SEATTLE GENETICS INC /WA
Form 10-Q
November 08, 2013
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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, 2013

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 5, 2013, there were 122,481,320 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, 2013

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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, 2013	December 31, 2012
Assets		
Current assets		
Cash and cash equivalents	$ 119,529	$ 54,663
Short-term investments	254,319	309,595
Interest receivable	220	893
Accounts receivable, net	29,208	33,443
Inventories	26,004	37,747
Prepaid expenses and other current assets	5,700	4,519
Total current assets	434,980	440,860
Property and equipment, net	37,229	24,752
Other non-current assets	5,421	5,810
Total assets	$ 477,630	$ 471,422
Liabilities and Stockholders Equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 56,611	$ 56,130
Current portion of deferred revenue	43,026	44,447
Total current liabilities	99,637	100,577
Long-term liabilities		
Deferred revenue, less current portion	138,092	138,767
Deferred rent and other long-term liabilities	5,521	5,930
Total long-term liabilities	143,613	144,697
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; 122,469 shares issued and outstanding at September 30, 2013 and 119,710 shares issued and outstanding at December 31, 2012	122	120
Additional paid-in capital	948,842	893,773
Accumulated other comprehensive income	47	37
Accumulated deficit	(714,631)	(667,782)

Total stockholders equity	234,380	226,148
Total liabilities and stockholders equity	$ 477,630	$ 471,422

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		Nine months ended	
	September 30,		September 30,	
	2013	2012	2013	2012
Revenues				
Net product sales	$ 36,485	$ 33,658	$ 106,141	$ 102,845
Collaboration and license agreement revenues	29,234	14,476	84,525	41,119
Royalty revenues	5,250	1,698	11,189	2,936
Total revenues	70,969	49,832	201,855	146,900
Costs and expenses				
Cost of sales	3,528	2,742	10,008	8,808
Cost of royalty revenues	1,927	613	4,299	1,115
Research and development	67,847	41,392	167,855	122,634
Selling, general and administrative	21,451	18,842	66,873	60,889
Total costs and expenses	94,753	63,589	249,035	193,446
Loss from operations	(23,784)	(13,757)	(47,180)	(46,546)
Investment and other income, net	98	105	331	3,360
Net loss	$ (23,686)	$ (13,652)	$ (46,849)	$ (43,186)
Net loss per share basic and diluted	$ (0.19)	$ (0.12)	$ (0.39)	$ (0.37)
Shares used in computation of net loss per share basic and diluted	121,990	118,471	121,260	117,361
Comprehensive loss:				
Net loss	$ (23,686)	$ (13,652)	$ (46,849)	$ (43,186)
Other comprehensive gain (loss) unrealized gain (loss) on securities available for sale	47	50	10	(7)
Comprehensive loss	$ (23,639)	$ (13,602)	$ (46,839)	$ (43,193)

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,	
	2013	**2012**
Operating activities		
Net loss	$ (46,849)	$ (43,186)
Adjustments to reconcile net loss to net cash used in operating activities		
Share-based compensation expense	21,617	17,909
Depreciation and amortization	6,057	4,562
Amortization of premiums, accretion of discounts and gain on investments	1,530	1,770
Deferred rent and other long-term liabilities	(409)	(175)
Changes in operating assets and liabilities		
Interest receivable	673	(855)
Accounts receivable, net	4,235	19,799
Inventories	11,743	(24,827)
Prepaid expenses and other current assets	(1,181)	(876)
Accounts payable and accrued liabilities	(2,683)	(10,523)
Deferred revenue	(2,096)	(2,915)
Net cash used in operating activities	(7,363)	(39,317)
Investing activities		
Purchases of securities available for sale	(340,443)	(346,394)
Proceeds from maturities of securities available for sale	394,200	317,851
Proceeds from sales of securities available for sale	0	10,825
Purchases of property and equipment	(14,793)	(4,679)
Purchases of other non-current assets	(189)	0
Net cash provided by (used in) investing activities	38,775	(22,397)
Financing activities		
Proceeds from exercise of stock options and employee stock purchase plan	33,454	29,011
Net cash provided by financing activities	33,454	29,011
Net increase (decrease) in cash and cash equivalents	64,866	(32,703)
Cash and cash equivalents at beginning of period	54,663	87,634
Cash and cash equivalents at end of period	$ 119,529	$ 54,931

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, 2012 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, 2012, 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, 2013 are not necessarily indicative of the results to be expected for the full year.

Non-cash investing activities

The Company had $3.2 million of accrued capital expenditures as of September 30, 2013. This amount has been treated as a non-cash investing activity and, accordingly, has not been included in the statement of cash flows for the nine month period ended September 30, 2013.

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

The Company sells ADCETRIS through a limited number of pharmaceutical distributors in the U.S. and Canada. Customers order ADCETRIS through these distributors and the Company typically ships product directly to the customer. The Company records product sales when title and risk of loss pass, which generally occurs upon delivery of the product to the customer. Product sales are recorded net of estimated government-mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions. Accruals are established for these deductions and actual amounts incurred are offset against applicable accruals. The Company reflects these accruals 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 deductions are based on management s estimates that consider payer mix in target markets, industry benchmarks and experience to date. These estimates involve a substantial degree of judgment.

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 estimates Medicaid rebates based on a third party study of the payer mix for ADCETRIS, information on utilization by Medicaid-eligible patients who received assistance through SeaGen Secure®, the Company s patient assistance program, and experience to date. The Company has also completed a Federal Supply Schedule, or FSS, agreement under which certain U.S. government purchasers receive a discount on eligible purchases of ADCETRIS. The Company has entered into a Pharmaceutical Pricing Agreement with the Secretary of Health and Human Services, which enables certain 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 applicable discounted price. 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 historical rebate and chargeback information to further refine these estimates.

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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 which is determined based on sales volume 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 estimates product returns based on its experience to date and historical industry information of return rates for other specialty pharmaceutical products. In addition, the Company considers 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 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 under SeaGen Secure are deducted from gross sales and are based on an analysis of expected plan utilization. These estimates are adjusted as necessary to reflect the Company s actual experience.

Collaboration and license agreement revenues

The Company licenses its intellectual property to third parties that use the intellectual property to develop product candidates. If there are continuing performance obligations, the Company uses a time-based proportional performance model to recognize revenue over the Company s performance period for the related agreement. 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. 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 development period used in each agreement is a reasonable estimate of the performance obligation period of such agreement. Accordingly, all amounts received or due, including any upfront payments, maintenance fees, development and regulatory 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. When no performance obligations are required of the Company, or following the completion of the performance obligation period, such amounts will be recognized as revenue when collectibility is reasonably assured.

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 the suitability 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 1 clinical trial. Generally, phase 1 clinical trials may take one to two years to complete.

Initiation or completion of a phase 2 clinical trial. Generally, phase 2 clinical trials may take one to three years to complete.

Initiation or completion of a phase 3 clinical trial. Generally, phase 3 clinical trials may take two to six years to complete.

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 may take 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 may take 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, Europe, Japan or rest-of-world countries.

Product sales in excess of a pre-specified threshold. 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 proprietary technologies for linking cytotoxic agents to monoclonal antibodies called antibody-drug conjugates, or ADCs. These proprietary technologies are 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 typically provides technology transfer services, technical advice, supplies and services for a period of time of between two and fourteen years,

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depending on the terms of each agreement. 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 ADCETRIS collaboration with Millennium: the Takeda Oncology Company, or Takeda, the Company may be involved in certain development activities; however, the achievement of milestone events under the agreement is based on activities undertaken by Takeda.

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 Takeda, 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 and licensees 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 Takeda. Royalties are based on a percentage of Takeda s net sales in its territory at rates that range from the mid-teens to the mid-twenties based on sales volume. Takeda bears a portion of third party royalty costs owed on sales of ADCETRIS in its territory. This amount is included in royalty revenue in the Company s consolidated financial statements. Cost of royalty revenues reflects amounts owed to the Company s third party licensors related to the sale of ADCETRIS in Takeda s territory. These amounts are recognized in the quarter in which Takeda reports its sales activity to the Company, which is the quarter following the related sales.

Recent Accounting Pronouncements

In February 2013, the Financial Accounting Standards Board, or FASB, issued ASU 2013-2 Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income that revises the disclosure requirements related to significant reclassifications of items out of accumulated other comprehensive income and into the line items included in net income. The Company adopted this standard in the first quarter of 2013 and its adoption did not impact the Company s consolidated financial statements.

In July 2013, the FASB issued ASU 2013-11 Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists that provides for disclosure requirements related to unrecognized tax benefits in certain situations. The Company will adopt this standard in the first quarter of 2014 and does not expect the adoption of this standard to have an impact on its consolidated financial statements.

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 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. The weighted-average number of restricted stock units and options to purchase common stock that have been excluded from the number of shares used to calculate basic and diluted net loss per share totaled 11,511 and 13,104 for the three months ended September 30, 2013 and 2012, and 11,678 and 13,513 for the nine months ended September 30, 2013 and 2012, respectively (amounts in thousands).

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3. Short-term Investments

Short-term investments consisted of available-for-sale securities as follows (in thousands):

	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
September 30, 2013				
U.S. Treasury securities	$ 254,272	$ 47	$ (0)	$ 254,319
Contractual Maturities				
Due in one year or less	$ 254,272			$ 254,319

	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
December 31, 2012				
U.S. Treasury securities	$ 309,558	$ 42	$ (5)	$ 309,595
Contractual Maturities				
Due in one year or less	$ 309,558			$ 309,595

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

	Period of continuous unrealized loss			
	12 Months or less		Greater than 12 months	
	Fair value	Gross unrealized losses	Fair value	Gross unrealized losses
September 30, 2013				
U.S. Treasury securities	$ NA	$ NA	$ NA	$ NA
December 31, 2012				
U.S. Treasury securities	$ 76,015	$ (5)	$ 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. The Company did not hold any Level 2 or 3 investments as of December 31, 2012 or September 30, 2013 and did not transfer any investments between Levels 1, 2 and 3 during the nine month period ended September 30, 2013.

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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, 2013				
Short-term investments U.S. Treasury securities	$ 254,319	$ 0	$ 0	$ 254,319

	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, 2012				
Cash equivalents U.S. Treasury securities	$ 10,016	$ 0	$ 0	$ 10,016
Short-term investments U.S. Treasury securities	309,595	0	0	309,595
Total	$ 319,611	$ 0	$ 0	$ 319,611

5. Inventories

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

	September 30, 2013	December 31, 2012
Raw materials	$ 24,515	$ 32,293
Work in process	106	4,605
Finished goods	1,383	849
Total	$ 26,004	$ 37,747

The Company capitalizes ADCETRIS inventory costs. 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. The Company does not capitalize manufacturing costs for any of its other product candidates.

6. Legal Matters

In the normal course of its business, the Company may become involved in various legal proceedings. The Company does not expect any current legal proceedings to have a material adverse effect on the Company s business. Legal fees incurred as a result of our involvement in legal proceedings are expensed as incurred.

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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. We discuss many of these risks, uncertainties and other factors in this Quarterly Report on Form 10-Q in greater detail under the heading Item 1A Risk Factors. 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. Our marketed product ADCETRIS®, or brentuximab vedotin, received accelerated approval in the United States in August 2011 and approval with conditions in Canada in February 2013 for patients with relapsed Hodgkin lymphoma or relapsed systemic anaplastic large cell lymphoma, or sALCL. 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 or mature T-cell lymphoma, or MTCL, and in other CD30-positive malignancies. In July 2013 we received notification from the U.S. Food and Drug Administration, or FDA, regarding a supplemental Biologics License Application, or sBLA, that we submitted in March 2013. The 16-cycle limitation on duration of use of ADCETRIS was removed from the U.S. prescribing information as a result of this sBLA. However, a requested label claim for retreatment that we submitted as part of the sBLA was not approved.

We are collaborating with Millennium: the Takeda Oncology Company, or Takeda, to develop and commercialize ADCETRIS on a global basis. Under this collaboration, Seattle Genetics has retained commercial rights for ADCETRIS in the United States and its territories and in Canada, and Takeda has commercial rights in the rest of the world. ADCETRIS was granted conditional marketing authorization in the European Union in October 2012 for patients with relapsed Hodgkin lymphoma or relapsed sALCL. Takeda has also received and continues to pursue marketing approvals in multiple other countries. In addition, we have five clinical-stage ADC programs, which consist of SGN-CD19A, SGN-CD33A, SGN-LIV1A, ASG-22ME, and ASG-15ME. We recently determined to discontinue development of SGN-75, an ADC targeted to CD70; however, we plan to advance a novel ADC that also targets CD70, SGN-CD70A, into phase 1 clinical development during 2014. We also have collaborations for our ADC technology with a number of biotechnology and pharmaceutical companies, including AbbVie Biotechnology Ltd. (formerly part of Abbott Laboratories), or AbbVie; Bayer Pharma AG, 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; Pfizer, Inc., or Pfizer, PSMA Development Company LLC, a subsidiary of Progenics Pharmaceuticals Inc., or Progenics; and Takeda; 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.

The commercial potential of ADCETRIS and the ability to realize that potential by us and Takeda remains uncertain. Our success in commercializing ADCETRIS will require, among other things, effective sales, marketing, manufacturing, distribution, information systems and pricing strategies, our ability to demonstrate in the medical community the safety and efficacy of ADCETRIS and its potential advantages, and our ability to comply with applicable laws and regulations. Our success could be unfavorably impacted by adverse events or competition. 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 are exploring the use of ADCETRIS in earlier lines of therapy in patients with Hodgkin lymphoma and MTCL, including sALCL, and in other CD30-positive malignancies. In order to do this, we are required to conduct additional extensive clinical studies and, if these studies are successful, we intend to seek additional regulatory approvals.

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We and Takeda are conducting four phase 3 clinical trials of ADCETRIS, one in relapsed Hodgkin lymphoma patients following autologous stem cell transplant, or ASCT, called the AETHERA trial, one in relapsed cutaneous T-cell lymphoma, or CTCL, called the ALCANZA trial, one in frontline advanced classical Hodgkin lymphoma, called the ECHELON-1 trial, and one in frontline MTCL, including sALCL, called the ECHELON-2 trial. The FDA has agreed to special protocol assessment, or SPA, agreements for the ALCANZA, ECHELON-1 and ECHELON-2 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 BLA submission to the FDA if the trial achieves its primary endpoints. The primary endpoint in the AETHERA trial is progression free survival versus placebo following ASCT. The primary end point in the ECHELON-1 and ECHELON-2 trials is progression free survival per independent review facility assessment in patients treated with ADCETRIS compared to that achieved with therapy in the control arm. The primary endpoint in the ALCANZA trial is overall response rate, lasting at least 4 months, in patients treated with ADCETRIS compared to that achieved with therapy in the control arm.

We have an agreement with Ventana Medical Systems, Inc., a member of the Roche Group, or Ventana, under which Ventana is working to 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. 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 recognize revenue from ADCETRIS product sales in the United States and Canada, we have only limited experience commercializing ADCETRIS and our future ADCETRIS product sales will be difficult to accurately predict from period to period. In this regard, our product sales may vary significantly from period to period and may be affected by a variety of factors, including customer ordering patterns, the level of demand for ADCETRIS, the duration of therapy for patients receiving ADCETRIS, and the extent to which coverage and reimbursement for ADCETRIS is available from government and other third-party payers, particularly in an increasingly challenging environment due to, among other things, the attention being paid to healthcare cost containment and other austerity measures in the U.S. and worldwide. In addition, we believe that our initial sales of ADCETRIS in the United States have depleted the prevalence pool of patients in its approved indications and therefore, our ongoing sales of ADCETRIS will be primarily dependent on the incidence rate of new patients who have recently failed earlier lines of cancer therapy and become eligible for ADCETRIS within the current approved indications. Accordingly, we believe that the level of our ongoing ADCETRIS sales in the United States is now largely subject to the incidence flow of patients eligible for treatment with ADCETRIS, which could vary significantly from period to period. Moreover, while the incidence rate of newly relapsing patients in ADCETRIS approved indications has not been definitely determined, we believe that the incidence rate is relatively low. For these and other reasons, we expect that future ADCETRIS sales growth, if any, will be primarily dependent on future price increases and our ability to expand the labeled indications of use. Our efforts to expand ADCETRIS labeled indications of use will require additional time and investment in clinical trials to complete and we may not be successful. Our ability to successfully commercialize ADCETRIS and to expand its labeled indications of use are subject to a number of risks and uncertainties, including those discussed in Part II, Item 1A of this Quarterly Report on Form 10-Q. 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, clinical and commercial milestones by our collaborators under our existing collaboration and license agreements, including, in particular, our ADCETRIS collaboration with Takeda, 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

For the nine months ended September 30, 2013, total revenues increased to $201.9 million, compared to $146.9 million for the same period in 2012. This increase was primarily due to growth in collaboration revenue. Net product sales of ADCETRIS were $106.1 million for the nine months ended September 30, 2013 compared to $102.8 million for the nine months ended September 30, 2012. For the nine months ended September 30, 2013, total costs and expenses increased to $249.0 million, compared to $193.4 million for the same period in 2012. This primarily reflects increases in ADCETRIS collaboration activities, including product supply to Takeda and

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clinical development efforts to explore additional potential applications of ADCETRIS, as well as investment in our ADC pipeline programs. As of September 30, 2013, we had $373.8 million in cash and short-term investments, and $234.4 million in total stockholders equity.

Results of operations

Three and nine months ended September 30, 2013 and 2012

Net product sales

We sell ADCETRIS in the U.S. and Canada. Our net product sales were as follows:

	Three months ended September 30,			Nine months ended September 30,		
	2013	2012	% Change	2013	2012	% Change
Net sales	$ 36,485	$ 33,658	8%	$ 106,141	$ 102,845	3%

The increases in net sales for the three and nine months ended September 30, 2013, over the comparable periods in 2012, were primarily due to a higher average selling price for ADCETRIS resulting from price increases that we instituted in January and July 2013. Sales volume in the three months ended September 30, 2013 increased slightly from the comparable period in 2012; however, sales volume for the nine month period ended September 30, 2013 was slightly lower than in the comparable period in 2012. We believe that the lower sales volume in the nine month period was primarily due to the depletion of the prevalence pool of patients in ADCETRIS approved indications and the transition to an incidence-based flow of patients eligible for treatment with ADCETRIS as discussed above. We sell ADCETRIS through a limited number of pharmaceutical distributors. Customers order ADCETRIS through these distributors and we typically ship product directly to the customer. We record product sales when title and risk of loss pass, which generally occurs upon delivery of the product to the customer. Product sales are recorded net of estimated government-mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions. Accruals are established for these deductions and actual amounts incurred are offset against applicable accruals. We reflect these accruals 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 deductions are based on our estimates that consider payer mix in target markets, industry benchmarks and experience to date. These estimates involve a substantial degree of judgment.

Government-mandated rebates and chargebacks: We have entered into a Medicaid Drug Rebate Agreement 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 estimate Medicaid rebates based on a third party study of the payer mix for ADCETRIS, information on utilization by Medicaid-eligible patients who received assistance through SeaGen Secure, our patient assistance program and experience to date. We also have completed our Federal Supply Schedule, or FSS, agreement under which certain U.S. government purchasers receive a discount on eligible purchases of ADCETRIS. We have entered into a Pharmaceutical Pricing Agreement with the Secretary of Health and Human Services which enables certain 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 applicable discounted price. 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 rebate and 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 which is determined based on sales volume 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 estimate product returns based on our experience to date and historical industry information of return rates for other specialty pharmaceutical products. In addition, we consider 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 under SeaGen Secure are deducted from gross sales. These contributions are based on an analysis of expected plan utilization. These estimates are adjusted as necessary to reflect our actual experience.

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We record product sales net of estimated government-mandated rebates and chargebacks, distribution fees, product returns and other deductions. These are generally referred to as gross-to-net deductions. Gross-to-net deductions, net of related payments and credits, are summarized as follows (in thousands):

	Rebates and chargebacks	Distribution fees, product returns and other	Total
Balance as of December 31, 2012	$ 4,131	$ 1,601	$ 5,732
Provision related to current period sales	14,338	2,604	16,942
Adjustment for prior period sales	(702)	(178)	(880)
Payments/credits for current period sales	(11,989)	(1,942)	(13,931)
Payments/credits for prior period sales	(827)	(656)	(1,483)
Balance as of September 30, 2013	$ 4,951	$ 1,429	$ 6,380

Deductions from gross sales increased in the 2013 periods over the comparable 2012 periods as a result of increased discounts attributable to government programs. We expect future gross-to-net discounts to fluctuate based on the volume of purchases eligible for government mandated discounts and rebates as well as changes in the discount percentage which is impacted by potential future price increases, the rate of inflation, and other factors.

Collaboration and license agreement revenues

We license our intellectual property to third parties that use the intellectual property to develop product candidates. If there are continuing performance obligations, we use a time-based proportional performance model to recognize revenue over our performance period for the related agreement. 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. 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 development period used in each agreement is a reasonable estimate of the performance obligation period of such agreement. Accordingly, all amounts received or due, including any upfront payments, maintenance fees, development and regulatory 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. When we have no further performance obligations or following the completion of the performance obligation period, such amounts will be recognized as revenue when collectibility is reasonably assured.

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 the suitability 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 1 clinical trial. Generally, phase 1 clinical trials may take one to two years to complete.

Initiation or completion of a phase 2 clinical trial. Generally, phase 2 clinical trials may take one to three years to complete.

Initiation or completion of a phase 3 clinical trial. Generally, phase 3 clinical trials may 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 BLA in the United States or a Marketing Authorization Application in Europe. Generally, it may take up to twelve months to prepare and submit regulatory filings.

Receiving marketing approval in a major market, such as in the United States, Europe, Japan or rest-of-world countries. Generally it may take 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, Europe, Japan or rest-of-world countries.

Product sales in excess of a pre-specified threshold. 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 technologies are the basis of our ADC collaborations that we have entered into in the ordinary course of business with a number of biotechnology and pharmaceutical companies. Under these ADC collaboration agreements, we grant our collaborators research and commercial licenses to our technology and typically provide technology transfer services, technical advice,

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supplies and services for a period of time of between two and fourteen years depending on the terms of each agreement. Our 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 our ADCETRIS collaboration with Takeda, we may be involved in certain development activities; however, the achievement of milestone events under the agreement is based on activities undertaken by Takeda.

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 associated with our ADC collaborations 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 Takeda, 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 and licensees 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. Any deferred revenue arising from amounts received in advance of the culmination of the earnings process 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)	**2013**	**2012**	**% Change**	**2013**	**2012**	**% Change**
Takeda	$ 16,188	$ 7,030	130%	$ 35,154	$ 20,623	70%
Agensys	248	738	(66%)	6,630	4,096	62%
Bayer	0	0	N/A	12,000	0	N/A
AbbVie	3,584	1,265	183%	11,508	3,866	198%
GSK	2,829	768	268%	5,758	2,322	148%
Genentech	1,096	3,045	(64%)	5,458	5,264	4%
Pfizer	5,000	1,126	344%	5,009	3,379	48%
Other	289	504	(43%)	3,008	1,569	92%
Total	$ 29,234	$ 14,476	102%	$ 84,525	$ 41,119	106%

Takeda

Revenues earned under our ADCETRIS and ADC collaborations with Takeda represented 55% and 49% of our collaboration and license agreement revenues during the three month periods ended September 30, 2013 and 2012, respectively, and 42% and 50% during the nine month periods ended September 30, 2013 and 2012, respectively. Revenues from Takeda increased over the comparable periods in 2012 as a result of increased activity related to the ADCETRIS collaboration including reimbursement for clinical trial and drug supply activities.

Under the ADCETRIS collaboration, we are entitled to receive progress-dependent milestone payments based on Takeda s achievement of certain events related to ADCETRIS for which Takeda is responsible, payment for product supplied to Takeda and development funding equal to 50% of joint development costs. 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 Takeda s licensed territories. Takeda also bears a portion of third party royalty costs owed on sales of ADCETRIS in its territory. Total future potential milestone payments to us under the ADCETRIS collaboration could total approximately $205 million. 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. To date, we have received $30 million in milestone payments related to the application acceptance and conditional marketing authorization of ADCETRIS by the European Commission.

We recognize as collaboration revenue the $60 million upfront collaboration payment, as well as other amounts earned to date, including regulatory milestones, product supply and net development cost reimbursements over the ten-year development period of the collaboration. We receive reimbursement funding from Takeda equal to one-half of the cost of joint development activities that are performed by us under the collaboration. We also receive reimbursement for the cost of drug product supplied to Takeda for its use at our cost, plus a markup. To the extent that Takeda performs development activities under the collaboration, our development cost

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reimbursement payments from Takeda are reduced by an amount equal to half of the costs incurred by Takeda. We expect that development activities performed by Takeda will continue to increase, including certain clinical trials of ADCETRIS, which will lead to a reduction in the level of net reimbursement funding that we receive from Takeda.

Agensys

We have entered into an agreement with Agensys to jointly research, develop and commercialize ADCs for cancer. 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-22ME and ASG-15ME, a program we opted into in June 2013. We and Agensys recently determined to discontinue development of ASG-5ME under our collaboration. Agensys has the right to develop and commercialize other ADC product candidates on its own, subject to paying us annual maintenance 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 are recognized as revenue.

Revenues attributable to the Agensys agreement decreased during the three month period ended September 30, 2013 from the comparable period in 2012 due to the completion of the research term in the second quarter of 2013. Revenues attributable to the Agensys agreement increased during the nine month period ended September 30, 2013 from the comparable period in 2012 due to a payment made to us in the second quarter of 2013 to exercise an exclusive license for an ADC product candidate and Agensys decision in the second quarter of 2013 not to extend the research term of the collaboration, which accelerated recognition of the remaining deferred revenue. Revenue attributable to the Agensys collaboration is expected to decline over the remainder of the year.

Other ADC collaboration agreements

We have other active ADC collaborations with a number of 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 typically 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. These amounts are recognized as revenue as they are achieved, or over the performance obligation period of the agreements during which we provide limited support to the collaborator, if any. As of September 30, 2013, our ADC collaborations had generated more than $235 million, primarily in the form of upfront payments. Total milestone payments provided for under our ADC collaborations as of September 30, 2013 could approximate up to $3.7 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 $1.5 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. 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.

In the aggregate, revenues from our other ADC collaboration agreements increased during the three and nine months ended September 30, 2013 from the comparable periods in 2012, primarily as a result of the expansion of the collaboration with AbbVie in October 2012 and an increase in the earned portion of license fees and milestones achieved by our ADC collaborators, including a milestone achieved by Pfizer in the three months ended September 30, 2013. The collaboration revenue increase during the nine months ended September 30, 2013 over the comparable period in 2012 was also driven by our entering into a new collaboration agreement with Bayer in June 2013.

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. 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 have a significant balance of

deferred revenue, representing prior payments from our collaborators that have not yet been recognized as revenue. This deferred revenue will be recognized as revenue in future periods using a time-based approach as we fulfill our performance obligations.

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Royalty Revenues and Cost of Royalty Revenues

Royalty revenues reflect amounts earned under the ADCETRIS collaboration with Takeda. Royalties are based on a percentage of Takeda s net sales in its territory at rates that range from the mid-teens to the mid-twenties based on sales volume. Takeda bears a portion of third party royalty costs owed on sales of ADCETRIS in its territory. This amount is included in our royalty revenue. In October 2012, Takeda began its commercial launch of ADCETRIS in the European Union upon receiving conditional marketing authorization from the European Commission for ADCETRIS in two indications. Takeda received regulatory approval in additional countries during 2013 and, where applicable, Takeda also made ADCETRIS available under its international named patient program. Cost of royalty revenues reflect amounts owed to our third party licensors related to the sale of ADCETRIS in Takeda s territory.

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 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 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 previously, is consumed. This cost benefit is expected to continue to some extent for at least the next twelve months, but is expected to decline based on when the components of the specific drug lots sold were produced. 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 low-to-mid teens. Cost of sales increased during both the three and nine month periods ended September 30, 2013 from the comparable periods in 2012 due to a higher average cost of product sold and increased sales volume during the three months ended September 30, 2013.

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)	**2013**	**2012**	**% Change**	**2013**	**2012**	**% Change**
Research	$ 5,921	$ 4,710	26%	$ 20,735	$ 12,158	71%
Development and contract manufacturing	34,168	15,046	127%	69,174	42,307	64%
Clinical	24,014	18,684	29%	68,123	59,791	14%
Share-based compensation expense	3,744	2,952	27%	9,823	8,378	17%
Total research and development expenses	$ 67,847	$ 41,392	64%	$ 167,855	$ 122,634	37%

Research expenses include, among other things, personnel, occupancy and laboratory expenses and technology access fees associated with the discovery and identification of new monoclonal antibodies and related technologies and the development of novel classes of stable linkers and cell-killing agents for our ADC technology. Research expenses also include research activities associated with our product candidates, such as preclinical translational biology and in vitro and in vivo studies. The increase in research expenses during the three and nine month periods ended September 30, 2013 as compared to the same periods in 2012 reflects increased discovery activities in support of growing our pipeline of product candidates. The nine month period ended September 30, 2013 also increased compared to the same period in 2012, reflecting an opt in fee we paid to Agensys to co-develop ASG-15ME.

Development and contract manufacturing expenses include personnel and occupancy expenses and external contract manufacturing costs for the scale up and pre-approval manufacturing of drug product used in research and our clinical trials and for drug product supplied to our collaborators. Development and contract manufacturing expenses also include quality control and assurance activities, and storage and shipment of our product candidates. The increase in development and contract manufacturing expenses in 2013 primarily reflects an increase in drug product provided to Takeda under the ADCETRIS collaboration. We are reimbursed for such product at cost, plus a mark-up. These

reimbursements are included in our collaboration revenues.

Clinical expenses include personnel expenses, travel, occupancy costs and external clinical trial costs including clinical site expenses, clinical research organization charges, contractors and regulatory activities associated with conducting human clinical trials, including IND-enabling pharmacology and toxicology studies. The increase during the three and nine month periods ended September 30, 2013 as compared to the prior year periods reflects increased clinical trial activity related to ADCETRIS, SGN-CD19A, SGN-CD33A and SGN-LIV1A, as well as higher compensation costs due to increased staffing levels.

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Share-based compensation expense reflects the non-cash charge associated with stock options, restricted stock units and our employee stock purchase plan. The increase in share-based compensation expense during both the three and nine month periods ended September 30, 2013 was primarily due to a higher average fair value per share for our more recent equity grants, primarily attributable to an increase in our stock price.

We utilize our employee and infrastructure resources across multiple development projects as well as our discovery and research programs directed towards identifying monoclonal antibodies and new classes of stable linkers and cell-killing agents for our ADC program. We track human resource efforts expended on many of our programs for purposes of billing our collaborators for time incurred at agreed upon rates and for resource planning. We do not account for actual costs on a project-by-project basis as it relates to our infrastructure, facility, employee and other indirect costs. We do, however, separately track significant third party costs including clinical trial costs, manufacturing costs and other contracted service costs on a project-by-project basis.

The following table shows expenses incurred for research, contract manufacturing of our product candidates and clinical and regulatory services provided by third parties as well as milestone payments for in-licensed technology for ADCETRIS and each of our clinical-stage product candidates. The table also presents other costs and overhead consisting of personnel, facilities and other indirect costs not directly charged to these development programs.

	Three months ended September 30,		Nine months ended September 30,		Five years ended September 30, 2013
Development program ($ in thousands)	**2013**	**2012**	**2013**	**2012**	
ADCETRIS (brentuximab vedotin)	$ 30,651	$ 9,601	$ 61,577	$ 29,954	$ 249,927
ASG-15ME	456	0	5,411	0	5,411
SGN-CD33A	1,085	3,464	2,592	7,277	15,288
SGN-CD19A	1,130	422	2,400	3,411	4,415
SGN-LIV1A	385	1,555	2,050	3,483	8,103
ASG-22ME	517	882	1,986	5,160	14,441
	34,224	15,924	76,016	49,285	297,585
Other costs and overhead	29,879	22,516	82,016	64,971	458,052
Share-based compensation expense	3,744	2,952	9,823	8,378	49,042
Total research and development	$ 67,847	$ 41,392	$ 167,855	$ 122,634	$ 804,679

Third-party costs for ADCETRIS increased during both the three and nine month periods ended September 30, 2013 from the comparable periods in 2012, primarily due to increased ADCETRIS collaboration activities related to drug supply costs. ADCETRIS costs also reflect increased clinical trial activity including the initiation of the ECHELON-2 trial in early 2013.

The development costs for our product candidates accelerate in preparation for an IND submission to the FDA and then decrease until the subsequent clinical trials commence. The decrease in costs for SGN-CD33A and SGN-LIV1A in 2013 reflect preparation in 2012 for the related INDs. Costs for SGN-19A reflect the same dynamic for the nine month period ended September 2013 compared to the comparable period in 2012, whereas development costs increased in the three month period ended September 30, 2013 over the comparable period in 2012 due to increasing clinical trial activities.

Our ASG-15ME and ASG-22ME product candidates are being co-developed with Agensys. The costs for these programs include an opt in fee and our share of the related development costs subsequent to our opt in. The opt in fee for ASG-15ME was incurred during the second quarter of 2013 and the opt in fee for ASG-22ME was incurred during the second quarter of 2011. The higher cost of development for ASG-22ME during the nine months ended September 30, 2012 reflects manufacturing activities in preparation for clinical trials.

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Other costs and overhead include costs associated with personnel and facilities. These costs increased during both the three and nine month periods ended September 30, 2013 from the comparable periods in 2012, primarily reflecting an increase in staffing levels in our development and clinical groups and the cost of additional laboratory facilities in the 2013 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 ADCETRIS post-approval confirmatory studies that are required as a condition to our regulatory approvals.

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.

We anticipate that our total research and development expenses in 2013 will increase compared to 2012 due to increased clinical trial expenses for ADCETRIS related to additional studies to evaluate other potential uses of ADCETRIS, some of which are post-approval commitment trials, drug supply costs under the ADCETRIS collaboration and as a result of amounts incurred to continue the development of our ADC product candidates. Certain ADCETRIS development activities, including some clinical studies, will be conducted by Takeda, the costs of which will not be reflected in our research and development expenses but rather as a reduction in development funding we receive under the collaboration. Because of these and other factors, expenses will fluctuate based upon many factors, including the degree of collaborative activities, timing of manufacturing campaigns, numbers of patients enrolled in our clinical trials and the outcome of each clinical trial event.

The risks and uncertainties associated with our research and development projects are discussed more fully in Item 1A Risk Factors. As a result of these risks and uncertainties, 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.

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Selling, general and administrative

Selling, general and administrative ($ in thousands)	Three months ended September 30, 2013	2012	% Change	Nine months ended September 30, 2013	2012	% Change
Selling, general and administrative, excluding share-based compensation expense	$ 16,964	$ 15,522	9%	$ 55,079	$ 51,358	7%
Share-based compensation expense	4,487	3,320	35%	11,794	9,531	24%
Total selling, general and administrative expenses	$ 21,451	$ 18,842	14%	$ 66,873	$ 60,889	10%

Selling, general and administrative expenses, excluding share-based compensation expense, increased during both the three and nine month periods ended September 30, 2013 from the comparable periods in 2012, primarily reflecting an increase in legal expenses, and higher compensation costs due to increased staffing levels. Share-based compensation expense reflects the non-cash charge associated with stock options, restricted stock units and our employee stock purchase plan. Share-based compensation expense increased during both the three and nine month periods ended September 30, 2013 from the comparable periods in 2012 due to a higher average fair value per optioned share for our more recent grants primarily attributable to an increase in our stock price.

Investment and other income, net

Investment and other income, net was $0.1 million for both the three months ended September 30, 2013 and September 30, 2012, and $0.3 million and $3.4 million for the nine month periods ended September 30, 2013 and September 30, 2012, respectively. Investment and other income 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, 2013	December 31, 2012
Cash, cash equivalents and investments	$ 373,848	$ 364,258
Working capital	335,343	340,283
Stockholders equity	234,380	226,148

	Nine months ended September 30, 2013	2012
Cash provided by (used in):		
Operating activities	$ (7,363)	$ (39,317)
Investing activities	38,775	(22,397)
Financing activities	33,454	29,011

Our combined cash, cash equivalents and investment securities increased during the nine months ended September 30, 2013 primarily reflecting working capital fluctuations and proceeds of stock option exercises.

Net cash used in operating activities decreased during the nine months ended September 30, 2013 from the comparable period in 2012 due to working capital fluctuations, particularly a decrease in inventory on hand related to the supply of drug product to Takeda.

Net cash provided by (used in) investing activities increased during the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012 reflecting higher amounts of cash invested during 2012, partially offset by an increase in the costs incurred in 2013 for tenant improvements and laboratory equipment for our newest facility.

Net cash provided by financing activities for both the nine months ended September 30, 2013 and September 30, 2012 resulted from the proceeds of stock option exercises and our employee stock purchase plan.

We have financed the majority of our operations through the issuance of equity securities, by amounts received pursuant to product collaborations, our ADC collaborations and, more recently, through collections from commercial sales of ADCETRIS. To a lesser degree, we have also financed our operations through royalty revenues and interest earned on cash, cash equivalents and investment securities. These financing sources have historically allowed us to maintain adequate levels of cash and investments.

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Our cash 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, 2013, we had $373.8 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 and royalty revenues 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. Further, in the event of a termination of the ADCETRIS collaboration agreement with Takeda, we would regain worldwide rights to ADCETRIS, but not receive development cost sharing payments, nor would we receive milestone payments or royalties for the development or sale of ADCETRIS in Takeda s territories. Marketing and sales of ADCETRIS outside of the U.S. and Canada, in the event of a termination of the collaboration, would require us to engage another collaborator to complete the ADCETRIS development process and to commercialize ADCETRIS outside the U.S. and Canada or would require us to develop worldwide regulatory, sales and marketing capabilities. Any of these factors could lead to a need for us to raise additional capital.

We are required to conduct additional confirmatory phase 3 post-approval studies of ADCETRIS as part of our regulatory approvals. These are large studies that are being conducted over a lengthy period of time and although we have commenced 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 would have material adverse consequences to us, including the loss of marketing approval for ADCETRIS. These required post-approval studies will also continue to 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 are required to and are currently conducting 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

Our future minimum contractual commitments were reported in our Annual Report on Form 10-K for the year ended December 31, 2012, as filed with the SEC. There have been no material changes from the contractual commitments previously disclosed in that Annual Report on Form 10-K.

Recent Accounting Pronouncements

In February 2013, the Financial Accounting Standards Board, or FASB, issued ASU 2013-2 Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income that revises the disclosure requirements related to significant reclassifications of items out of accumulated other comprehensive income and into the line items included in net income. We adopted this standard in the first quarter of 2013 and its adoption did not impact our consolidated financial statements.

In July 2013, the FASB issued ASU 2013-11 Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists that provides for disclosure requirements related to unrecognized tax benefits in certain situations. We will adopt this standard in the first quarter of 2014 and we do not expect the adoption of this standard to have an impact on our consolidated financial statements.

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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, 2013 has not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2012 filed with the SEC. Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. We had holdings in U.S. Treasury securities totaling $254.3 million and $309.6 million as of September 30, 2013 and December 31, 2012, respectively.

We have estimated the effect on our investment portfolio of a hypothetical increase in interest rates by one percent to be a reduction of $1.0 million in the fair value of our investments as of September 30, 2013. 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, 2013.

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. Our commercial sales in Canada are denominated in Canadian Dollars. We also had other transactions denominated in foreign currencies during the nine months ended September 30, 2013, 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, British Pound, Canadian Dollar and Swiss Franc. 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, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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, 2012, filed with the SEC.

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Risks Related to Our Business

Our near-term prospects are substantially dependent on ADCETRIS. If we and/or Takeda are unable to successfully commercialize ADCETRIS for the treatment of patients in its approved indications and to expand its labeled indications of use, our ability to generate significant revenue or achieve profitability will be adversely affected. *

ADCETRIS® (brentuximab vedotin), our only marketed product, received accelerated approval in the United States in August 2011 and approval with conditions in Canada in February 2013 for patients with relapsed Hodgkin lymphoma or relapsed systemic anaplastic large cell lymphoma, or sALCL. ADCETRIS is our only product approved for marketing 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 and to expand its labeled indications of use. We may not be able to fully realize the commercial potential of 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 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 and future therapeutics;
- 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;
- we may not be able to obtain and maintain regulatory approvals to market ADCETRIS for any additional indications, including for frontline Hodgkin lymphoma or mature T-cell lymphoma, or MTCL, or otherwise expand its labeled indications of use;
- the estimated incidence rate of new patients in ADCETRIS approved indications may be lower than our projections;
- results from our required post-approval studies may fail to verify the clinical benefit of ADCETRIS in some or all of its approved indications, which could result in the withdrawal of ADCETRIS from the market;
- adverse results or events reported in any of the clinical trials that we and/or Takeda are conducting or may in the future conduct for ADCETRIS;
- our inability to successfully market, sell and distribute 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 such as our phase 3 frontline Hodgkin lymphoma and MTCL or AETHERA clinical trials 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.

In December 2009, we entered into an agreement with Takeda to develop and commercialize ADCETRIS, under which we have commercial rights in the United States and its territories and Canada, and Takeda has commercial rights in the rest of the world. The success of this collaboration and the activities of Takeda will significantly impact the potential commercialization of ADCETRIS in countries other than the United States and in Canada. In October 2012, Takeda announced that it had received conditional marketing authorization for ADCETRIS from the European Commission for patients with relapsed Hodgkin lymphoma or relapsed sALCL, and has since obtained marketing approvals for ADCETRIS in several other countries. 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 Takeda received conditional marketing authorization from the European Commission and several other countries, we cannot control the amount and timing of resources that Takeda dedicates to the commercialization of ADCETRIS, or to its marketing and distribution, and our ability to generate revenues from ADCETRIS product sales by Takeda depends on Takeda s ability to achieve market acceptance of, and to otherwise effectively market, ADCETRIS for its approved indications in its territory.

We believe that our ongoing ADCETRIS sales in the United States have predominately transitioned to being subject to an incidence flow of patients in ADCETRIS approved indications. We also believe that the incidence rate of new patients in ADCETRIS approved indications is relatively low. As a result, we currently expect that future ADCETRIS sales growth, if any, will depend primarily on our ability to expand ADCETRIS labeled indications of use. Accordingly, we are exploring the use of ADCETRIS as a single agent and in combination therapy regimens earlier in the treatment of Hodgkin lymphoma and MTCL, including sALCL, and in a range of CD30-positive hematologic malignancies, including relapsed cutaneous T-cell lymphoma, or CTCL. This will

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require additional time and investment in clinical trials and there can be no assurance that we and/or Takeda will obtain and maintain the necessary regulatory approvals to market ADCETRIS for any additional indications. We and Takeda have formed a collaboration with Ventana Medical Systems, Inc., or Ventana, under which Ventana is working to 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 Takeda receive the required regulatory approvals to market ADCETRIS for any additional indications or in additional jurisdictions, we and Takeda may not be able to successfully commercialize ADCETRIS, including for the reasons set forth above. Our ability to grow ADCETRIS product sales in future periods is also dependent on price increases and we have periodically increased the price of ADCETRIS. We cannot assure you that price increases we have taken or may take in the future have not already negatively affected, or will not in the future negatively affect, ADCETRIS sales volumes.

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

Our operating results are difficult to predict and may fluctuate significantly from quarter to quarter and year to year. We have a limited amount of historical sales data and although we provide sales guidance for ADCETRIS from time to time, you should not rely on ADCETRIS sales results in any period as being indicative of future performance. 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 have been below prior period sales, and sales of ADCETRIS in the future may also 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 incidence rate of new patients in ADCETRIS approved indications;
- customer ordering patterns for ADCETRIS, which may vary significantly from period to period;
- the level of demand for ADCETRIS and the duration of therapy for patients receiving 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 because of changes to the government discount percentage or due to different levels of utilization by entities entitled to government rebates and discounts and changes in patient demographics;
- increases in the scope of eligibility for customers to purchase ADCETRIS at the discounted government price or to obtain government-mandated rebates on purchases of ADCETRIS;
- 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 Takeda, as well as entering into new collaboration and license agreements. These upfront and milestone payments may vary significantly from quarter to quarter and any such variance could cause a significant fluctuation in our operating results from one quarter to the next. Further, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award, and recognize the cost as an expense over the employee s requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price, the magnitude of the expense that we must recognize may vary significantly.

For these and other reasons, it is difficult for us to accurately forecast future 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.

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Reports of adverse events or safety concerns involving ADCETRIS 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 could interrupt, delay or halt clinical trials of ADCETRIS, including the ongoing FDA-required ADCETRIS post-approval confirmatory studies as well as the post-approval confirmatory studies that Takeda 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 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. There are no assurances that patients receiving ADCETRIS 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 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 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.*

We believe that our initial sales of ADCETRIS in the United States depleted the prevalence pool of patients in its approved indications and therefore, our ongoing sales of ADCETRIS will be primarily dependent on the incidence rate of new patients who have recently failed earlier lines of cancer therapy and become eligible for ADCETRIS within the current approved indications. The incidence rate of new patients in ADCETRIS approved indications has not been definitively determined, but we believe that the incidence rate is relatively low. In addition, the number of such patients may turn out to be lower than expected or those patients 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.

Even though we have obtained approval to market ADCETRIS 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 accelerated approval regulations in the U.S. and approval with conditions in Canada, which allow for approval of 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 types of approvals, we are subject to certain post-approval requirements pursuant to which we are conducting additional confirmatory phase 3 trials to verify and describe the clinical benefit of ADCETRIS in its two approved indications. Our failure to complete these required post-approval studies, or to confirm a clinical benefit during these post-approval studies, could result in the withdrawal of approval of ADCETRIS, which would seriously harm our business. In addition, we are subject to extensive ongoing obligations and continued regulatory review from 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 post-marketing obligations, all of which may result in significant expense and limit our ability to commercialize ADCETRIS in the United States, Canada or potentially other jurisdictions. Similarly, the conditional marketing authorization of ADCETRIS for two indications by the European Commission includes obligations to provide additional clinical data at a later stage to confirm the positive benefit-risk balance. Takeda 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 Takeda 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

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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 Takeda;
- 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 Takeda might not be permitted to market ADCETRIS and our business would suffer.

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 received our permanent reimbursement codes for ADCETRIS in the United States, healthcare providers prescribing ADCETRIS may incorrectly use these 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 applicable regulatory agency 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 to market ADCETRIS in two indications in the United States and Canada and Takeda has obtained approval in the European Union and several additional countries, our commercial opportunity for ADCETRIS will be adversely affected if competitive products are developed and marketed that are more effective, have fewer side effects or are less expensive than ADCETRIS for its two approved indications or any other potential indication. Potential 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, or that would render our technology obsolete or noncompetitive.

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We are subject to various state and federal healthcare related laws and regulations that may impact the commercialization of ADCETRIS 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.

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.

The U.S. Foreign Corrupt Practices Act, or FCPA, prohibits companies and individuals from engaging in specified activities to obtain or retain business or to influence a person working in an official capacity. Under the FCPA, it is illegal to pay, offer to pay, or authorize the payment of anything of value to any foreign government official, governmental staff members, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls.

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. Accordingly, we expect to continue to incur net losses and may not achieve profitability for some time, if at all. Although we now recognize revenue from ADCETRIS product sales and we continue to earn amounts under our collaboration agreements, our revenue and profit potential is unproven and our limited operating and commercialization 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.

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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, including CTCL, and we are currently conducting multiple clinical trials for ADCETRIS. However, we and/or Takeda 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 three of our phase 3 clinical trials of ADCETRIS that we are conducting with Takeda, are being conducted under a special protocol assessment, or SPA, with the FDA, this 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, an 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, an 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 an 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 ADCETRIS in additional indications.

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 ADCETRIS could take a significantly longer time to gain regulatory approval in additional indications than we expect or may never gain regulatory approval, which could delay or eliminate any potential product revenue from sales of ADCETRIS in any additional indications, which could significantly delay or prevent us from achieving profitability.

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 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 Takeda, 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 enroll larger numbers of patients required for phase 3 studies of ADCETRIS that we are required to conduct, and are currently conducting, 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.

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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 applicable 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 applicable 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 applicable product candidate may not appear to be more effective than current therapies;
- the quality or stability of ADCETRIS or the applicable product candidate may fall below acceptable standards;
- our inability to produce or obtain sufficient quantities of ADCETRIS or the applicable product candidate to complete the trials;
- our inability to reach agreement on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- our inability to obtain IRB approval to conduct a clinical trial at a prospective site;
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties;
- our inability to recruit and enroll patients to participate in clinical trials for reasons including competition from other clinical trial programs for the same or similar indications; or

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

In addition, we may experience significant setbacks in advanced clinical trials, even after promising results in earlier trials, such as unexpected adverse events that occur when our product candidates are combined with other therapies, which often occur in later-stage clinical trials. For example, during 2011 we announced that, based on a phase 1 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 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, 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/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 Takeda in December 2009 that granted Takeda rights to develop and commercialize ADCETRIS outside of the United States and Canada. We also have ADC collaborations with AbbVie, Bayer, Celldex, Daiichi Sankyo, GSK, Genentech, Pfizer, Progenics and Takeda, 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. In addition, we cannot control the amount and timing of resources our collaborators may devote to products incorporating our

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technology. Moreover, our relationships with our collaborators may 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 Takeda 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 Takeda. Furthermore, if our collaborators do not prioritize and commit substantial resources to programs associated with our product candidates, we may be unable to commercialize our product candidates, which would limit our ability to generate revenue and become profitable. In the future, we may not be able to locate third-party collaborators to develop and market our product candidates and we may lack the capital and resources necessary to develop all our product candidates alone.

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

In March 2010, the 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 include increased Medicaid rebates, expanded Medicaid eligibility, extension of Public Health Service eligibility, annual reporting of financial relationships with physicians and teaching hospitals, and a new Patient-Centered Outcomes Research Institute. Many of these provisions will have the effect of reducing the revenue generated by our sales of ADCETRIS and any future commercial products we may have. In addition, 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. For example, increased discounts, rebates or chargebacks may be mandated which could significantly affect the revenue generated by sales of our products, including ADCETRIS. 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 Takeda in the European Union.

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, a substantial portion 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 Takeda s ability and willingness to market the approved product outside of the United States and Canada. The loss of our collaborators, especially Takeda, 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 and Canada, we sell ADCETRIS through a limited number of pharmaceutical distributors. Customers order ADCETRIS through these distributors. We generally receive orders from distributors and ship product directly to the customer. 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.

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

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 AbbVie for clinical and commercial supply. For ADCETRIS and other ADCs, several contract manufacturers, including SAFC, supply us with drug-linker and other contract manufacturers perform conjugation of the drug-linker to the antibody and fill/finish of drug product into vials. In addition, we rely on other third parties to perform additional steps in the manufacturing process, including shipping and storage of ADCETRIS. 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 for use in our clinical trials and for commercial sale. If our contract manufacturers or other third parties fail to deliver ADCETRIS 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. Moreover, contract manufacturers have a limited number of facilities in which ADCETRIS 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 the inability to sell our products in the U.S. or abroad. In addition, we depend on outside vendors for the supply of raw materials used to produce ADCETRIS. 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 manufactured to meet commercial and clinical requirements would be adversely affected.

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

ADCETRIS and our SGN-CD19A, SGN-CD33A, SGN-LIV1A, SGN-CD70A, ASG-22ME, and ASG-15ME product candidates are all based on our ADC technology, which utilizes proprietary stable linkers and potent cell-killing synthetic agents. Our ADC technology is also the basis of our collaborations with AbbVie, Agensys, Bayer, Celldex, Daiichi Sankyo, Genentech, Genmab, GSK, Takeda, Pfizer and Progenics, and our co-development agreements with Agensys, Genmab, and OBT. Although ADCETRIS has received marketing approval in the United States, Canada, the European Union and several other countries, 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 in its current or any potential future approved indications and on 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.

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 five clinical-stage ADC programs, which consist of SGN-CD19A, SGN-CD33A, SGN-LIV1A, ASG-22ME, and ASG-15ME. If a product candidate fails at any stage of development or we otherwise determine to discontinue development of that product candidate, we will not have the anticipated revenues from that product candidate to fund our operations, and we may not receive any return on our investment in that product candidate. In this regard, we recently determined to discontinue the development of SGN-75 and we will not receive any return on our investment in that product candidate. Moreover, we still have only limited data from our phase 1 trials of our product candidates. As a result, we may conduct lengthy and expensive clinical trials of our product candidates only to learn that a 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. Due to 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 the additional clinical development of and commercialization activities associated with ADCETRIS, which may restrict or delay our ability to develop our clinical and preclinical product candidates.

We may need to raise significant amounts of additional capital that may not be available to us.

We expect to make additional capital outlays and to increase operating expenditures over the next several years as we hire additional employees and support our preclinical development, manufacturing and clinical trial activities, as well as commercialize ADCETRIS and conduct required post-approval, and other clinical studies of ADCETRIS. Although some of these expenditures related to ADCETRIS are expected to be shared with Takeda, 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 and we do

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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 additional indications, if any;
- the size, complexity, timing, progress 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 Takeda;
- the cost of establishing and maintaining clinical and commercial supplies of ADCETRIS;
- 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 potential costs associated with international, state and federal taxes; 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 and our ADC technology. Failure to maintain these license agreements or to secure any required new licenses could prevent us from continuing to develop and commercialize ADCETRIS and our other product candidates. *

We have entered into agreements with third-party commercial and academic institutions to license technology for use in ADCETRIS and our ADC technology. Currently, we have license agreements with Bristol-Myers Squibb, CLB-Research and Development, the University of Miami and Spirogen, 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

other product candidates. Further, we may have disputes with our licensors, which may impact our ability to develop and commercialize ADCETRIS or our other product candidates or require us to enter into additional licenses. An adverse result in this dispute, or other potential future disputes with our licensees, may impact our ability to develop and commercialize ADCETRIS and our other product candidates, or may require us to enter into additional licenses or to incur additional costs. In addition, continued development and commercialization of ADCETRIS and our other 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 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.

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. For example, the U.S. Supreme Court has recently modified some legal standards applied by the U.S.

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Patent and Trademark Office in examination of U.S. patent applications, which may decrease the likelihood that we will be able to obtain patents and may increase the likelihood of challenges to patents we obtain or license. In addition, changes to the U.S. patent system continue to come into force under the Leahy-Smith America Invents Act, including changes from a first-to-invent system to a first to file system, changes to examination of U.S. patent applications and changes to the processes for challenging issued patents. These changes may increase the uncertainties and costs surrounding our patent prosecution and the protection, if any, given by our patents if we attempt to enforce them or if they are challenged in court.

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 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. 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.

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.

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,

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including Pfizer s crizotinib, Millennium s alistertib, Pharmacyclics ibrutinib and Gilead s idealisib, 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, Bayer, Biogen IDEC, Bristol-Myers Squibb, Celgene, Eisai, Genentech, GSK, Gilead, ImmunoGen, Infinity, Merck, Novartis, Pfizer, Pharmacyclics, Sanofi-Aventis, Spectrum Pharmaceuticals, Takeda, and Teva are developing and/or marketing products or technologies that may compete with ours, and some of these companies, including AstraZeneca, 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. 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.

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 by us and our corporate collaborators in clinical trials and the sale of ADCETRIS, 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 or breaches of data security, our business could be adversely affected. **

We rely on information technology systems to keep financial records, maintain laboratory, patient and corporate records, communicate with staff and external parties and operate other critical functions. Our information technology systems are potentially vulnerable to disruption due to breakdown, malicious intrusion and computer viruses. If we were to experience a prolonged system

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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.

In addition, our information technology systems are potentially vulnerable to data security breaches whether by employees or others which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers and others, any of which could have a material adverse effect on our business, financial condition and results of operations.

Increasing use of social media could give rise to liability. *

We are increasingly relying on social media tools as a means of communications. To the extent that we continue to use these tools as a means to communicate about ADCETRIS and our product candidates or about the diseases that ADCETRIS and our product candidates are intended to treat, there are significant uncertainties as to either the rules that apply to such communications, or as to the interpretations that health authorities will apply to the rules that exist. As a result, despite our efforts to comply with applicable rules, there is a significant risk that our use of social media for such purposes may cause us to nonetheless be found in violation of them. Such uses of social media could have a material adverse effect on our business, financial condition and results of operations.

We may engage in future acquisitions that increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We actively evaluate various strategic transactions on an ongoing basis, including licensing or acquiring complementary products, technologies or businesses. Any potential acquisitions may entail numerous risks, including increased operating expenses and cash requirements, assimilation of operations and products, retention of key employees, diversion of our management s attention and uncertainties in our ability to maintain key business relationships of the acquired entities. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

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

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future and as a result we may be required to make changes in our accounting policies. Those changes could adversely affect our reported revenues and expenses, future profitability or financial position. Compliance with new regulations regarding corporate governance and public disclosure may result in additional expenses. As a result, we intend to invest all 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.

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 2013, our closing stock price fluctuated between $32.71 and $48.48 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, Canada, the European Union and other countries in which Takeda has received approval by relevant regulatory authorities;

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 clinical trials we and/or Takeda are conducting or may in the future conduct for ADCETRIS, including 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, Health Canada s Notice of Compliance with conditions, and the conditional marketing authorization of ADCETRIS by the European Commission;

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announcements regarding, or negative publicity concerning, adverse events associated with the use of ADCETRIS;

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 ADCETRIS, or specific label indications for or restrictions, warnings or limitations in its use, or delays in the regulatory review or approval process;

termination of or changes in our existing collaborations or licensing arrangements, especially our ADCETRIS collaboration with Takeda or establishment of new collaborations or licensing arrangements;

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

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

market conditions for equity investments in general, or the biotechnology or pharmaceutical industries in particular;

developments or disputes concerning our proprietary rights;

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

changes in government regulations; and

economic or other external factors.

The stock markets in general, and the markets for biotechnology stocks in particular, have historically experienced significant volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock. In the past, class action or derivative 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 52.9 percent of our voting power as of November 5, 2013. 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+	XBRL Instance Document
101.SCH+	XBRL Taxonomy Extension Schema Document.
101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB+	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE+	XBRL Taxonomy Extension Presentation Linkbase Document.

+ Filed 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.

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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 8, 2013

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