SEATTLE GENETICS INC /WA
Form 10-Q
November 07, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2014

OR

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

For the transition period from_____ to _____

Commission file number 0-32405

SEATTLE GENETICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**91-1874389**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

21823 30th Drive SE

Bothell, Washington 98021

(Address of principal executive offices, including zip code)

(Registrant s telephone number, including area code): (425) 527-4000

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definition of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer x	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

As of November 4, 2014, there were 123,891,580 shares of the registrant s common stock outstanding.

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Seattle Genetics, Inc.

Quarterly Report on Form 10-Q

For the Quarter Ended September 30, 2014

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

Seattle Genetics, Inc.

Condensed Consolidated Balance Sheets

(Unaudited)

(In thousands, except par value)

	September 30, 2014	December 31, 2013
Assets		
Current assets		
Cash and cash equivalents	$ 50,168	$ 64,116
Short-term investments	289,393	310,151
Accounts receivable, net	43,817	29,508
Inventories	37,541	27,073
Prepaid expenses and other current assets	8,269	6,408
Total current assets	429,188	437,256
Property and equipment, net	43,958	40,787
Other non-current assets	5,102	5,855
Total assets	$ 478,248	$ 483,898
Liabilities and Stockholders Equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 71,323	$ 59,348
Current portion of deferred revenue	47,806	39,850
Total current liabilities	119,129	99,198
Long-term liabilities		
Deferred revenue, less current portion	129,238	149,191
Deferred rent and other long-term liabilities	4,695	5,324
Total long-term liabilities	133,933	154,515
Commitments and contingencies (note 6)		
Stockholders equity		
Preferred stock, $0.001 par value, 5,000 shares authorized; none issued	0	0
Common stock, $0.001 par value, 250,000 shares authorized; 123,880 shares issued and outstanding at September 30, 2014 and 122,615 shares issued and outstanding at December 31, 2013	124	123
Additional paid-in capital	1,004,320	960,375
Accumulated other comprehensive income (loss)	501	(11)
Accumulated deficit	(779,759)	(730,302)
Total stockholders equity	225,186	230,185

Total liabilities and stockholders equity	$ 478,248	$ 483,898

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

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Seattle Genetics, Inc.

Condensed Consolidated Statements of Comprehensive Loss

(Unaudited)

(In thousands, except per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Revenues				
Net product sales	$ 48,209	$ 36,485	$ 131,707	$ 106,141
Collaboration and license agreement revenues	19,501	29,234	52,575	84,525
Royalty revenues	8,143	5,250	28,150	11,189
Total revenues	75,853	70,969	212,432	201,855
Costs and expenses				
Cost of sales	4,725	3,528	12,477	10,008
Cost of royalty revenues	2,901	1,927	8,009	4,299
Research and development	58,510	67,847	166,700	167,855
Selling, general and administrative	25,342	21,451	74,885	66,873
Total costs and expenses	91,478	94,753	262,071	249,035
Loss from operations	(15,625)	(23,784)	(49,639)	(47,180)
Investment and other income, net	59	98	182	331
Net loss	$ (15,566)	$ (23,686)	$ (49,457)	$ (46,849)
Net loss per share basic and diluted	$ (0.13)	$ (0.19)	$ (0.40)	$ (0.39)
Shares used in computation of net loss per share basic and diluted	123,591	121,990	123,234	121,260
Comprehensive loss:				
Net loss	$ (15,566)	$ (23,686)	$ (49,457)	$ (46,849)
Other comprehensive gain (loss) unrealized gain (loss) on securities available for sale	(255)	47	512	10
Comprehensive loss	$ (15,821)	$ (23,639)	$ (48,945)	$ (46,839)

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

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Seattle Genetics, Inc.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(In thousands)

	Nine months ended September 30,	
	2014	**2013**
Operating activities		
Net loss	$ (49,457)	$ (46,849)
Adjustments to reconcile net loss to net cash used in operating activities		
Share-based compensation	29,018	21,617
Depreciation and amortization	9,108	6,057
Amortization of premiums and accretion of discounts	665	1,530
Deferred rent and other long-term liabilities	(629)	(409)
Changes in operating assets and liabilities		
Accounts receivable, net	(14,309)	4,235
Inventories	(10,468)	11,743
Prepaid expenses and other assets	(1,201)	(697)
Accounts payable and accrued liabilities	10,054	(2,683)
Deferred revenue	(11,997)	(2,096)
Net cash used in operating activities	(39,216)	(7,552)
Investing activities		
Purchases of securities available for sale	(331,079)	(340,443)
Proceeds from maturities of securities available for sale	351,200	394,200
Purchases of property and equipment	(9,781)	(14,793)
Net cash provided by investing activities	10,340	38,964
Financing activities		
Proceeds from exercise of stock options and employee stock purchase plan	14,928	33,454
Net cash provided by financing activities	14,928	33,454
Net increase (decrease) in cash and cash equivalents	(13,948)	64,866
Cash and cash equivalents at beginning of period	64,116	54,663
Cash and cash equivalents at end of period	$ 50,168	$ 119,529

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

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Seattle Genetics, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Basis of presentation and summary of significant accounting policies

Basis of presentation

The accompanying unaudited condensed consolidated financial statements reflect the accounts of Seattle Genetics, Inc. and its wholly-owned subsidiary, Seattle Genetics UK, Ltd. (collectively Seattle Genetics or the Company). The condensed consolidated balance sheet data as of December 31, 2013 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, 2013, as filed with the SEC.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results could differ from those estimates. The results of the Company s operations for the three and nine month periods ended September 30, 2014 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, industry benchmarks and experience to date. These estimates involve a substantial degree of judgment.

Government-mandated rebates and chargebacks: The Company has entered into a Medicaid Drug Rebate Agreement, or MDRA, with the Centers for Medicare & Medicaid Services. This agreement provides for a rebate 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 third-party study of the payer mix for ADCETRIS, information on utilization by Medicaid-eligible patients who received assistance through SeaGen Secure®, the Company s patient assistance program, and experience to date. The Company has also completed a Federal Supply Schedule, or FSS, agreement under which certain U.S. government purchasers receive a discount on eligible purchases of ADCETRIS. The Company has entered into a Pharmaceutical Pricing Agreement with the Secretary of Health and Human Services, which enables certain entities that qualify for government pricing under the Public Health Services Act, or PHS,

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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 fee for distribution services that they perform on behalf of the Company which is determined based on sales volume to each distributor. The Company allows for the return of product that is within 30 days of its expiration date or that is damaged. The Company estimates product returns based on its experience to date. 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 used in each agreement is a reasonable estimate of the performance obligation period of such agreement. Accordingly, all amounts received or due, including any upfront payments, maintenance fees, development and regulatory milestone payments and reimbursement payments, are recognized as revenue over the performance obligation periods of each agreement. These performance obligation periods have ranged 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 preclinical studies. The Company s collaborators must undertake significant preclinical research and studies to make a determination of the suitability of a product candidate and the time from those studies or designation to initiation of a clinical trial may take several years.

Initiation of a phase 1 clinical trial. Generally, phase 1 clinical trials may take one to two years to complete.

Initiation 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 full 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 development, regulatory and commercial 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 our ADC collaborations.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board issued an accounting standards update entitled ASU 2014-09, Revenue from Contracts with Customers. The standard requires entities to recognize revenue through the application of a five-step model, which 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. The standard will become effective for the Company beginning January 1, 2017. 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 11,790,000 and 11,511,000 for the three months ended September 30, 2014 and 2013, respectively, and 11,622,000 and 11,678,000 for the nine months ended September 30, 2014 and 2013, 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
September 30, 2014				
U.S. Treasury securities	$ 289,376	$ 19	$ (2)	$ 289,393
Contractual Maturities				
Due in one year or less	$ 289,376			$ 289,393

	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
December 31, 2013				
U.S. Treasury securities	$ 310,162	$ 7	$ (18)	$ 310,151
Contractual Maturities				
Due in one year or less	$ 310,162			$ 310,151

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

	Period of continuous unrealized loss			
	12 Months or less		Greater than 12 months	
	Fair value	Gross unrealized losses	Fair value	Gross unrealized losses
September 30, 2014				
U.S. Treasury securities	$ 66,018	$ (2)	$ NA	$ NA
December 31, 2013				
U.S. Treasury securities	$ 188,599	$ (18)	$ 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 September 30, 2014 or December 31, 2013 and did not transfer any investments between Levels 1, 2 and 3 during the nine month period ended September 30, 2014.

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

	Fair value measurement using:			
	Quoted prices in active markets for identical assets (Level 1)	Other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
As of September 30, 2014				
Cash equivalents U.S. Treasury securities	$ 11,003	$ 0	$ 0	$ 11,003
Short-term investments U.S. Treasury securities	289,393	0	0	289,393
	$ 300,396	$ 0	$ 0	$ 300,396

	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, 2013				
Short-term investments U.S. Treasury securities	$ 310,151	$ 0	$ 0	$ 310,151

5. Inventories

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

	September 30, 2014	December 31, 2013
Raw materials	$ 28,115	$ 25,386
Work in process	5,557	431
Finished goods	3,869	1,256
Total	$ 37,541	$ 27,073

The Company capitalizes ADCETRIS inventory costs. ADCETRIS inventory that is deployed into clinical, research or development use is charged to research and development expense when it is no longer available for use in commercial sales. The Company does not capitalize manufacturing costs for any of its other product candidates.

6. Legal Matters

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

On March 31, 2014, Arizona State University and related entities, or Arizona State, filed a patent infringement lawsuit against the Company concerning a U.S. patent licensed from Arizona State. The Company believes that it has meritorious defenses to Arizona State s claims. At this time, the Company does not believe that a loss is probable and does not have a reasonable basis on which to develop a range of potential loss in

the event of an unfavorable outcome in this dispute. While the Company believes a loss is not probable, it is possible that a liability could be incurred 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 document are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Any or all of our forward-looking statements in this document may turn out to be wrong. Actual events or results may differ materially. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks, uncertainties and other factors. We discuss many of these risks, uncertainties and other factors in this Quarterly Report on Form 10-Q in greater detail under the heading Item 1A Risk Factors. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Overview

Seattle Genetics is a biotechnology company focused on the development and commercialization of 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 more than 45 countries, including those described above, as well as Japan, Australia, Switzerland, South Korea, Singapore and Mexico, 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, including sALCL, or MTCL, 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 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), which equates to a 75 percent improvement in PFS. PFS was assessed after a minimum of two years post initiation of treatment for all study patients. 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 received a variety of subsequent therapies. Notably, most patients on the placebo arm received ADCETRIS after progression. 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 was not conducted under a Special Protocol Assessment, or SPA, agreement from the FDA and has not been designated as a confirmatory trial to convert either accelerated approval or conditional marketing authorization to regular approval; however, this trial will provide drug safety data analyses that fulfills one of our post-approval requirements with both the FDA and the European Medicines Agency, or EMA. An abstract has been accepted for an oral presentation of the full AETHERA data set at the American Society of Hematology, or ASH, annual meeting in December 2014. ADCETRIS is not currently approved in the AETHERA treatment setting. Based upon the positive PFS outcome of the AETHERA trial, we have requested a meeting with the FDA to discuss our plans to submit a supplemental Biologics License Application, or sBLA, for a new indication in the AETHERA treatment setting in the first half of 2015.

We and Takeda are conducting three additional phase 3 clinical trials of ADCETRIS, one in relapsed cutaneous T-cell lymphoma, or CTCL, called the ALCANZA trial, one in front-line advanced classical Hodgkin lymphoma, called the ECHELON-1 trial, and one in front-line MTCL, including sALCL, called the ECHELON-2 trial. We have entered into 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

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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 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 full approval in the currently approved indications. The primary endpoint in 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 encouraging 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 are evaluating the potential that event rates may be slower than expected in both the ECHELON-1 and ECHELON-2 trials and are in discussions with appropriate regulatory agencies on proposed trial modifications. 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.

In addition to ADCETRIS, our pipeline includes six clinical-stage ADC programs consisting of SGN-CD19A, SGN-CD33A, SGN-LIV1A, SGN-CD70A, ASG-22ME, and ASG-15ME, and multiple preclinical programs including SEA-CD40, a novel non-fucosylated anti-CD40 antibody utilizing a proprietary immuno-oncology technology that we plan to advance into phase 1 clinical development in early 2015. 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; Daiichi Sankyo Co., Ltd., or Daiichi Sankyo; Genentech, Inc., a member of the Roche Group, or Genentech; GlaxoSmithKline LLC, or GSK; Pfizer, Inc., or Pfizer; PSMA Development Company LLC, a subsidiary of Progenics Pharmaceuticals Inc., or Progenics; and Takeda; as well as ADC co-development agreements with Agensys, Inc., an affiliate of Astellas Pharma, Inc., or Agensys; Genmab A/S, or Genmab; and Oxford BioTherapeutics Ltd., or OBT.

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 ongoing 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 meaningful future ADCETRIS sales growth, if any, will depend primarily on our ability to expand ADCETRIS labeled indications of use and to a lesser extent, on potential future price increases. 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 I, 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 nine months ended September 30, 2014, total revenues increased to $212.4 million, compared to $201.9 million for the same period in 2013. This increase resulted from increased ADCETRIS net product sales and royalty revenues, partially offset by reduced collaboration and license agreement revenues. Net product sales of ADCETRIS were $131.7 million for the nine months ended September 30, 2014 compared to $106.1 million for the nine months ended September 30, 2013. For the nine months ended September 30, 2014, total costs and expenses increased to $262.1 million, compared to $249.0 million for the same period in 2013. This primarily reflects increases in clinical development efforts to explore additional potential applications of ADCETRIS, as well as investment in our ADC pipeline programs, partially offset by decreased costs attributable to our ADCETRIS collaboration with Takeda. As of September 30, 2014, we had $339.6 million in cash and short-term investments, and $225.2 million in total stockholders equity.

Results of operations

Three and nine months ended September 30, 2014 and 2013

Net product sales

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

	Three months ended September 30,			Nine months ended September 30,		
	2014	2013	% Change	2014	2013	% Change
Net product sales	$ 48,209	$ 36,485	32%	$ 131,707	$ 106,141	24%

The increase in net product sales for the three and nine months ended September 30, 2014 over the comparable periods in 2013 primarily resulted from an increase in sales volume in the 2014 periods and, to a lesser extent, from the effect of price increases instituted since the 2013 periods. The increases in sales volume in the 2014 periods were 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 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. Variation in customer order timing between periods and increased unit sales in Canada during the 2014 periods also contributed to the increase in sales volume. Unit sales in Canada were augmented by the commencement of provincial reimbursement in most of the key provinces during the first half of 2014.

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, 2013	$ 4,525	$ 1,523	$ 6,048
Provision related to current period sales	22,868	3,225	26,093
Adjustment for prior period sales	(745)	(85)	(830)
Payments/credits for current period sales	(20,081)	(2,587)	(22,668)
Payments/credits for prior period sales	(1,700)	(459)	(2,159)
Balance as of September 30, 2014	$ 4,867	$ 1,617	$ 6,484

Our gross-to-net deductions include government-mandated rebates and chargebacks, distribution fees, product returns and commercial co-insurance assistance. 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 and nine months ended September 30, 2014 as a result of price increases we have instituted 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. We also expect gross-to-net deductions, as a percentage of gross product sales, to be in the mid to upper teens for the remainder of 2014.

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Collaboration and license agreement revenues

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

Collaboration and license agreement revenue by collaborator ($ in thousands)	Three months ended September 30, 2014	2013	% Change	Nine months ended September 30, 2014	2013	% Change
Takeda	$ 9,007	$ 16,188	(44%)	$ 25,818	$ 35,154	(27%)
AbbVie	2,923	3,584	(18%)	10,560	11,508	(8%)
Genentech	1,382	1,096	26%	5,298	5,458	(3%)
Bayer	3,000	0	100%	4,500	12,000	(63%)
GSK	2,706	2,829	(4%)	2,923	5,758	(49%)
Pfizer	0	5,000	(100%)	0	5,009	(100%)
Other	483	537	(10%)	3,476	9,638	(64%)
Total	$ 19,501	$ 29,234	(33%)	$ 52,575	$ 84,525	(38%)

Takeda

Revenues earned under our ADCETRIS and ADC collaborations with Takeda represented 46% and 55% of our collaboration and license agreement revenues during the three month periods ended September 30, 2014 and 2013, respectively, and 49% and 42% during the nine month periods ended September 30, 2014 and 2013, respectively. The decreases in revenues from Takeda for the three and nine month periods ended September 30, 2014 from the comparable periods in 2013 were driven by reduced development cost reimbursements earned under the ADCETRIS collaboration, offset partially for the nine month period by the earned amount of regulatory milestones achieved during the first half of 2014. The lower development cost reimbursements in both the three and nine month periods ended September 30, 2014 reflect an increase in collaboration activities performed by Takeda in the 2014 periods.

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. 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 these payments is also reflected as a component of collaboration revenue. We expect that development activities performed by Takeda will continue to increase, particularly with respect to the conduct of clinical trials of ADCETRIS.

As of September 30, 2014, 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. Royalties and commercial sales-based milestones earned under the collaboration are classified as royalty revenues. Takeda also bears a portion of third-party royalty costs owed on sales of ADCETRIS in its territory which are included in royalty revenues.

Other ADC collaboration agreements

We have other active ADC collaborations with a number of companies to allow them to use our proprietary ADC technology. Under our ADC collaborations, which we enter into in the ordinary course of business, we typically receive or are entitled to receive upfront cash payments, progress-dependent milestones and royalties on net sales of products incorporating our ADC technology, as well as annual maintenance fees and support fees for research and development services and materials provided under the agreements. These amounts are recognized as revenue as they are realized, or over the performance obligation period of the agreements during which we provide limited support to the collaborator, if any.

Revenues from our agreements with AbbVie decreased during the three and nine month periods ended September 30, 2014 from the comparable periods in 2013. The decrease for the three month period reflects a milestone achieved during the third quarter of 2013. The decrease during the nine month period is attributable to the completion of the performance obligation period of our first collaboration agreement with AbbVie in early 2013.

Revenues from our agreements with Genentech increased during the three month period ended September 30, 2014 from the comparable period in 2013 primarily as a result of increased reimbursements for product supply activities. Revenues were relatively consistent for the nine month periods ended September 30, 2014 and 2013.

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Revenues from our agreement with Bayer during the three and nine month periods ended September 30, 2014 reflect exclusive licenses and developmental milestones earned. Bayer revenues during the nine month period ended September 30, 2013 reflect the earned portion of an upfront payment received from Bayer under the collaboration which began in June 2013.

Revenues from our agreement with GSK were relatively consistent for the three month periods ended September 30, 2014 and 2013. Revenues for the nine month period ended September 30, 2014 decreased from the comparable period in 2013 primarily resulting from a modification to our collaboration agreement with GSK in December 2013 that involved an upfront payment and an extension of the performance obligation period. As a result, the time period over which we recognize the related revenues was increased.

Pfizer revenues during the three and nine month periods ended September 30, 2013 primarily reflect a development milestone achieved in the three month period ended September 30, 2013.

Revenues from our other ADC collaboration agreements decreased during the three and nine month periods ended September 30, 2014 from the comparable periods in 2013. This primarily resulted from Agensys decision in the second quarter of 2013 not to extend the research term of their collaboration, which accelerated recognition of the remaining deferred revenue.

Our ADC collaborations have generated approximately $300 million, primarily in the form of upfront payments. Total milestone payments provided for under our ADC collaborations could total up to approximately $4.8 billion if all potential product candidates achieved all of the milestone events under all of our current ADC collaborations. Of this amount, approximately $0.8 billion relates to the achievement of development milestones, approximately $2.0 billion relates to the achievement of regulatory milestones and approximately $2.0 billion relates to the achievement of commercial milestones.

Our ADC collaborators are responsible for development, manufacturing and commercialization of any ADC product candidates that result from the collaborations and are solely responsible for the achievement of any of the potential milestones under these collaborations. Since we do not control the research, development or commercialization of any products generated by our ADC collaborators, we are not able to reasonably estimate when, if at all, any milestone payments or royalties may be payable by our ADC collaborators. In addition, most of our current ADC collaborations are at early stages of development. Successfully developing a product candidate, obtaining regulatory approval and ultimately commercializing it is a significantly lengthy and highly uncertain process which entails a significant risk of failure. In addition, business combinations, changes in an ADC collaborator s business strategy and financial difficulties or other factors could result in an ADC collaborator abandoning or delaying development of its ADC product candidates. As such, the milestone payments associated with our ADC collaborations involve a substantial degree of risk to achieve and may never be received. Accordingly, we do not expect, and investors should not assume, that we will receive all of the potential milestone payments provided for under our ADC collaborations and it is possible that we may never receive any significant milestone payments under our ADC collaborations.

Our collaboration and license agreement revenues are impacted by the term and duration of our collaboration and co-development agreements and by progress-dependent milestones, annual maintenance fees and reimbursement of materials and support services as our collaborators advance their ADC product candidates through the development process. Collaboration 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, our ability to enter into additional collaboration and co-development agreements, and the level of co-development funding received by us under the ADCETRIS collaboration with Takeda which is a component of collaboration revenue. We expect our collaboration and license agreement revenues to decrease in 2014 compared to 2013, primarily as a result of a decrease in development funding from Takeda as the level of development activities performed by Takeda under the collaboration expands, as well as lower expected revenue from our ADC collaborations. 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 the period during which we fulfill our performance obligations expires.

Royalty Revenues and Cost of Royalty Revenues

	Three months ended September 30,			Nine months ended September 30,		
	2014	**2013**	**% Change**	**2014**	**2013**	**% Change**
Royalty revenues	$ 8,143	$ 5,250	55%	$ 28,150	$ 11,189	152%

Cost of royalty revenues	$ 2,901	$ 1,927	51%	$ 8,009	$ 4,299	86%

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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. In October 2012, Takeda began its commercial launch of ADCETRIS in the European Union upon receiving conditional marketing authorization from the European Commission for ADCETRIS in two indications. Takeda has since received regulatory approval in additional countries and, where applicable, Takeda also made ADCETRIS available under its international named patient program. Increases in royalty revenues for the three and nine month periods ended September 30, 2014 from the comparable periods in 2013 reflect increased sales in Takeda s territory. Royalties for the nine-month period ended September 30, 2014 also include a $5 million sales milestone triggered by Takeda. Cost of royalty revenues reflect amounts owed to our third-party licensors related to the sale of ADCETRIS in Takeda s territory, which increase as our related royalty revenues increase.

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. We expect that our cost of sales as a percentage of sales will continue to increase in future periods as product manufactured prior to FDA approval, and therefore fully expensed previously, is consumed. This cost benefit is expected to continue to a lesser extent over the next twelve months, 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, as this reduced-cost inventory is used, the percentage of total cost of sales for sales of ADCETRIS will increase into the low-to-mid teens. Cost of sales increased during the three and nine month periods ended September 30, 2014 from the comparable periods in 2013 primarily due to an increase in sales volume and a higher average cost of product sold.

Research and development

Our research and development expenses are summarized as follows:

	Three months ended September 30,			Nine months ended September 30,		
Research and development ($ in thousands)	**2014**	**2013**	**% Change**	**2014**	**2013**	**% Change**
Research	$ 7,439	$ 6,414	16%	$ 20,195	$ 21,958	(8%)
Development and contract manufacturing	21,419	35,581	(40%)	60,178	72,836	(17%)
Clinical	29,652	25,852	15%	86,327	73,061	18%
Total research and development expenses	$ 58,510	$ 67,847	(14%)	$ 166,700	$ 167,855	(1%)

Research expenses include, among other things, personnel, occupancy and laboratory expenses and technology access fees associated with the discovery and identification of new monoclonal antibodies and related technologies and the development of novel classes of stable linkers and cell-killing agents for our ADC technology. Research expenses also include research activities associated with our product candidates, such as preclinical translational biology and *in vitro* and *in vivo* studies. The increase in research expenses during the three month period ended September 30, 2014 as compared to the same period in 2013 reflects increases in compensation costs due to increased staffing levels. The decrease in research expenses during the nine month period ended September 30, 2014 as compared to the same period in 2013 reflects the opt-in fee to Agensys to co-develop ASG-15ME paid in 2013, partially offset by increased discovery activities in support of our growing pipeline of product candidates and increased compensation costs due to increased staffing levels.

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. These expenses decreased during the three and nine month periods ended September 30, 2014 as compared to the

prior year periods due to activities undertaken in 2013 for product supplied to Takeda, partially offset by increases in activities to support our growing pipeline of product candidates.

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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 in clinical expenses during the three and nine month periods ended September 30, 2014 as compared to the prior year periods reflects increased staffing and other costs to support clinical trial activity for ADCETRIS and our product candidates.

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

The following table shows expenses incurred for research, contract manufacturing of our product candidates and clinical and regulatory services provided by third parties as well as 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.

	Three months ended September 30,		Nine months ended September 30,		Five years ended
Development program ($ in thousands)	**2014**	**2013**	**2014**	**2013**	**September 30, 2014**
ADCETRIS (brentuximab vedotin)	$ 14,560	$ 30,651	$ 37,749	$ 61,577	$ 264,405
SGN-CD19A	1,074	1,130	5,653	2,400	26,502
SGN-CD33A	2,759	1,085	4,948	2,592	20,728
SGN-CD70A	729	2,496	3,263	4,242	10,852
ASG-22ME	526	517	1,771	1,986	16,636
SGN-LIV1A	525	385	1,627	2,050	10,158
ASG-15ME	417	456	1,126	5,411	6,906
	20,590	36,720	56,137	80,258	356,187
Other costs and overhead	37,920	31,127	110,563	87,597	538,161
Total research and development	$ 58,510	$ 67,847	$ 166,700	$ 167,855	$ 894,348

Third-party costs for ADCETRIS decreased during the three and nine month periods ended September 30, 2014 from the comparable periods in 2013, primarily due to a decrease in activities related to drug product supplied to Takeda, partially offset by increased clinical trial costs.

Third-party costs for SGN-CD19A were relatively consistent for the three month periods ended September 30, 2014 and 2013. Third-party costs for SGN-CD19A increased during the nine month period ended September 30, 2014 from the comparable period in 2013 due to increased clinical trial costs for ongoing studies and additional drug supply activities.

Third-party costs for SGN-CD33A increased during the three and nine month periods ended September 30, 2014 from the comparable periods in 2013 due to increased clinical trial costs for ongoing studies and additional drug supply activities.

The development costs for product candidates generally accelerate in preparation for an IND submission to the FDA and then decrease until subsequent clinical trials commence. The decrease in costs for SGN-CD70A during the three and nine month periods ended September 30, 2014 from the comparable periods in 2013 reflects preparation in 2013 and the first half of 2014 for the related IND, which was filed in August of 2014. The decrease in costs for SGN-LIV1A during the nine month period ended September 30, 2014 from the comparable period in 2013 reflects preparation in 2013 for the related IND, offset partially in 2014 by the cost of clinical trials that are now underway.

Our ASG-15ME and ASG-22ME product candidates are being co-developed with Agensys. The costs for these programs include an opt-in fee and our share of the related development costs subsequent to our opt-in. The decrease in costs for ASG-15ME for the nine month period ended September 30, 2014 is due to the opt-in fee for ASG-15ME incurred during the second quarter of 2013, offset partially by the cost of clinical trials that are now 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 and nine month periods ended September 30, 2014 from the comparable periods in 2013, primarily due to increases in staffing levels and investment in our earlier-stage ADC pipeline programs.

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

We anticipate that our total research and development expenses in 2014 will increase compared to 2013 due to increased clinical trial expenses for ADCETRIS related to additional 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 ADC 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

Selling, general and administrative ($ in thousands)	Three months ended September 30, 2014	2013	% Change	Nine months ended September 30, 2014	2013	% Change
Selling, general and administrative	$ 25,342	$ 21,451	18%	$ 74,885	$ 66,873	12%

Selling, general and administrative expenses increased during the three and nine month periods ended September 30, 2014 from the comparable periods in 2013 primarily due to higher costs for the commercialization of ADCETRIS and compensation costs driven by increased staffing levels.

We anticipate that selling, general and administrative expenses will increase in 2014 compared to 2013 as we continue our commercial activities in support of the commercialization of ADCETRIS, as well as our support of general operations.

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Investment and other income, net

Investment and other income, net ($ in thousands)	Three months ended September 30, 2014	2013	% Change	Nine months ended September 30, 2014	2013	% Change
Investment and other income, net	$ 59	$ 98	(40%)	$ 182	$ 331	(45%)

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

Liquidity and capital resources

Selected balance sheet and cash flow data ($ in thousands)	September 30, 2014	December 31, 2013
Cash, cash equivalents and investments	$ 339,561	$ 374,267
Working capital	310,059	338,058
Stockholders equity	225,186	230,185

	Nine months ended September 30, 2014	2013
Cash provided by (used in):		
Operating activities	$ (39,216)	$ (7,552)
Investing activities	10,340	38,964
Financing activities	14,928	33,454

Our combined cash, cash equivalents and investment securities decreased during the nine months ended September 30, 2014 primarily reflecting our net loss, partially offset by cash generated from investing and financing activities.

Net cash used in operating activities increased during the nine months ended September 30, 2014 from the comparable period in 2013 as a result of increases in working capital, partially offset by an increase in non-cash expenses. Working capital increases included higher accounts receivable balances due to increased commercial sales of ADCETRIS, as well as higher inventory balances due to increased production. Increases in non-cash expenses reflect higher share-based compensation costs, as well as increases in depreciation expense resulting from a laboratory facilities expansion completed in 2013.

Net cash provided by investing activities decreased during the nine months ended September 30, 2014 from the comparable period in 2013 primarily reflecting lower proceeds from maturities of investments compared to the 2013 period.

Net cash provided by financing activities for both the nine months ended September 30, 2014 and September 30, 2013 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 through collections from commercial sales of ADCETRIS. To a lesser degree, we have also financed our operations through royalty revenues and interest earned on cash, cash equivalents and investment securities. These financing 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 September 30, 2014, we had $339.6 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.

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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 preclinical development, manufacturing and clinical trial activities, including the post-approval studies we are required to and are currently conducting for ADCETRIS, as well as position ADCETRIS for potential additional regulatory approvals, and we may therefore need to raise significant amounts of additional capital. We may seek additional funding through some or all of the following methods: corporate collaborations, licensing arrangements and public or private debt or equity financings. We do not know whether additional capital will be available when needed, or that, if available, we will obtain financing on terms favorable to us or our stockholders. If we are unable to raise additional funds when we need them, we may be required to delay, reduce the scope of, or eliminate one or more of our development programs, which may adversely affect our business and operations.

Commitments

Our future minimum contractual commitments were reported in our Annual Report on Form 10-K for the year ended December 31, 2013, as filed with the SEC.

In March 2014, the Company entered into an operating lease for approximately 60,000 square feet of a facility to be used for general office purposes. The lease term commenced on April 1, 2014. The lease includes an abated rent period at the end of the lease. The approximate aggregate base rent due over the initial term of the lease is $7.5 million. The lease includes an early termination option, subject to payment of a termination fee. The lease expires in December 2024 with two extension options of five years each.

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

Critical accounting policies

The preparation of our condensed consolidated financial statements in conformity with generally accepted accounting principles requires us to make estimates and assumptions that affect the amounts reported in the financial statements and the notes to the financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions. A summary of our critical accounting policies is presented in Part II, Item 7, of our Annual Report on Form 10-K for the year ended December 31, 2013. There have been no material changes to our critical accounting policies during the nine months ended September 30, 2014.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board issued an accounting standards update entitled ASU 2014-09, Revenue from Contracts with Customers. The standard requires entities to recognize revenue through the application of a five-step model, which 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. The standard will become effective for us beginning January 1, 2017. 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.

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 September 30, 2014 has not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2013 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 $300.4

million and $310.2 million as of September 30, 2014 and December 31, 2013, respectively.

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We have estimated the effect on our investment portfolio of a hypothetical increase in interest rates by one percent to be a reduction of $1.0 million in the fair value of our investments as of September 30, 2014. In addition, a hypothetical decrease of 10% in the effective yield of our investments would reduce our expected investment income by less than $0.1 million over the next twelve months based on our investment balance at September 30, 2014.

Foreign Currency Risk

Most of our revenues and expenses are denominated in U.S. dollars and as a result, we have not experienced significant foreign currency transaction gains and losses to date. Our commercial sales in Canada are denominated in Canadian Dollars. We also had other transactions denominated in foreign currencies during the nine months ended September 30, 2014, 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. Also, Takeda converts its sales of ADCETRIS from various currencies to U.S. Dollars for purposes of determining royalties owed to us. We do not anticipate that foreign currency transaction gains or losses will be significant at our current level of operations. However, transaction gains or losses may become significant in the future as we continue to expand our operations internationally. We have not engaged in foreign currency hedging to date; however, we may do so in the future.

Item 4. Controls and Procedures

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

(b) *Changes in internal control over financial reporting.* There were no changes in our internal control over financial reporting during the quarter ended September 30, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

Item 1A. Risk Factors

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

We have marked with an asterisk (*) those risks described below that reflect substantive changes from, or additions to, the risks described in our Annual Report on Form 10-K for the year ended December 31, 2013, 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. *

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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;

- 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;

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