirmatory studies that Millennium is required to conduct as a condition to the conditional marketing authorization of ADCETRIS by the European Commission. In addition, reports of adverse events or safety concerns involving ADCETRIS could result in the FDA or European or other regulatory authorities denying or withdrawing approval of ADCETRIS for any or all indications, including the use of ADCETRIS for the treatment of patients in its approved indications. We cannot assure you that patients receiving ADCETRIS or any of our product candidates will not experience serious adverse events in the future.

Adverse events may also negatively impact the sales of ADCETRIS. We may also be required to further update the ADCETRIS package insert based on reports of adverse events or safety concerns or implement a Risk Evaluation and Mitigation Strategy, which could adversely affect ADCETRIS acceptance in the market, make competition easier or make it more difficult or expensive for us to distribute ADCETRIS. For example, in January 2012, we announced that the prescribing information for ADCETRIS had been updated to include the following updated information: (1) a boxed warning related to the risk that JC virus infection resulting in progressive multifocal leukoencephalopathy, or PML, and death can occur in patients receiving ADCETRIS, (2) a discussion in the PML warning and precaution provision regarding other possible contributing factors to PML such as other prior therapies and underlying disease, symptoms to be aware of and suggested methodologies for diagnosis of PML, and (3) a contraindication warning of the concomitant use of ADCETRIS and bleomycin due to pulmonary toxicity.

The target patient population for ADCETRIS two approved indications is small, has not been definitively determined and may turn out to be lower than expected, which could adversely affect our ability to achieve profitability in the future.

The incidence and prevalence of patients in ADCETRIS two approved indications has not been definitively determined, but we believe the number of patients in ADCETRIS two approved indications is relatively low. The number of such patients in the United States may turn out to be lower than expected or may not otherwise be amenable to treatment with ADCETRIS, all of which would adversely affect our results of operations and our ability to achieve profitability. Further, 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 could 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 if such requirements are not met.*

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 serious or life threatening illnesses based on a surrogate endpoint or on a clinical endpoint other than survival or irreversible morbidity. 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 approval of ADCETRIS, 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. Similarly, the recent conditional marketing authorization of ADCETRIS for the two indications by the European Commission includes obligations to provide additional clinical data at a later stage to confirm the positive benefit-risk balance. Millennium s failure to provide this additional clinical data or to confirm the positive benefit-risk balance, could result in the European Commission withdrawing approval of ADCETRIS in the European Union, which would negatively impact anticipated royalty revenue from ADCETRIS sales by Millennium in the European Union and could adversely affect our results of operations.

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.

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.

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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 established a sales and marketing organization for 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. 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 whether our customers will receive adequate reimbursement for ADCETRIS.

Government and other third-party payers increasingly are attempting to contain healthcare 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.

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 healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act and HIPAA/HITECH. 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.

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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.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters and was amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information.

In order to comply with these laws, we have implemented a comprehensive compliance program to actively identify, prevent and mitigate risk through the implementation of compliance policies and systems and by promoting a culture of compliance. Although we take our obligation to maintain our compliance with these various laws and regulations seriously and our compliance program is designed to prevent 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 for 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. Although we are commercializing 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 in relatively early stages of development, and it is possible that none of these 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 and SGN-CD33A. 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, during 2011 we announced that we had discontinued the development of dacetuzumab and SGN-70 to focus our efforts on our pipeline of ADC product candidates, and we previously discontinued our lintuzumab development program following negative clinical trial results. As a result of the uncertain and time-consuming clinical development and regulatory approval process, we may not successfully develop any of our product candidates and it is possible that none of our 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 or develop ADCETRIS for additional indications.

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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 payers 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, which we cannot control. 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 or to market and sell ADCETRIS for additional indications, we must demonstrate, through extensive preclinical studies and clinical trials, that the product or 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, ASG-22ME, or our future product candidates, 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, including ADCETRIS for additional indications, 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.

If we or our collaborators are not able to obtain or maintain required regulatory approvals, we or our collaborators will not be able to commercialize our product candidates.*

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. Neither we nor our collaborators are permitted to market our product candidates in the United States or foreign countries until we obtain marketing approval from the FDA or other foreign regulatory authorities, and we or our collaborators may never receive regulatory approval for the commercial sale of any of our product candidates. In addition, part of our strategy is to continue to explore the use of ADCETRIS earlier in the treatment of Hodgkin lymphoma and MTCL and in other CD30-positive malignancies, and we are currently conducting multiple clinical trials for ADCETRIS. However, we and/or Millennium may be unable to obtain or maintain any regulatory approvals for the commercial sale of ADCETRIS for any additional indications. Obtaining marketing approval is a lengthy, expensive and uncertain process and approval is never

assured, and we have only limited experience in preparing and submitting the applications necessary to gain regulatory approvals. Further, the FDA and other foreign regulatory agencies have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for any product candidate we develop, including any regulatory approvals for the potential commercial sale of ADCETRIS in additional indications or in any additional territories. In this regard, even if we believe the data collected from clinical trials of ADCETRIS and our other product candidates are promising, such data may not be sufficient to support approval by the FDA or any other foreign regulatory authority. In addition, the FDA or their advisors may disagree with our interpretations of data from preclinical studies and clinical trials. Moreover, even though certain of our clinical trials, including our two phase III clinical trials of ADCETRIS that we are conducting with Millennium, are being or may be conducted under a special protocol assessment, or SPA, with the FDA, a SPA with the FDA is not a guarantee or indication of approval, and we cannot be certain that the design of, or data collected from, any of our current or potential future clinical trials that are being conducted under SPAs with the FDA will be sufficient to support FDA approval. Further, a SPA agreement is not binding on the FDA if public health concerns unrecognized at the time the SPA agreement is entered into become evident, other new scientific concerns regarding product safety or efficacy arise, new drugs are approved in the same indication, or if we have failed to comply with the agreed upon trial protocols. In addition, a SPA agreement may be changed by us or the FDA on written agreement of both parties, and the FDA retains significant latitude and discretion in interpreting the terms of a SPA agreement and the data and results from the applicable clinical trial. Regulatory agencies also may approve a product candidate for fewer indications than requested or may grant approval subject to the performance of post-approval studies or risk evaluation and mitigation strategies for a product candidate. Similarly, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates, including with respect to the potential commercialization of ADCETRIS in additional indications.

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

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 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;

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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 occur in later-stage clinical trials. For example, during 2011 we 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. The FDA has since approved changes to the ADCETRIS label to add a contraindication warning relating to the concomitant use of ADCETRIS and bleomycin due to pulmonary toxicity. 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. For example, 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, or OBT.

Under certain conditions, our collaborators may terminate their agreements with us and discontinue use of our technologies. For example, in December 2009, Genentech notified us that it had elected to terminate our collaboration agreement for dacetuzumab. If we had decided to continue the development of dacetuzumab, we would have been responsible for funding any further dacetuzumab development and clinical trial activities. In addition, we cannot control the amount and timing of resources our collaborators may devote to products incorporating our technology. Moreover, our relationships with our collaborators divert significant time and effort of our scientific staff and management team and require effective allocation of our resources to multiple internal and collaborative projects. Our collaborators may separately pursue competing products, therapeutic approaches or technologies to develop treatments for the diseases targeted by us or our collaborators. Even if our collaborators continue their contributions to the collaborative arrangements, they may nevertheless determine not to actively pursue the development or commercialization of any resulting products. Our collaborators may fail to perform their obligations under the collaboration agreements or may be slow in performing their obligations. If any of our collaborators terminate or breach our agreements with them, or otherwise fail to complete their obligations in a timely manner, it may have a detrimental effect on our financial position by reducing or eliminating the potential for us to receive technology access and license fees, milestones and royalties, reimbursement of development costs, as well as possibly requiring us to devote additional efforts and incur costs associated with pursuing internal development of product candidates. In particular, if Millennium were to terminate the 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.

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

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA, became law in the U.S. PPACA substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Among the provisions of PPACA of greatest importance to the pharmaceutical industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, beginning in 2011;
- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;
- extension of manufacturers Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, effective March 23, 2010;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in April 2010 and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing manufacturers Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program, effective in January 2010;
- new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting any transfer of value made or distributed to prescribers and other healthcare providers, beginning in 2013, and reporting any investment interests held by physicians and their immediate family members during the preceding calendar year;
- a licensure framework for follow-on biologic products; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

The United States Supreme Court heard a constitutional challenge to the PPACA and in June 2012 held that the PPACA is constitutional. However, states are allowed to opt out of the expansion of eligibility criteria for Medicaid under the PPACA. We anticipate that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and an additional downward pressure on the price that we receive for any approved product, which may harm our business. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Insurers may also refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals. In addition, although ADCETRIS is approved in two indications in the European Union, European government austerity measures or further healthcare reform measures in the European Union could adversely affect demand and pricing for ADCETRIS, which would negatively impact anticipated royalty revenue from ADCETRIS sales by Millennium in the European Union.

We also cannot be certain that ADCETRIS or any other products that may result from our product candidates will successfully be placed on the list of drugs covered by particular health plan formularies, nor can we predict the negotiated price for such products, which will be determined by market factors. Many states have also created preferred drug lists and include drugs on those lists only when the manufacturers agree to pay a

supplemental rebate. If ADCETRIS or other products that may result from our product candidates are not included on these preferred drug lists, physicians may not be inclined to prescribe it to their patients, thereby diminishing the potential market for such products. Millennium also faces similar pricing and reimbursement restrictions with respect to sales of ADCETRIS in the European Union which could limit the amount of royalty revenue we receive from ADCETRIS sales by Millennium in the European Union.

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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, most of our revenue has resulted from payments made under agreements with our corporate collaborators, and although ADCETRIS sales currently comprise a greater proportion of our revenue, we expect that a portion of our revenue will continue to come from corporate collaborations. 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 through a limited number of pharmaceutical distributors. Healthcare providers order ADCETRIS through these distributors. We receive orders from distributors and ship product directly to the healthcare provider. We do not promote ADCETRIS to these distributors and they do not set or determine demand for ADCETRIS; however, 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 relatively short notice, the loss of a major distributor could materially and adversely affect our results of operations and financial condition.

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 supply. For ADCETRIS and other ADCs, several contract manufacturers, including SAFC, supply us with drug-linker and other contract manufacturers, including Piramal, perform conjugation of the drug-linker to the antibody. 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 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.

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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 in the future 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.

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, SGN-CD19A, and SGN-CD33A 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, Pfizer and Progenics, and our co-development agreements with Agensys, Genmab, and OBT. Although ADCETRIS has received marketing approval in the United States and in the European Union, 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, conduct required post-approval, and other clinical studies of ADCETRIS, and position our other product candidates for potential regulatory approval and commercial sale. Although some of these expenditures related to ADCETRIS are expected to be shared with Millennium, and we expect to offset some of these costs with sales proceeds of ADCETRIS, we may need to raise significant amounts of additional capital. In addition, we may require significant additional capital in order to acquire additional technologies, products or companies. 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, including with respect to the continued deterioration in the creditworthiness of Eurozone countries, which, along with current economic conditions, may make it more difficult for us to raise equity and

debt financing when we need it.

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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 post-approval 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 Canada and in additional indications, including the preparation for potential commercialization in Canada and in additional indications;
- the size, complexity, timing, and number of our clinical programs;
- the timing, receipt and amount of milestone-based payments or other revenue from our collaborations or license arrangements, including royalty revenue generated from commercial sales of ADCETRIS by Millennium;
- 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 technologies, products, or companies, including licenses we may need to commercialize our products;
- the terms and timing of any future collaborative, licensing and other arrangements that we may establish;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- the potential costs associated with state and federal taxes;
- the timing and cost of milestone payment obligations as our product candidates progress towards commercialization; and
- competing technological and market developments.

In addition, changes in our business may occur that would consume available capital resources sooner than we expect. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration and licensing arrangements, we may be required to relinquish some rights to our technologies or product candidates,

or grant licenses on terms that are not favorable to us.

We rely on license agreements for certain aspects of 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, 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. Further, we may have disputes with our licensors, which may impact our ability to develop and commercialize ADCETRIS and our product candidates or require us to enter into additional licenses. For example, we have filed for declaratory relief against one of our licensors with respect to the use of our proprietary drug conjugation technologies and they have made additional claims against us related to our use of these technologies. An adverse result in this dispute, or other potential future disputes with our licensees, may impact our ability to develop and commercialize ADCETRIS, our product candidates and our ADC technology, or may require us to enter into additional licenses or to incur additional costs. 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 and Bristol-Myers Squibb, among others. In addition, we have licensed our U.S. and foreign patents and patent applications to third parties.

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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. Some provisions of the Leahy-Smith Act are currently in force and some will not become effective until 18 months after its enactment. These include provisions that affect the way patent applications are currently, or will be, prosecuted and the way patents are, or will be, challenged in the United States Patent and Trademark Office, and some of these provisions also affect patent litigation. The United States Patent and Trademark Office is currently developing regulations and procedures to govern the full implementation 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 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, academic institutions or others 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 organizations 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 administrative proceeding in the United States and elsewhere. These proceedings are costly and time consuming. Successful challenges to our patent or other intellectual property rights through these proceedings could result in a loss of rights in the relevant jurisdiction 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. 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.

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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. *

With respect to ADCETRIS, there are currently no FDA-approved drugs other than ADCETRIS for the treatment of relapsed Hodgkin lymphoma or specifically indicated for relapsed sALCL; however, Celgene s Istodax and Spectrum Pharmaceuticals Folotyn are both approved for relapsed or refractory PTCL and we are aware of multiple investigational agents that are currently being studied, including Pfizer s crizotinib and Millennium s alistertib, which, if successful, may compete with ADCETRIS in the future. In addition, there are many existing approaches used in the treatment of patients in ADCETRIS two approved indications, including ASCT, combination chemotherapy, clinical trials with experimental agents and single agent regimens, which represent competition for ADCETRIS.

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 Amgen, Aventis, Bayer, Biogen IDEC, Bristol-Myers Squibb, Celgene, Eisai, Genentech, GSK, Gilead, ImmunoGen, Merck, Millennium, Novartis, Pfizer, Pharmacyclics, Sanofi-Aventis, Spectrum Pharmaceuticals, and Teva 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 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 or interrupt the sales process for ADCETRIS. 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 or the coordination of our sales activities, 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 may cause a material disruption in our business if we are not capable of restoring function on an acceptable timeframe.

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.

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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 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 and long-term investments and our ability to fund our planned operations.*

Our cash, cash equivalents and investments are held in a variety of 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, commercial paper, bank checking accounts and money market accounts. As a result of the uncertain global credit and financial market conditions, investments in some financial instruments pose risks arising from liquidity and credit concerns. Given that future deterioration in the global credit and financial markets is a possibility, no assurance can be made that losses or other significant deterioration in the fair value of our cash equivalents or investments will not occur. If any such losses or other significant deteriorations occur, it may negatively impact or impair our current portfolio of cash equivalents and investments and our ability to fund our planned operations. Further, unless and until current global credit and financial market conditions have sufficiently improved, it may be difficult for us to generate a return on our investments or 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 2012, our closing stock price fluctuated between $23.87 and $29.68 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 and in the European Union;
- 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 post-approval 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 and/Millennium are conducting or may in the future conduct for ADCETRIS, including the post-approval confirmatory studies that Millennium is required to conduct as a condition to the conditional marketing authorization of ADCETRIS by the European Commission;
- announcements regarding, or negative publicity concerning, adverse events associated with the use of ADCETRIS and our product candidates;
- issuance of new or changed analysts reports and recommendations regarding us or our competitors;

announcements of FDA or foreign regulatory approval or non-approval of our product candidates, including ADCETRIS, or specific label indications for or restrictions, warnings or limitations in its use, or delays in the regulatory 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;

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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 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 62.6 percent of our voting power as of November 1, 2012. 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.

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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(1)	Investor Rights Agreement dated July 8, 2003 among Seattle Genetics, Inc. and certain of its stockholders.
31.1+	Certification of Chief Executive Officer pursuant to Rule 13a-14(a).
31.2+	Certification of Chief Financial Officer pursuant to Rule 13a-14(a).
32.1+	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.
32.2+	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350.
101.INS+(5)	XBRL Instance Document
101.SCH+(5)	XBRL Taxonomy Extension Schema Document.
101.CAL+(5)	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF+(5)	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB+(5)	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE+(5)	XBRL Taxonomy Extension Presentation Linkbase Document.

+ Filed or furnished herewith.

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

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

(3) Previously filed as an exhibit to the Registrant s quarterly report on Form 10-Q for the quarter ended June 30, 2003 filed with the Commission on August 12, 2003 (File No. 333-50266) and incorporated herein by reference.

(4) Previously filed as an exhibit to the Registrant s registration statement on Form S-1 (File No. 333-50266) originally filed with the Commission on November 20, 2000, as subsequently amended, and incorporated herein by reference.

(5) 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.

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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 7, 2012

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