SEATTLE GENETICS INC /WA
Form 10-Q
May 01, 2015
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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 March 31, 2015

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	**(I.R.S. Employer**
incorporation or organization)	**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 April 28, 2015, there were 124,886,861 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 March 31, 2015

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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)

	March 31, 2015	December 31, 2014
Assets		
Current assets		
Cash and cash equivalents	$ 62,571	$ 56,927
Short-term investments	233,442	256,486
Accounts receivable, net	49,587	39,248
Inventories	43,069	43,451
Prepaid expenses and other current assets	8,247	11,874
Total current assets	396,916	407,986
Property and equipment, net	44,922	46,129
Other non-current assets	4,635	4,850
Total assets	$ 446,473	$ 458,965
Liabilities and Stockholders Equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 80,454	$ 77,681
Current portion of deferred revenue	47,698	48,212
Total current liabilities	128,152	125,893
Long-term liabilities		
Deferred revenue, less current portion	104,636	117,648
Deferred rent and other long-term liabilities	4,396	4,590
Total long-term liabilities	109,032	122,238
Commitments and contingencies (note 6)		
Stockholders equity		
Preferred stock, $0.001 par value, 5,000 shares authorized; none issued	0	0
	125	124

Common stock, $0.001 par value, 250,000 shares authorized; 124,796 shares issued and outstanding at March 31, 2015 and 123,973 shares issued and outstanding at December 31, 2014		
Additional paid-in capital	1,037,308	1,017,182
Accumulated other comprehensive income loss	(11)	(29)
Accumulated deficit	(828,133)	(806,443)
Total stockholders equity	209,289	210,834
Total liabilities and stockholders equity	$ 446,473	$ 458,965

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 March 31,	
	2015	2014
Revenues		
Net product sales	$ 48,886	$ 38,716
Collaboration and license agreement revenues	22,221	16,882
Royalty revenues	11,050	12,673
Total revenues	82,157	68,271
Costs and expenses		
Cost of sales	5,210	3,664
Cost of royalty revenues	3,174	2,464
Research and development	63,395	54,496
Selling, general and administrative	32,121	24,018
Total costs and expenses	103,900	84,642
Loss from operations	(21,743)	(16,371)
Investment and other income, net	53	70
Net loss	$ (21,690)	$ (16,301)
Net loss per share basic and diluted	$ (0.17)	$ (0.13)
Shares used in computation of net loss per share basic and diluted	124,312	122,896
Comprehensive loss:		
Net loss	$ (21,690)	$ (16,301)
Other comprehensive gain unrealized gain on securities available for sale	18	20
Comprehensive loss	$ (21,672)	$ (16,281)

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)

	Three months ended March 31,	
	2015	**2014**
Operating activities		
Net loss	$ (21,690)	$ (16,301)
Adjustments to reconcile net loss to net cash used in operating activities		
Share-based compensation	7,735	9,304
Depreciation and amortization	3,423	2,837
Amortization of premiums and accretion of discounts	308	332
Deferred rent and other long-term liabilities	(194)	(195)
Changes in operating assets and liabilities		
Accounts receivable, net	(10,339)	(8,388)
Inventories	382	(1,971)
Prepaid expenses and other assets	3,652	(654)
Accounts payable and accrued liabilities	3,118	(521)
Deferred revenue	(13,526)	(7,685)
Net cash used in operating activities	(27,131)	(23,242)
Investing activities		
Purchases of securities available for sale	(63,346)	(128,207)
Proceeds from maturities of securities available for sale	86,100	127,500
Purchases of property and equipment	(2,371)	(3,141)
Net cash provided by (used in) investing activities	20,383	(3,848)
Financing activities		
Proceeds from exercise of stock options and employee stock purchase plan	12,392	7,786
Net cash provided by financing activities	12,392	7,786
Net increase (decrease) in cash and cash equivalents	5,644	(19,304)
Cash and cash equivalents at beginning of period	56,927	64,116
Cash and cash equivalents at end of period	$ 62,571	$ 44,812

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). All significant intercompany transactions and balances have been eliminated. The condensed consolidated balance sheet data as of December 31, 2014 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, 2014, as filed with the SEC.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results could differ from those estimates. The results of the Company s operations for the three month period ended March 31, 2015 are not necessarily indicative of the results to be expected for the full year.

Non-cash investing activities

Accrued capital expenditures have been treated as a non-cash investing activity and, accordingly, have not been included in the statement of cash flows.

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 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 based on covered purchases of ADCETRIS. Medicaid rebates are invoiced to the Company by the various state programs. The Company estimates Medicaid rebates based on a variety of factors, including its 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.

Distribution fees, product returns and other deductions: The Company s distributors charge a volume-based fee for distribution services that they perform for the Company. 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. 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 and treatment 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 has developed a proprietary technology for linking cytotoxic agents to monoclonal antibodies called antibody-drug conjugates, or ADCs. This proprietary technology is the basis of ADC collaborations that the Company has entered into in the ordinary course of its business with a number of biotechnology and pharmaceutical companies. Under these ADC collaboration agreements, the Company grants its collaborators research and commercial licenses to the Company s technology and provides technology transfer services, technical advice, supplies and services for a period of time.

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 pre-commercial 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 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. These performance obligation periods currently range from two to fourteen years. When no performance obligations are required of the Company, or following the completion of the performance obligation period, such amounts are recognized as revenue when collectibility is reasonably assured. Generally, all amounts received or due other than sales-based milestones and royalties are classified as collaboration and license agreement revenues as they are earned. Sales-based milestones and royalties are recognized as royalty revenue as they are reported to the Company.

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 pre-clinical studies. The Company s collaborators must undertake significant pre-clinical 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 of a phase 2 clinical trial. Generally, phase 2 clinical trials may take one to three years to complete.

Initiation 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, Japan or other significant countries. Generally it may take up to three years after a marketing application is submitted to obtain approval for marketing and pricing from the applicable regulatory agency.

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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 other significant 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 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 Takeda Pharmaceutical Company Limited (Takeda), the Company may be involved in certain development activities; however, the achievement of milestone events under the agreement is primarily 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 primarily reflect amounts earned under the ADCETRIS collaboration with Takeda. These royalties include sales royalties, which are based on a percentage of Takeda s net sales at rates that range from the mid-teens to the mid-twenties based on sales volume, and commercial sales-based milestones. Takeda bears a portion of third-party royalty costs owed on its sales of ADCETRIS. 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 Takeda s sales of ADCETRIS. 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. Royalty revenues also include amounts earned in connection with the Company s ADC collaborations.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued an accounting standards update entitled ASU 2014-09, Revenue from Contracts with Customers. The standard requires entities to recognize revenue through an evaluation that includes identification of the contract, identification of the performance obligations, determination of the transaction price, allocation of the transaction price to the performance obligations, and recognition of revenue as the entity satisfies the performance obligations. Based on a recent announcement by the FASB, the Company believes that the standard will become effective for its fiscal year beginning January 1, 2018. The Company is currently evaluating the guidance to determine the potential impact on its financial condition, results of operations and cash flows, and financial statement disclosures.

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 12,204,000 and 11,653,000 for the three months ended March 31, 2015 and 2014, respectively.

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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
March 31, 2015				
U.S. Treasury securities	$ 233,453	$ 8	$ (19)	$ 233,442
Contractual Maturities				
Due in one year or less	$ 233,453			$ 233,442

	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
December 31, 2014				
U.S. Treasury securities	$ 256,515	$ 2	$ (31)	$ 256,486
Contractual Maturities				
Due in one year or less	$ 256,515			$ 256,486

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

	Period of continuous unrealized loss			
	12 Months or less		Greater than 12 months	
	Fair value	Gross unrealized losses	Fair value	Gross unrealized losses
March 31, 2015				
U.S. Treasury securities	$ 180,047	$ (19)	$ NA	$ NA
December 31, 2014				
U.S. Treasury securities	$ 205,966	$ (31)	$ 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 March 31, 2015 or December 31, 2014 and did not transfer any investments between Levels 1, 2 and 3 during the three month period ended March 31, 2015.

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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 March 31, 2015				
Short-term investments U.S. Treasury securities	$ 233,442	$ 0	$ 0	$ 233,442

	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, 2014				
Cash equivalents U.S. Treasury securities	$ 5,003	$ 0	$ 0	$ 5,003
Short-term investments U.S. Treasury securities	256,486	0	0	256,486
Total	$ 261,489	$ 0	$ 0	$ 261,489

5. Inventories

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

	March 31, 2015	December 31, 2014
Raw materials	$ 35,330	$ 35,865
Work in process	4,020	3,920
Finished goods	3,719	3,666
Total	$ 43,069	$ 43,451

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. For example, Arizona State University and related entities, or Arizona State, filed a patent infringement lawsuit against the Company concerning a U.S. patent owned by Arizona State. The Company believes that it has meritorious defenses to Arizona State s claims and does not currently expect that any current legal proceedings will have a material adverse effect on the Company s business. However, it is possible that this assessment could change in the future.

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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 Quarterly Report on Form 10-Q 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 targeted therapies for the treatment of cancer. Our marketed product ADCETRIS®, or brentuximab vedotin, 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. ADCETRIS received accelerated approval in the United States in August 2011, conditional marketing authorization in the European Union in October 2012 and approval with conditions in Canada in February 2013 for patients with relapsed Hodgkin lymphoma or relapsed systemic anaplastic large cell lymphoma, or sALCL. We are collaborating with Takeda Pharmaceutical Company Limited, or Takeda, to develop and commercialize ADCETRIS on a global basis. Under this collaboration, Seattle Genetics retains 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 is now approved in over 50 countries and Takeda continues to pursue marketing authorizations in multiple other countries. Beyond our current labeled indications, we and Takeda 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, including sALCL and in other CD30-positive malignancies.

On September 29, 2014, we and Takeda announced positive top line data from our AETHERA trial, a randomized, double-blind, placebo-controlled phase 3 clinical trial that evaluated ADCETRIS versus placebo in 329 patients with Hodgkin lymphoma at risk of relapse following autologous stem cell transplant, or ASCT. The AETHERA trial met its primary endpoint with ADCETRIS treatment resulting in a statistically significant improvement in progression-free survival, or PFS, versus placebo, as assessed by an independent central review committee (hazard ratio=0.57; p-value=0.001). At the December 2014 American Society of Hematology, or ASH, annual meeting, we announced the median PFS per independent review facility was 43 months for patients who received ADCETRIS versus 24 months for patients who received placebo. A pre-specified interim analysis of overall survival, a secondary endpoint in the trial, showed no statistically significant difference between the treatment arms. Patients on both study arms with

progression of Hodgkin lymphoma may have received a variety of subsequent therapies. In the placebo arm, 72 of 85 patients (85 percent) receiving subsequent therapy were treated with single agent ADCETRIS. Notably, in the ADCETRIS arm, only eight of 51 patients (16 percent) receiving subsequent therapy were treated with ADCETRIS following relapse. A further analysis of overall survival is planned in 2016. The safety profile of ADCETRIS in the AETHERA trial was generally consistent with the existing prescribing information. The AETHERA trial provides drug safety data analyses that fulfills one of our post-approval requirements with both the U.S. Food and Drug Administration, or FDA, and the European Medicines Agency, or EMA. ADCETRIS is not currently approved in the AETHERA treatment setting. Based upon the positive PFS outcome of the AETHERA trial, we submitted a supplemental Biologics License Application, or sBLA, to the FDA to seek approval for a new indication in the AETHERA treatment setting and this sBLA was recently accepted for filing and designated for priority review by the FDA with a Prescription Drug User Fee Act, or PDUFA, target action date of August 18, 2015.

We and Takeda are conducting three additional phase 3 clinical trials of ADCETRIS, one in relapsed CD30-positive 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 CD30-positive MTCL, called the ECHELON-2 trial. We have entered into Special Protocol Assessment, or SPA, agreements with the FDA for the ALCANZA, ECHELON-1 and ECHELON-2 trials and we also received scientific advice from the EMA with respect to these trials. An SPA is an agreement with the FDA regarding the design of the clinical trial, including size and

clinical endpoints, to support an efficacy claim in a Biologics License Application, or BLA, submission to the FDA if the trial achieves its primary endpoints. The ECHELON-1 and ECHELON-2 trials would fulfill post-approval commitment obligations for ADCETRIS regarding drug efficacy, and positive results from either trial would form the basis for a submission to potentially convert the approval of ADCETRIS in the United States from accelerated approval to regular approval in its currently approved indications. The primary endpoint in the ALCANZA trial is overall response rate lasting at least four months in patients treated with ADCETRIS compared to that achieved with therapy in the control arm. The primary endpoint in both of the ECHELON-1 and ECHELON-2 trials is PFS per independent review facility assessment in patients treated with ADCETRIS compared to that achieved with therapy in the control arm. Given PFS trends in our phase 1 data combining ADCETRIS with standard frontline chemotherapy regimens and the positive PFS outcome in the AETHERA trial, we and Takeda have evaluated the potential that event rates may be slower than expected in both the ECHELON-1 and ECHELON-2 trials and have discussed with appropriate regulatory agencies proposed trial modifications. In April 2015, the FDA approved proposed amendments to the SPA agreements for both trials to increase target enrollment from 1,040 to 1,240 patients in ECHELON-1 and from 300 to 450 patients in ECHELON-2. This increase in our target enrollment for these clinical trials will also extend the patient treatment phase of the trials. With these increases in target enrollment, we expect to complete enrollment in ECHELON-1 later in 2015 and to complete enrollment in ECHELON-2 in 2016. No other changes were made to the SPA agreement for either trial and our projected timeline for reporting data from both trials continues to be in the 2017 to 2018 timeframe.

In addition to ADCETRIS, our clinical-stage pipeline includes six ADC programs consisting of SGN-CD33A, SGN-CD19A, SGN-LIV1A, SGN-CD70A, ASG-22ME, and ASG-15ME, as well as SEA-CD40, which is based on our sugar-engineered antibody, or SEA, technology. In addition, we have multiple pre-clinical and research-stage programs that employ our proprietary technologies. We also have collaborations for our ADC technology with a number of biotechnology and pharmaceutical companies, including AbbVie Biotechnology Ltd., or AbbVie; Bayer Pharma AG, or Bayer; Celldex Therapeutics, Inc., or Celldex; 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.

Our ongoing research, development and commercial activities will require substantial amounts of capital and may not ultimately be successful. Our product candidates are in relatively early stages of development. These product candidates will require significant further development, financial resources and personnel to pursue and 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 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 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 been commercializing ADCETRIS since August 2011 and our future ADCETRIS product sales will be difficult to accurately predict from period to period. In this regard, our product sales have varied, and may continue to vary, significantly from period to period and may be affected by a variety of factors, including the incidence rate of new patients in ADCETRIS approved indications, customer ordering patterns, the overall 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. We believe that the level of our current ADCETRIS sales in the United States is largely attributable to the incidence flow of patients eligible for treatment with ADCETRIS, which could vary significantly from period to period. Moreover, we believe that the incidence rate in ADCETRIS approved indications is relatively low, particularly when compared to many other oncology indications. For these and other reasons, we expect that our ability to accelerate ADCETRIS sales growth, if at all, will depend primarily on our ability to expand ADCETRIS labeled indications of use. Our efforts to expand ADCETRIS labeled indications of use will continue to 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.

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Financial summary

For the three months ended March 31, 2015, total revenues increased to $82.2 million, compared to $68.3 million for the same period in 2014. This increase was due to increased ADCETRIS net product sales and an increase in collaboration and license agreement revenues primarily resulting from development milestones achieved by our collaborators. Net product sales of ADCETRIS were $48.9 million for the three months ended March 31, 2015, compared to $38.7 million for the three months ended March 31, 2014. For the three months ended March 31, 2015, total costs and expenses increased to $103.9 million, compared to $84.6 million for the same period in 2014. This primarily reflects increased investment in our pipeline and on ADCETRIS as well as amounts associated with increased legal expenses and other increased administrative activities. As of March 31, 2015, we had $296.0 million in cash and short-term investments, and $209.3 million in total stockholders equity.

Results of operations

Three months ended March 31, 2015 and 2014

Net product sales

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

	Three months ended March 31,		
	2015	**2014**	**% Change**
Net product sales	$ 48,886	$ 38,716	26%

The increase in net product sales for the three months ended March 31, 2015 over the comparable period in 2014 primarily resulted from an increase in sales volume in the 2015 period and, to a lesser extent, from the effect of price increases instituted since the 2014 period. The increase in sales volume in 2015 was primarily driven by increased use of ADCETRIS across multiple lines of therapy for the treatment of Hodgkin lymphoma and sALCL and for treatment of other CD30-positive malignancies. The current approved label indications in the U.S. and Canada are (1) the treatment of patients with Hodgkin lymphoma after failure of ASCT, or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates, and (2) the treatment of patients with sALCL, after failure of at least one prior multi-agent chemotherapy regimen. Our ability to accelerate the rate of ADCETRIS sales growth, if at all, will be primarily dependent on our ability to expand the labeled indications of use.

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 and our 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 variety of factors, including our 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 volume-based fee for distribution services that they perform for us. 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. 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 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 and treatment 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 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, 2014	$ 5,268	$ 1,618	$ 6,886
Provision related to current period sales	9,926	1,150	11,076
Adjustment for prior period sales	(199)	38	(161)
Payments/credits for current period sales	(7,668)	(670)	(8,338)
Payments/credits for prior period sales	(1,246)	(600)	(1,846)
Balance as of March 31, 2015	$ 6,081	$ 1,536	$ 7,617

Mandatory government discounts are the most significant component of our total gross-to-net deductions and the discount percentage has been increasing. These discount percentages increased during the three months ended March 31, 2015 as a result of a price increase we instituted at the beginning of 2015 that exceeded the rate of inflation. Generally, the change in government prices is limited to the rate of inflation. We expect future gross-to-net deductions 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

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, supplies and services for a period of time.

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 pre-commercial 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 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. These performance obligation periods currently range from two to fourteen years. When we have no further performance obligations or following the completion of the performance obligation period, such amounts are recognized as revenue when collectibility is reasonably assured. Generally, all amounts received or due other than sales-based milestones and royalties are classified as collaboration and license agreement revenues as they are earned. Sales-based milestones and royalties are recognized as royalty revenue as they are reported to us.

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 pre-clinical studies. Our collaborators must undertake significant pre-clinical 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 of a phase 2 clinical trial. Generally, phase 2 clinical trials may take one to three years to complete.

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

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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 other significant countries. Generally it may take up to three years after a marketing application is submitted to obtain 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 other significant 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 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 development, regulatory and commercial milestone events under the agreement is primarily 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.

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

Collaboration and license agreement revenue by collaborator ($ in thousands)	Three months ended March 31, 2015	2014	% Change
AbbVie	$ 10,950	$ 3,240	238%
Takeda	4,893	7,402	(34%)
Agensys	2,875	0	NA
Genentech	1,545	2,008	(23%)
Celldex	50	2,550	(98%)
Other	1,908	1,682	13%
Total	$ 22,221	$ 16,882	32%

Revenues from our agreements with AbbVie represented 49% and 19% of our collaboration and license agreement revenues during the three month periods ended March 31, 2015 and 2014, respectively. These revenues increased during the three months ended March, 31, 2015 from the comparable period in 2014 as a result of a milestone payment due upon AbbVie s commencement of a phase 2 clinical trial. Revenues earned under our ADCETRIS and ADC collaborations with Takeda represented 22% and 44% of our collaboration and license agreement revenues during the three month periods ended March 31, 2015 and 2014, respectively. The decrease in revenues from Takeda from the comparable period in 2014 was driven by a regulatory milestone achieved in the 2014 period and reduced reimbursements earned under the ADCETRIS collaboration during the 2015 period. The lower reimbursements reflect an increase in clinical trial activity performed by Takeda as compared to the same period in 2014. Changes in revenues recognized from our other collaboration agreements, which include our ADC collaborations and our co-development collaborations, reflect the timing of development milestones and licensing fees.

Our collaboration and license agreement revenues are impacted by the term and duration of our collaboration agreements and by progress-dependent milestones, annual maintenance fees and reimbursement of materials and support services. Collaboration and license agreement 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, specifically to Takeda under our ADCETRIS collaboration, the timing of milestones achieved and our ability to enter into additional collaboration and co-development agreements. We expect our collaboration and license agreement revenues in 2015 to remain relatively consistent with 2014. We expect development funding from Takeda to decrease as a result of the level of development activities expected to be performed by Takeda under the ADCETRIS collaboration. We expect the decreases in revenue from the ADCETRIS collaboration to be largely offset by the earned portion of development milestones achieved by our other collaborators. 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.

Collaboration Agreements

Takeda

The ADCETRIS collaboration provides for the global co-development of ADCETRIS by the companies and the commercialization of ADCETRIS by Takeda in its territory. We received a $60 million upfront payment and are

entitled to receive progress-dependent milestone payments based on Takeda s achievement of certain events related to ADCETRIS development. Additionally, the companies equally co-fund the cost of development activities conducted under the collaboration. We recognize as collaboration revenue the upfront payment, progress-dependent development and regulatory milestone payments, and net development cost reimbursement payments from Takeda over the ten-year development period of the collaboration, which began in December 2009. When the performance of development activities under the collaboration results in us making a reimbursement payment to Takeda, the effect is to reduce the amount of collaboration revenue that we record. We also receive reimbursement for the cost of drug product supplied to Takeda for its use and, in some cases, pay Takeda for drug product they supply to us. The earned portion of such payments received is also reflected as a component of collaboration revenue. We expect that development activities performed by Takeda will continue to exceed activities that we perform, particularly with respect to the conduct of clinical trials of ADCETRIS.

As of March 31, 2015, total future potential milestone payments to us under the ADCETRIS collaboration could total approximately $185 million. Of the remaining amount, up to approximately $7 million relates to the achievement of development milestones, up to approximately $118 million relates to the achievement of regulatory milestones and up to approximately $60 million relates to the achievement of commercial milestones. To date, $50 million in milestones have been achieved as a result of regulatory and commercial progress by Takeda.

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Agensys Co-Development Collaboration

In January 2007, we entered into an agreement with Agensys to jointly research, develop and commercialize ADCs for the treatment of cancer. The collaboration encompasses combinations of our ADC technology with fully-human antibodies developed by Agensys to proprietary cancer targets. Under this collaboration, Agensys conducted research and development aimed at identifying ADC product candidates for multiple designated antigens and is now conducting clinical trials on various ADC product candidates.

The collaboration agreement included an initial co-development product candidate, ASG-5ME, and provided us with two options to co-develop additional product candidates. We have exercised all of our co-development options and are currently co-developing ASG-22ME and ASG-15ME. Development of ASG-5ME has been discontinued. We and Agensys are co-funding all development and commercialization costs for both ASG-22ME and ASG-15ME, and will share equally in any profits from these product candidates.

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 collaboration agreement. Amounts received for product candidates being developed solely by Agensys are recognized as revenue.

Other ADC collaboration agreements

We have other active 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 realized, or over the performance obligation period of the agreements during which we provide limited support to the collaborator, if any. 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.

As of March 31, 2015, our ADC collaborations and co-development agreements had generated more than $300 million, primarily in the form of upfront payments. Total milestone payments to us under our current ADC and co-development collaborations could total up to approximately $4.6 billion if all potential product candidates achieved all of their milestone events. Of this amount, approximately $0.8 billion relates to the achievement of development milestones, approximately $1.9 billion relates to the achievement of regulatory milestones and approximately $1.9 billion relates to the achievement of commercial milestones. Since we do not control the research, development or commercialization of any of the products that would generate these milestones, we are not able to reasonably estimate when, if at all, any milestone payments or royalties may be payable by our collaborators. In addition, most of our current 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 a collaborator s business strategy and financial difficulties or other factors could result in a collaborator abandoning or delaying development of its product candidates. As such, the milestone payments associated with our ADC and co-development 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 described above and it is possible that we may never receive any significant milestone payments under these collaborations.

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Royalty Revenues and Cost of Royalty Revenues

	Three months ended March 31,		
	2015	2014	% Change
Royalty revenues	$ 11,050	$ 12,673	(13%)
Cost of royalty revenues	$ 3,174	$ 2,464	29%

Royalty revenues primarily reflect amounts earned under the ADCETRIS collaboration with Takeda. These royalties include commercial sales-based milestones and sales royalties, which are based on a percentage of Takeda s net sales 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 revenues. Cost of royalty revenues reflect amounts owed to our third-party licensors related to the sale of ADCETRIS in Takeda s territory.

Royalty revenues for the quarter ended March 31, 2015 decreased from the comparable period in 2014 since the three months ended March 31, 2014 included a $5.0 million milestone related to Takeda s achievement of a sales-based target. Cost of royalty revenues fluctuates based on the amount of net sales of ADCETRIS by Takeda in its territories. We expect that royalty revenues and cost of royalties will increase in the future, as a result of commercialization efforts by Takeda in the additional countries where it has received regulatory approvals and to the extent that Takeda receives marketing authorizations in earlier lines of therapy for patients with Hodgkin lymphoma or MTCL and in other CD30-positive malignancies.

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 of ADCETRIS by the FDA. 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 became available for us to use commercially as well as for use in research and development. A modest cost benefit is expected to continue for the remainder of 2015, but is expected to decline based on when the components of the specific drug lots sold were produced and when they are consumed. 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 commercial sales, clinical development or other research activities, and the ability to utilize inventory prior to its expiration date. We expect the percentage of total cost of sales for sales of ADCETRIS will be in the range of 10% to 12% for the full year in 2015. Cost of sales increased during the three month period ended March 31, 2015 from the comparable period in 2014 primarily due to a higher average cost of product sold and increased sales volume during the three months ended March 31, 2015.

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Research and development

Our research and development expenses are summarized as follows:

	Three months ended March 31,		
Research and development ($ in thousands)	**2015**	**2014**	**% Change**
Research	$ 8,013	$ 6,593	22%
Development and contract manufacturing	23,350	19,592	19%
Clinical	32,032	28,311	13%
Total research and development expenses	$ 63,395	$ 54,496	16%

Research expenses include, among other things, personnel, occupancy and laboratory expenses and technology access fees associated with the discovery of novel therapies for the treatment of cancer, including the 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 pre-clinical translational biology and *in vitro* and *in vivo* studies. The increase in research expenses during the three month period ended March 31, 2015 as compared to the same period in 2014 reflects increased discovery activities in support of growing our pipeline of product candidates.

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 during the three month period ended March 31, 2015 as compared to the same period in 2014 reflects increases in activities to support our growing pipeline of product candidates and increased product supply to Takeda.

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 investigational new drug, or IND-enabling pharmacology and toxicology studies. The increase during the three month period ended March 31, 2015 as compared to the same period in 2014 reflects increased clinical trial activity related to our product candidates.

We utilize our employee and infrastructure resources across multiple development projects as well as our discovery and research programs. 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 pre-commercial milestone payments for in-licensed technology for ADCETRIS and each of our clinical-stage product candidates. The table also presents other third-party costs and overhead consisting of personnel, facilities and other indirect costs not directly charged to these

development programs.

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Development program ($ in thousands)	Three months ended March 31, 2015	Three months ended March 31, 2014	Five years ended March 31, 2015
ADCETRIS (brentuximab vedotin)	$ 13,628	$ 10,448	$ 275,785
SGN-CD33A	2,615	637	25,766
SGN-CD19A	1,312	2,476	29,428
SGN-CD70A	375	2,478	11,783
SEA-CD40	348	3,478	7,042
Other clinical stage programs	1,310	1,503	36,663
Total third-party costs	19,588	21,020	386,467
Other costs and overhead	43,807	33,476	576,085
Total research and development	$ 63,395	$ 54,496	$ 962,552

Third-party costs for ADCETRIS increased during the three month period ended March 31, 2015 from the comparable period in 2014, primarily due to an increase in activities related to drug product supply to Takeda.

Third-party costs for SGN-CD33A increased during the three month period ended March 31, 2015 from the comparable period in 2014 due to increased clinical trial costs as more patients enrolled in the ongoing studies and drug re-supply activities as we prepared for additional clinical trials.

Third-party costs for SGN-CD19A decreased during the three month period ended March 31, 2015 from the comparable period in 2014 primarily due to the timing of drug re-supply activities, which occurred in 2014.

The development costs for 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-CD70A and SEA-CD40 during the three month period ended March 31, 2015 from the comparable period in 2014 reflects preparation in 2014 for the related INDs, offset partially in 2015 by clinical trial costs now that the studies are underway.

Other costs and overhead include third-party costs of our other programs which are primarily in the pre-clinical phase and costs associated with personnel and facilities. These costs increased during the three month period ended March 31, 2015 from the comparable period in 2014 due to development activities to expand our product pipeline, including increases in staffing levels and the expansion of our facilities to accommodate our growth.

Our expenditures on our ADCETRIS clinical development program and on our current and future pre-clinical 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 pre-clinical 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. Likewise, in order to expand ADCETRIS labeled indications of use, we are required to conduct additional extensive clinical studies. 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 pre-clinical 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.

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We anticipate that our total research and development expenses in 2015 will increase compared to 2014 due to increased clinical trial expenses for ADCETRIS related to studies to evaluate other potential uses of ADCETRIS, some of which are required post-approval confirmatory studies, and as a result of amounts incurred to continue the development of our product candidates. Certain ADCETRIS development activities, including some clinical studies, will be conducted by Takeda, the costs of which are not reflected in our research and development expenses. 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 the uncertainties discussed above, we are unable to determine with any degree of certainty the duration and completion costs of our research and development projects, anticipated completion dates or when and to what extent we will receive cash inflows from the commercialization and sale of ADCETRIS in any additional approved indications or of any of our product candidates.

Selling, general and administrative

	Three months ended March 31,		
Selling, general and administrative ($ in thousands)	**2015**	**2014**	**% Change**
Selling, general and administrative	$ 32,121	$ 24,018	34%

Selling, general and administrative expenses increased during the three month period ended March 31, 2015 from the comparable period in 2014, primarily due to increased legal expenses and, to a lesser extent, other administrative activities, including increases in staffing levels.

We anticipate that selling, general and administrative expenses will increase in 2015 compared to 2014 as we continue our commercial activities in support of the commercialization of ADCETRIS, as well as our support of general operations and ongoing legal matters.

Investment and other income, net

	Three months ended March 31,		
Investment and other income, net ($ in thousands)	**2015**	**2014**	**% Change**
Investment and other income, net	$ 53	$ 70	(24%)

Investment and other income, net reflects amounts earned on our short-term investments in U.S. Treasury securities.

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Liquidity and capital resources

Selected balance sheet and cash flow data ($ in thousands)	March 31, 2015	December 31, 2014
Cash, cash equivalents and investments	$ 296,013	$ 313,413
Working capital	268,764	282,093
Stockholders equity	209,289	210,834

	Three months ended March 31, 2015	2014
Cash provided by (used in):		
Operating activities	$ (27,131)	$ (23,242)
Investing activities	20,383	(3,848)
Financing activities	12,392	7,786

Our combined cash, cash equivalents and investment securities decreased during the three months ended March 31, 2015 from the balance at December 31, 2014, primarily reflecting our net loss for the period.

The increase in net cash used in operating activities was primarily related to our net loss, changes in our non-cash expenses and working capital fluctuations which are highly variable. The changes in cash provided by (used in) investing activities primarily reflect differences between the proceeds received from sale and maturity of our investments and amounts reinvested. Net cash provided by financing activities 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 investments. These financing and revenue sources have historically allowed us to maintain adequate levels of cash and investments.

Our cash, cash equivalents and investments are held in a variety of non-interest bearing bank accounts and interest-bearing instruments subject to investment guidelines allowing for holdings in U.S. government and agency securities, corporate securities, taxable municipal bonds, commercial paper and money market accounts. Our investment portfolio is structured to provide for investment maturities and access to cash to fund our anticipated working capital needs. However, if our liquidity needs should be accelerated for any reason in the near term, or investments do not pay at maturity, we may be required to sell investment securities in our portfolio prior to their scheduled maturities, which may result in a loss. As of March 31, 2015, we had $296.0 million held in cash reserves or investments scheduled to mature within the next twelve months.

At our currently planned spending rates 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 ADCETRIS labeled indications of use or to advance our other ADC pipeline programs. Further, in the event of a termination of the ADCETRIS collaboration agreement with Takeda, we would not receive development cost sharing payments or milestone payments or royalties for the development or sale

of ADCETRIS in Takeda s territory, and we would be required to fund all ADCETRIS development and commercial activities. Any of these factors could lead to a need for us to raise additional capital.

We are required to conduct additional confirmatory and safety 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 pre-clinical 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, 2014, as filed with the SEC.

There have been no material changes from the contractual commitments previously disclosed in our Annual Report on Form 10-K.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued an accounting standards update entitled ASU 2014-09, Revenue from Contracts with Customers. The standard requires entities to recognize revenue through an evaluation that includes identification of the contract, identification of the performance obligations, determination of the transaction price, allocation of the transaction price to the performance obligations, and recognition of revenue as the entity satisfies the performance obligations. Based on a recent announcement by the FASB, we believe that the standard will become effective for our fiscal year beginning January 1, 2018. We are currently evaluating the guidance to determine the potential impact on our financial condition, results of operations and cash flows, and financial statement disclosures.

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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 three months ended March 31, 2015 has not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2014 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 $233.4 million and $256.5 million as of March 31, 2015 and December 31, 2014, 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 $0.6 million in the fair value of our investments as of March 31, 2015. 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 March 31, 2015.

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 three months ended March 31, 2015, 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) 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 have not been any changes in our internal control over financial reporting during the quarter ended March 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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Part II. Other Information

Item 1A. Risk Factors

You should carefully consider the following risk factors, in addition to the other information contained in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and related notes. If any of the events described in the following risk factors occurs, our business, operating results and financial condition could be seriously harmed. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Quarterly Report on Form 10-Q.

We have marked with an asterisk (*) those risks described below that reflect substantive changes from, or additions to, the risks described in our Annual Report on Form 10-K for the year ended December 31, 2014, filed with the SEC.

Risks Related to Our Business

Our near-term prospects are substantially dependent on ADCETRIS. If we and/or Takeda are unable to effectively 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) 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 continued ability to effectively commercialize ADCETRIS for the treatment of patients in its two approved indications and our ability 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:

- 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;
- as a result of increased target enrollments in the ECHELON-1 and ECHELON-2 trials, our ability to successfully complete these trials on a timely basis could be adversely affected, which in turn could adversely affect our ability to expand ADCETRIS labeled indications of use;
- 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;
- 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;

there may be additional changes to the label for ADCETRIS, including ADCETRIS 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 ECHELON-1, ECHELON-2 or AETHERA clinical trials, or as the result of adverse events observed in these or other studies, including in investigator-sponsored studies;

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;

the estimated incidence rate of new patients in ADCETRIS approved indications may be lower than our projections;

there may be 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;

new competitive therapies may be approved for marketing by regulatory authorities in ADCETRIS labeled indications;

we may be unable to continue to effectively market, sell and distribute ADCETRIS;

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- 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 or may be subject to pricing pressures enacted by industry organizations;
- the relative price of ADCETRIS may be higher than alternative treatment options;
- there may be changed or increased regulatory restrictions;
- we may not have adequate financial or other resources to effectively 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 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 many 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 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 the level of our ongoing ADCETRIS sales in the United States is largely attributable to the incidence flow of patients eligible for treatment with ADCETRIS. We also believe that the incidence rate of new patients in ADCETRIS approved indications is relatively low, particularly when compared to many other oncology indications. For these and other reasons, we expect that our ability to accelerate ADCETRIS sales growth, if at all, 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 continue to 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. In addition, while ADCETRIS product sales grew from 2012 to 2013 and from 2013 to 2014, and our future plans assume that sales of ADCETRIS will increase, we cannot assure you that we can maintain sales of ADCETRIS at or near current levels, or that ADCETRIS sales will continue to grow. 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 effectively 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, most recently in January 2015. We cannot assure you that price increases we have taken or may take in the future 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 only been commercializing ADCETRIS since August 2011 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:

- customer ordering patterns for ADCETRIS, which may vary significantly from period to period;
- the overall 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, including increases in the government discount percentage resulting from price increases we have taken or may take in the future, 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 incidence rate of new patients in ADCETRIS approved indications;

- 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.

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. For example, during 2013 concerns regarding pancreatitis caused an investigator conducting an independent study to temporarily halt enrollment in a trial to amend the eligibility criteria and monitoring for the trial. Subsequently, we have revised our prescribing information to add pancreatitis as a known adverse event. 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, we have revised the prescribing information for ADCETRIS to add pancreatitis, impaired hepatic function and impaired renal function as known adverse events as well as to include 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. In addition, we are currently in discussion with the FDA to update the prescribing information with respect to patients who may experience pulmonary toxicity. Further, based on the identification of future adverse events, we may be required to further revise the prescribing information, including ADCETRIS boxed warning, which could negatively impact sales of ADCETRIS or adversely affect ADCETRIS acceptance in the market.

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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 and safety 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 results of the two pivotal studies. Takeda s failure to provide these additional clinical data or to confirm the results of the pivotal studies, 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 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.

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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, delays in accumulating the required number of clinical events for data analyses, 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 U.S. dollar to the foreign currency where the trial is being conducted may impact our actual costs.

Clinical trials must be conducted in accordance with FDA or other applicable foreign government guidelines and are subject to oversight by the FDA, other foreign governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our product candidates produced under cGMP and other requirements in foreign countries, and may require large numbers of test patients. We, the FDA or other foreign governmental agencies could delay, suspend, halt or modify our clinical trials of ADCETRIS or any of our product candidates, as well as any related special protocol assessment, or SPA, agreements, for numerous reasons, including:

- 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;
- 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;

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 institutional review board, or IRB, approval to conduct a clinical trial at a prospective site;

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- 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, it is currently unknown if ADCETRIS may be safely and effectively combined with human programmed death receptor-1, or PD-1, inhibitors, including nivolumab. As a further 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. As a result, we added 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 clinical trial results could negatively affect our ability to market ADCETRIS or expand into other indications. For example, although we reported positive top line data from our AETHERA trial and the FDA has accepted for filing our supplemental Biologics License Application, or sBLA, that we submitted to the FDA to seek approval for a new indication in the AETHERA treatment setting, regulatory agencies, including the FDA, or their advisors, may disagree with our interpretations of data from the AETHERA trial and may not approve the expansion of ADCETRIS labeled indications of use based on the results of the AETHERA trial or any other of our clinical trials. Further, given the progression-free survival, or PFS, trends in our phase 1 data combining ADCETRIS with standard chemotherapy regimens and the positive PFS outcome in the AETHERA trial, we and Takeda have evaluated the potential that event rates may be slower than expected in both the ECHELON-1 and ECHELON-2 trials and have discussed with regulatory agencies proposed trial modifications. In April 2015, the FDA approved proposed amendments to the ECHELON-1 and ECHELON-2 SPAs for both trials to increase target enrollment from 1,040 to 1,240 patients in ECHELON-1 and from 300 to 450 patients in ECHELON-2. This increase in our target enrollment for these clinical trials will also extend the patient treatment phase of the trials. Although we continue to expect the timeline for reporting data from these clinical trials to be in the 2017 to 2018 timeframe, it is possible that these trial modifications could adversely impact our ability to successfully complete the ECHELON-1 and ECHELON-2 trials on a timely basis, which in turn could adversely affect our ability to expand ADCETRIS labeled indications of use. Adverse medical events, including patient fatalities that may be attributable to ADCETRIS during a clinical trial, could cause a trial to be redone or terminated. Further, some of our clinical trials may be overseen by an independent data monitoring committee, or IDMC, and an IDMC may determine to delay or suspend one or more of these trials due to safety or futility findings based on events occurring during a clinical trial.

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 peripheral T-cell lymphoma. Compelling data have been presented involving several developing technologies, including antibody therapies that target PD-1 and

CAR modified T-cell therapies, that may compete with ADCETRIS in the future. For example, the FDA recently granted breakthrough therapy designation for Bristol-Myers Squibb s nivolumab therapy to treat patients with Hodgkin lymphoma after failure of ASCT and ADCETRIS therapy. In addition, we are aware of multiple investigational agents that are currently being studied, including Pfizer s crizotinib, Takeda s alistertib, Pharmacyclics ibrutinib, and Gilead s idelalisib, 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, Bristol-Myers Squibb, Celgene, Eisai, Genentech, Gilead, GSK, ImmunoGen, Infinity, Merck, Novartis, Pfizer, Pharmacyclics, Sanofi-Aventis, Spectrum Pharmaceuticals, Takeda, Teva and Xencor 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 ADCETRIS or 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.

We are subject to various state and federal healthcare related laws and regulations that may impact our business 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, federal civil and criminal false claims laws, HIPAA/HITECH, the federal civil monetary penalties statute, and the federal transparency requirements under the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively PPACA. 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. Additionally, PPACA amended the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. 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.

The federal civil and criminal false claims laws prohibit, among other things, persons or entities from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from or approval by the federal government, including the Medicare and Medicaid programs, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease, or conceal an obligation to pay money to the federal government. PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. Suits filed under the civil 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 civil False Claims Act action. When an entity is determined to have violated the civil 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.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a healthcare benefit

program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. Similar to the Anti-Kickback Statute, PPACA amended the intent requirement of the criminal healthcare fraud statutes such that a person or entity no longer needs to have actual knowledge of the statute or intent to violate it.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information.

The federal civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal transparency requirements under PPACA require certain manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests.

There may be foreign and state law equivalents of these laws, such as anti-kickback, false claims, and data privacy and security laws, to which we may be subject. We may also be subject to state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Many of these state laws differ from each other in significant ways, thus complicating compliance efforts.

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.

The FDA and other governmental authorities also actively investigate allegations of off-label promotion activities in order to enforce regulations prohibiting these types of activities. If we are found to have promoted an approved product, including ADCETRIS, for off-label uses we may be subject to significant liability, including civil and administrative financial penalties and other remedies as well as criminal financial penalties and other sanctions. Even when a company is not determined to have engaged in off-label promotion, the allegation from government authorities or market participants that a company has engaged in such activities could have a significant impact on the company s sales, business and financial condition. The U.S. government has also required companies to enter into complex corporate integrity agreements and/or non-prosecution agreements that impose significant reporting and other burdens on the affected companies.

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/or the curtailment or restructuring of our operations, any of which could have a material adverse effect on our business and results of operations. Any action against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal, state and foreign healthcare laws is costly and time-consuming for our management.

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.

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 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 pre-clinical studies and clinical trials. For example, both the FDA and its Oncologic Drugs Advisory Committee, which provides the FDA with independent expert advice and recommendations, have expressed concerns about whether the AETHERA trial could support label expansion. The AETHERA trial was not conducted under a SPA agreement with the FDA and, accordingly, we have not reached any agreement with the FDA regarding either the design or the clinical endpoints of the trial. Based upon the positive PFS outcome of the AETHERA trial, we submitted a sBLA to the FDA to seek approval for a new indication in the AETHERA treatment setting. While the FDA has accepted this sBLA for filing with priority review, the FDA may disagree with our interpretations of the data from the AETHERA trial and/or may otherwise determine not to approve the sBLA in a timely manner or at all. Moreover, even though three of our phase 3 clinical trials of ADCETRIS that we are conducting with Takeda are being conducted under SPA agreements 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, a SPA agreement is not binding on the FDA if public health concerns unrecognized at the time the SPA agreement is entered into become evident, other new scientific concerns regarding product safety or efficacy arise, new drugs are approved in the same indication, or if we have failed to comply with the agreed upon trial protocols. In addition, a SPA agreement may be changed by us or the FDA on written agreement of both parties, and the FDA retains significant latitude and discretion in interpreting the terms of a SPA agreement and the data and results from the applicable clinical trial. Regulatory agencies also may approve a product candidate for fewer indications than requested or may grant approval subject to the performance of post-approval studies or risk evaluation and mitigation strategies for a product candidate. Similarly, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of ADCETRIS in additional indications.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols and/or related SPA agreements to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. In addition, as part of the U.S. Prescription Drug User Fee Act, or PDUFA, the FDA has a goal to review and act on a percentage of all regulatory submissions in a given time frame. In this regard, the sBLA that we submitted to the FDA to seek approval for a new indication in the AETHERA treatment was accepted for filing and designated for priority review with a PDUFA targeted action date of August 18, 2015. However, the FDA does not always meet its PDUFA targeted action dates for standard and priority BLAs and it is possible that the FDA s review of our sBLA will not be completed within the FDA s target timelines and may be delayed, in which case, the commercialization of ADCETRIS in the AETHERA treatment setting may be delayed, perhaps substantially. 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.

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 ADCETRIS and 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, Genentech, GSK, Pfizer, Progenics and Takeda, and ADC co-development agreements with Agensys, Genmab and 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 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 PPACA became law in the United States. 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 have had the effect of reducing the revenue generated by our sales of ADCETRIS and will have the effect of reducing any revenue generated by sales of any future commercial products we may have. In addition, we anticipate that 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 by governmental or private insurers or fee caps and pricing pressures enacted by industry organizations or state and federal governments, any of 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, Japan and other countries, government austerity measures or further healthcare reform measures in other countries could adversely affect demand and pricing for ADCETRIS, which would negatively impact anticipated royalty revenue from ADCETRIS sales by Takeda.

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 effectively commercialize ADCETRIS will depend, in part, on the performance of these distributors. Although we believe we can find alternative distributors on relatively short notice, the loss of a major distributor could materially and adversely affect our results of operations and financial condition.

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

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 therefore rely on corporate collaborators and contract manufacturing organizations to supply drug product for commercial supply and our IND-enabling studies and clinical trials. For the monoclonal antibody used in ADCETRIS, we have contracted with

AbbVie for clinical and commercial supplies. For the drug linker used in ADCETRIS, we have contracted with Sigma Aldrich Fine Chemicals, or SAFC, for clinical and commercial supplies. We have multiple contract manufacturers for conjugating the drug linker to the antibody and producing the ADCETRIS product. For our ADC product candidates, multiple contract manufacturers, including AbbVie and SAFC, perform antibody and drug-linker manufacturing and several other contract manufacturers perform conjugation of the drug-linker to the antibody and fill/finish of the drug product. In addition, we rely on other third parties to perform additional steps in the manufacturing process, including shipping and storage of ADCETRIS and our product candidates. For the foreseeable future, we expect to continue to rely on contract manufacturers and other third parties to produce, vial and store sufficient quantities of ADCETRIS 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 supply, or the inability to sell our products in the U.S. or abroad. In addition, we have committed to provide Takeda with their needs of certain parts of the ADCETRIS supply chain for a limited period of time, which may require us to arrange for additional manufacturing supply. Moreover, 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-CD33A, SGN-CD19A, 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, Genentech, GSK, Pfizer, Progenics and Takeda, and our co-development agreements with Agensys, Genmab and OBT. Although ADCETRIS has received marketing approval in the United States, Canada, the European Union, Japan and 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, our clinical-stage product candidates include six ADC programs, which consist of SGN-CD33A, SGN-CD19A, SGN-LIV1A, SGN-CD70A, ASG-22ME, and ASG-15ME, and SEA-CD40, which is based on our sugar-engineered antibody, or SEA, technology. 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 previously 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 pre-clinical 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 pre-clinical 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

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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 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 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 and the University of Miami, among others. Some of these license agreements contain diligence and milestone-based termination provisions, in which case our failure to meet any agreed upon diligence requirements or milestones may allow the licensor to terminate the agreement. Many of our license agreements grant us exclusive licenses to the underlying technologies. If our licensors terminate our license agreements or if we are unable to maintain the exclusivity of our exclusive license agreements, we may be unable to continue to develop and commercialize ADCETRIS or our product candidates. Further, we may have disputes with our licensors, which may impact our ability to develop and commercialize ADCETRIS or our product candidates or require us to enter into additional licenses. For example, on March 31, 2014, Arizona State University and related entities, or Arizona State, filed a patent infringement lawsuit against us concerning a U.S. patent owned by Arizona State. An adverse result in this dispute, or current or potential future disputes with our licensors, may impact our ability to develop and commercialize ADCETRIS and our product candidates, or may require us to enter into additional licenses or to incur additional costs in litigation or settlement. In addition, continued development and commercialization of ADCETRIS and our product candidates will likely require us to secure licenses to additional technologies. We may not be able to secure these licenses on commercially reasonable terms, if at all.

If we are unable to enforce our intellectual property rights or if we fail to sustain and further build our intellectual property rights, we may not be able to commercialize ADCETRIS and 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 certain of 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. 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 have come into force under the Leahy-Smith America Invents Act, or the 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 include provisions that affect the way patent applications are being filed, prosecuted and litigated. For example, the America Invents Act enacted proceedings involving post-issuance patent review procedures, such as inter partes review, or IPR, covered business method reviews and other post-grant reviews. These proceedings are conducted before the Patent Trial and Appeal Board, or PTAB, of the U.S. Patent and Trademark Office, or USPTO. Each proceeding has different eligibility criteria and different patentability challenges that can be raised. In this regard, the IPR process permits any person (except a party who has been litigating the patent for more than a year) to challenge the validity of the patent on the grounds that it was anticipated or made obvious by prior art. As a result, entities associated with hedge funds have recently begun challenging valuable pharmaceutical patents based on prior art through the IPR process. A decision in such a proceeding adverse to our interests could result in the loss of valuable patent rights which would have a material adverse effect on our business, financial condition, results of operations and growth prospects. In any event, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We rely on trade secrets and other proprietary information where we believe patent protection is not appropriate or obtainable. However, trade secrets and other proprietary information are difficult to protect. We have taken measures to protect our unpatented trade secrets and know-how, including the use of confidentiality and assignment of inventions agreements with our employees, consultants and certain contractors. It is possible, however, that these persons may breach the agreements or that our competitors may independently develop or otherwise discover our trade secrets or other proprietary information. Our research collaborators may publish confidential data or other restricted information to which we have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations, then our ability to receive patent protection or protect our proprietary information may be impaired.

We may incur substantial costs and lose important rights or may not be able to continue to commercialize ADCETRIS or to commercialize any of our product candidates that may be approved for commercial sale as a result of litigation or other proceedings relating to patent and other intellectual property rights, and we may be required to obtain patent and other intellectual property rights from others.*

We may face potential lawsuits by companies, academic institutions or others alleging infringement of their intellectual property. In this regard, on March 31, 2014, Arizona State filed a patent infringement lawsuit against us concerning a U.S. patent owned by Arizona State. 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 or future commercialization of our product candidates in development. In addition, we are monitoring the progress of multiple pending patent applications of other organizations that, if granted, may require us to license or challenge their enforceability in order to continue

commercializing ADCETRIS or to commercialize our product candidates that may be approved for commercial sale. As a result of the patent infringement lawsuits that have been filed or may be filed against us in the future by third parties alleging infringement by us of patent or other intellectual property rights, we may be required to pay substantial damages, including but not limited to treble damages, attorneys fees and costs, for past infringement if it is ultimately determined that our products infringe a third party s intellectual property rights. Even if infringement claims against us are without merit, the results may be unpredictable. In addition, defending lawsuits takes significant time, may be expensive and may divert management s attention from other business concerns. Further, we may be stopped from developing, manufacturing or selling our products until we obtain a license from the owner of the relevant technology or other intellectual property rights, or be forced to undertake costly design-arounds, if feasible. If such a license is available at all, it may require us to pay substantial royalties or other fees.

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, USPTO interference or reexamination proceeding, foreign opposition proceeding or related legal and administrative proceeding in the United States and elsewhere. In addition, if we choose to go to court to stop a third party from infringing our patents, that third party has the right to ask the court to rule that these patents are invalid and/or should not be enforced. Under the America Invents Act, a third party may also have the option to challenge the validity of certain patents with the PTAB, whether they are accused of infringing our patents or not, and certain entities associated with hedge funds have recently begun challenging valuable pharmaceutical patents through the IPR process. These lawsuits and administrative proceedings are expensive and consume time and other resources, and we may not be successful in these proceedings or in stopping infringement. In addition, there is a risk that a court will decide that these patents are not valid or infringed, or that the PTAB will decide that certain patents are not valid, and that we do not have the right to stop a third party from using the patented subject matter. Successful challenges to our patent or other intellectual property rights through these proceedings could result in a loss of rights in the relevant jurisdiction and may allow third parties to use our proprietary technologies without a license from us or our collaborators, which may also result in loss of future royalty payments. Furthermore, if such challenges to our rights are not resolved promptly in our favor, our existing business relationships may be jeopardized and we could be delayed or prevented from entering into new collaborations or from commercializing potential products, which could adversely affect our business and results of operations. In addition, we may challenge the patent or other intellectual property rights of third parties and if we are unsuccessful in actions we bring against the rights of such parties, through litigation or otherwise, and it is determined that we infringe the intellectual property rights of such parties, we may be prevented from commercializing potential products in the relevant jurisdiction, or may be required to obtain licenses to those rights or develop or obtain alternative technologies, any of which could harm our business.

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

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

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In addition, the competition for qualified personnel in the biotechnology field is intense, and our future success depends upon our ability to attract, retain and motivate highly skilled scientific, technical and managerial employees. In order to commercialize ADCETRIS, 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.

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 are interrupted, our business could be seriously harmed.

We conduct most of 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 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, patients, customers and others, any of which could have a material adverse effect on our business, financial condition and results of operations. Moreover, a security breach or privacy violation that leads to disclosure or modification of or prevents access to patient information, including personally identifiable information or protected health information, could harm our reputation, compel us to comply with federal and/or state breach notification laws, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive patient data. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

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 and write-offs. 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 first quarter of 2015, our closing stock price fluctuated between $30.54 and $39.69 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, Japan and other countries in which Takeda has received approval by relevant regulatory authorities;

- announcements regarding the results of discovery efforts and pre-clinical and clinical activities by us, including the clinical results of any of our current product candidates, or those of 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, including in connection with the recently filed sBLA seeking approval of ADCETRIS in the AETHERA treatment setting;

- 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;

- 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;

- 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 64.0 percent of our voting power as of April 28, 2015. 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

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
3.1	Fourth Amended and Restated Certificate of Incorporation of Seattle Genetics, Inc.	10-Q	000-32405	3.1	11/07/2008
3.2	Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation of Seattle Genetics, Inc.	8-K	000-32405	3.3	05/26/2011
3.3	Amended and Restated Bylaws of Seattle Genetics, Inc.	10-Q	333-50266	3.2	08/12/2003
4.1	Specimen Stock Certificate.	S-1/A	333-50266	4.1	02/08/2001
4.2	Investor Rights Agreement dated July 8, 2003 among Seattle Genetics, Inc. and certain of its stockholders.	10-Q	000-32405	4.3	11/07/2008
10.1*	Seattle Genetics, Inc. 2015 Senior Executive Annual Bonus Plan.	8-K	000-32405	10.1	2/06/2015
10.2*	Employment Agreement, dated as of February 18, 2015, between Seattle Genetics, Inc. and Darren Cline.	10-K	000-32405	10.42	2/27/2015
10.3*	Compensation Information for Executive Officers and Directors.	10-K	000-32405	10.45	2/27/2015
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.
* Indicates a management contract or compensatory plan or arrangement.

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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: May 1, 2015

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