SEATTLE GENETICS INC /WA Form 10-Q August 08, 2012 Table of Contents

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 June 30, 2012

OR

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

For the transition period from

to

Commission file number 0-32405

SEATTLE GENETICS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of

91-1874389 (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 August 2, 2012, there were 118,207,214 shares of the registrant s common stock outstanding.

Seattle Genetics, Inc.

Quarterly Report on Form 10-Q

For the Quarter Ended June 30, 2012

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

Seattle Genetics, Inc.

Condensed Consolidated Balance Sheets

(Unaudited)

(In thousands, except par value)

| | June 30, 2012 | December 31, 2011 |
|--|------------------|----------------------|
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | \$ 60,760 | \$ 87,634 |
| Short-term investments | 269,577 | 243,062 |
| Interest receivable | 879 | 641 |
| Accounts receivable, net | 31,553 | 54,955 |
| Inventories | 25,697 | 9,469 |
| Prepaid expenses and other current assets | 6,626 | 3,820 |
| Total current assets | 395,092 | 399,581 |
| Property and equipment, net | 19,339 | 19,652 |
| Other non-current assets | 5,598 | 5,983 |
| Total assets | \$ 420,029 | \$ 425,216 |
| Liabilities and Stockholders Equity | | |
| Current liabilities | | |
| Accounts payable and accrued liabilities | \$ 52,154 | \$ 53,048 |
| Current portion of deferred revenue | 32,490 | 38,092 |
| Total current liabilities | 84,644 | 91,140 |
| Long-term liabilities | | |
| Deferred revenue, less current portion | 111,735 | 110,013 |
| Deferred rent and other long-term liabilities | 5,133 | 5,214 |
| Total long-term liabilities | 116,868 | 115,227 |
| Commitments and contingencies Stockholders equity | | |
| Preferred stock, \$0.001 par value, 5,000 shares authorized; none issued | 0 | 0 |
| Common stock, \$0.001 par value, 250,000 shares authorized; 117,961 shares issued and outstanding at | | |
| June 30, 2012 and 116,023 shares issued and outstanding at December 31, 2011 | 118 | 116 |
| Additional paid-in capital | 861,970 | 832,713 |
| Accumulated other comprehensive income (loss) | (37) | 20 |
| Accumulated deficit | (643,534) | (614,000) |
| Total stockholders equity | 218,517 | 218,849 |

Total liabilities and stockholders equity

\$ 420,029

\$ 425,216

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

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Seattle Genetics, Inc.

Condensed Consolidated Statements of Comprehensive Loss

(Unaudited)

(In thousands, except per share amounts)

| | | Three months ended June 30, | | hs ended |
|--|-------------|-----------------------------|-------------|-------------|
| | 2012 | 2011 | 2012 | 2011 |
| Revenues | | | | |
| Net product sales | \$ 34,691 | \$ 0 | \$ 69,187 | \$ 0 |
| Collaboration and license agreement revenues | 12,894 | 13,054 | 26,643 | 25,225 |
| Royalty revenues | 1,238 | 0 | 1,238 | 0 |
| Total revenues | 48,823 | 13,054 | 97,068 | 25,225 |
| Costs and expenses | | | | |
| Cost of sales | 2,995 | 0 | 6,066 | 0 |
| Cost of royalty revenues | 502 | 0 | 502 | 0 |
| Research and development | 42,755 | 49,643 | 81,242 | 82,077 |
| Selling, general and administrative | 19,862 | 15,197 | 42,047 | 27,910 |
| Total costs and expenses | 66,114 | 64,840 | 129,857 | 109,987 |
| Loss from operations | (17,291) | (51,786) | (32,789) | (84,762) |
| Investment and other income, net | 55 | 280 | 3,255 | 582 |
| Net loss | \$ (17,236) | \$ (51,506) | \$ (29,534) | \$ (84,180) |
| Net loss per share - basic and diluted | \$ (0.15) | \$ (0.45) | \$ (0.25) | \$ (0.76) |
| Shares used in computation of net loss per share - basic and diluted | 117,252 | 113,996 | 116,800 | 111,270 |
| Comprehensive loss: | | | | |
| Net loss | \$ (17,236) | \$ (51,506) | \$ (29,534) | \$ (84,180) |
| Other comprehensive loss - unrealized gain (loss) on securities available for sale | (2) | (40) | (57) | 169 |
| Comprehensive loss | \$ (17,238) | \$ (51,546) | \$ (29,591) | \$ (84,011) |

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

Seattle Genetics, Inc.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(In thousands)

| | Six months ended June 30, | |
|--|------------------------------|-------------|
| | 2012 | 2011 |
| Operating activities | | |
| Net loss | \$ (29,534) | \$ (84,180) |
| Adjustments to reconcile net loss to net cash used in operating activities | | |
| Share-based compensation expense | 11,637 | 8,530 |
| Depreciation and amortization | 3,023 | 1,771 |
| Amortization of premiums, accretion of discounts and gain on investments | 1,016 | 2,125 |
| Deferred rent and other long-term liabilities | (81) | 232 |
| Changes in operating assets and liabilities | | |
| Interest receivable | (238) | (410) |
| Accounts receivable | 23,402 | 8,268 |
| Inventories | (16,228) | 0 |
| Prepaid expenses and other current assets | (2,806) | (2,117) |
| Accounts payable and accrued liabilities | (894) | 8,053 |
| Deferred revenue | (3,880) | 12,904 |
| | | ŕ |
| Net cash used in operating activities | (14,583) | (44,824) |
| Investing activities | | |
| Purchases of securities available for sale | (255,263) | (323,619) |
| Proceeds from maturities of securities available for sale | 221,851 | 250,910 |
| Proceeds from sales of securities available-for-sale | 5,825 | 0 |
| Purchases of property and equipment | (2,326) | (1,585) |
| Purchases of other non-current assets | 0 | (203) |
| Net cash used in investing activities | (29,913) | (74,497) |
| Financing activities | | |
| Net proceeds from issuance of common stock | 0 | 168,053 |
| Proceeds from exercise of stock options and employee stock purchase plan | 17,622 | 9,938 |
| Net cash provided by financing activities | 17,622 | 177,991 |
| Net increase (decrease) in cash and cash equivalents | (26,874) | 58,670 |
| Cash and cash equivalents at beginning of period | 87,634 | 21,127 |
| Cash and cash equivalents at end of period | \$ 60,760 | \$ 79,797 |

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

Seattle Genetics, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Basis of presentation and summary of significant accounting policies

Basis of presentation

The accompanying unaudited condensed consolidated financial statements reflect the accounts of Seattle Genetics, Inc. and its wholly-owned subsidiary, Seattle Genetics UK, Ltd. (collectively Seattle Genetics or the Company). The condensed consolidated balance sheet data as of December 31, 2011 were derived from audited financial statements not included in this quarterly report on Form 10-Q. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission, or SEC, and generally accepted accounting principles in the United States of America, or GAAP, for unaudited condensed consolidated financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. The accompanying unaudited condensed consolidated financial statements reflect all adjustments consisting of normal recurring adjustments which, in the opinion of management, are necessary for a fair statement of the Company s financial position and results of its operations, as of and for the periods presented. Management has determined that the Company operates in one segment: the development and sale of pharmaceutical products on its own behalf or in collaboration with others.

Unless indicated otherwise, all amounts presented in financial tables are presented in thousands, except for per share and par value amounts.

These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and accompanying notes included in the Company s Annual Report on Form 10-K for the year ended December 31, 2011, as filed with the SEC.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results could differ from those estimates. The results of the Company s operations for the three and six month periods ended June 30, 2012 are not necessarily indicative of the results to be expected for the full year.

In August 2011, the U.S. Food and Drug Administration, or FDA, granted accelerated approval of ADCETRIS®, or brentuximab vedotin, in two indications: (1) the treatment of patients with Hodgkin lymphoma after failure of autologous stem cell transplant, or ASCT, or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates, and (2) the treatment of patients with systemic anaplastic large cell lymphoma, or sALCL, after failure of at least one prior multi-agent chemotherapy regimen. There are no data available demonstrating improvement in patient-reported outcomes or survival with ADCETRIS. In connection with the accelerated approval, the Company is required to conduct post-approval studies intended to confirm patient benefit. The Company is also investigating the use of ADCETRIS in other oncology indications.

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 in the United States through a limited number of pharmaceutical distributors. Healthcare providers order ADCETRIS through these distributors. The Company receives orders from distributors and ships product directly to the healthcare provider. The Company records product sales upon delivery of the product to the healthcare provider at which time title and risk of loss pass. Product sales are recorded net of estimated government-mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions. Reserves are established for these deductions and actual amounts incurred are offset against applicable reserves. The Company reflects these reserves as either a reduction in the related account receivable from the distributor, or as an accrued liability depending on the nature of the sales deduction. Sales reserves are based on management s estimates that consider payer mix in target markets, industry benchmarks and experience to date. These estimates involve a high degree of judgment and are periodically reviewed and adjusted as necessary.

Government-mandated rebates and chargebacks: The Company has entered into a Medicaid Drug Rebate Agreement, or MDRA, with the Centers for Medicaie & Medicaid Services. This agreement provides for a rebate to participating states based on covered purchases of ADCETRIS. Medicaid rebates are invoiced to the Company by participating states. The Company estimated Medicaid rebates based on a third party study of the payer mix for ADCETRIS and information on utilization by Medicaid-eligible patients who received assistance through SeaGen Secure . These estimates are compared to historical experience and adjusted as

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necessary. The Company has also completed an interim Federal Supply Schedule, or FSS, agreement under which certain U.S. government purchasers receive a discount on their purchases of ADCETRIS. The Company has entered into a Pharmaceutical Pricing Agreement, or PPA, with the Secretary of Health and Human Services, which enables certain private entities that qualify for government pricing under the Public Health Services Act, or PHS, to receive discounts on their qualified purchases of ADCETRIS. Under these agreements, distributors process a chargeback to the Company for the difference between wholesale acquisition cost and the discounted price for healthcare providers entitled to FSS discounts and PHS pricing. As a result of the Company s direct-ship distribution model, it can determine the entities purchasing ADCETRIS and this information enables the Company to estimate expected chargebacks for FSS and PHS purchases based on each entity s eligibility for the FSS and PHS programs. The Company also reviews actual chargeback information to further refine these estimates.

Distribution fees, product returns and other deductions: The Company s distributors charge a fee for distribution services that they perform on behalf of the Company. The Company is able to calculate the amount due for each distributor based on the amount of sales to each distributor. The Company allows for the return of product that is within 30 days of its expiration date or that is damaged. The Company estimated product returns based on historical industry information of return rates for other specialty pharmaceutical products. In addition, the Company considered its direct-ship distribution model, its belief that product is typically not held in the distribution channel, and the expected rapid use of the product by healthcare providers. The Company provides financial assistance to qualifying patients that are underinsured or cannot cover the cost of commercial coinsurance amounts through its patient assistance program, SeaGen Secure. SeaGen Secure is available to patients in the U.S. and its territories who meet various financial need criteria. Estimated contributions for commercial coinsurance are deducted from gross sales. These contributions are based on an analysis of expected plan utilization and are adjusted as necessary to reflect our actual experience.

Collaboration and license agreement revenues

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

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

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

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

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

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

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

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

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

Receiving marketing approval in a major market, such as in the United States, Europe or Japan. Generally it takes up to three years after a marketing application is submitted to obtain full approval for marketing and pricing from the applicable regulatory agency. Commercialization milestones in the Company s collaborations may include the following types of events:

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

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

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

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

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

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

Royalty revenues and cost of royalty revenues

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

2. Net loss per share

Basic and diluted net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. The Company excluded all restricted stock units, warrants and options to purchase common stock from the calculation of diluted net loss per share as such securities are anti-dilutive for all periods presented.

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

| | Three months ended June 30, | | Six months ended June 30, | |
|---|-----------------------------|--------|---------------------------|--------|
| | 2012 | 2011 | 2012 | 2011 |
| Warrants to purchase common stock | 0 | 1,113 | 0 | 1,113 |
| Options to purchase common stock and restricted stock units | 13,399 | 12,490 | 13,720 | 12,643 |
| Total | 13,399 | 13,603 | 13,720 | 13,756 |

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3. Investments

The Company classifies its securities as available-for-sale, which are reported at estimated fair value with unrealized gains and losses included in accumulated other comprehensive income (loss) in stockholders—equity. Investments in securities with a maturity of less than one year, or where management—s intent is to use the investments to fund current operations, or to make them available for current operations, are classified as short-term investments.

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

| | Amortized cost | Gre unrea gai | alized | unre | ross alized sses | Fair value |
|---|--|---------------------|---------------|-------------|------------------------|--|
| June 30, 2012 | | | | | | |
| U.S. treasury securities | \$ 259,935 | \$ | 2 | \$ | (23) | \$ 259,914 |
| Corporate obligations | 9,983 | | 0 | | (16) | 9,967 |
| | | | | | | |
| Total | \$ 269,918 | \$ | 2 | \$ | (39) | \$ 269,881 |
| | | | | | | |
| Contractual Maturities | | | | | | |
| Due in one year or less | \$ 269,918 | | | | | \$ 269,881 |
| | | Gr | nee | Gı | ross | |
| | Amortized cost | unrea gai | alized | unre | alized sses | Fair value |
| December 31, 2011 | cost | unrea gai | alized ins | unre los | alized sses | value |
| U.S. treasury securities | cost \$ 228,001 | unrea | alized ins | unre | alized sses | value \$ 228,022 |
| U.S. treasury securities Corporate obligations | \$ 228,001 9,565 | unrea gai | alized ins | unre los | alized sses (3) (1) | value \$ 228,022 9,564 |
| U.S. treasury securities | cost \$ 228,001 | unrea gai | alized ins | unre los | alized sses | value \$ 228,022 |
| U.S. treasury securities Corporate obligations | \$ 228,001 9,565 | unrea gai | alized ins | unre los | alized sses (3) (1) | value \$ 228,022 9,564 |
| U.S. treasury securities Corporate obligations Auction rate securities | \$ 228,001 9,565 5,780 | unrea gai \$ | 24 0 | unre los | (3) (1) | \$ 228,022 9,564 5,780 |
| U.S. treasury securities Corporate obligations Auction rate securities | \$ 228,001 9,565 5,780 | unrea gai \$ | 24 0 | unre los | (3) (1) | \$ 228,022 9,564 5,780 |
| U.S. treasury securities Corporate obligations Auction rate securities Total | \$ 228,001 9,565 5,780 | unrea gai \$ | 24 0 | unre los | (3) (1) | \$ 228,022 9,564 5,780 |
| U.S. treasury securities Corporate obligations Auction rate securities Total Contractual Maturities | \$ 228,001 9,565 5,780 \$ 243,346 | unrea gai \$ | 24 0 | unre los | (3) (1) | \$ 228,022 9,564 5,780 \$ 243,366 |
| U.S. treasury securities Corporate obligations Auction rate securities Total Contractual Maturities Due in one year or less | \$ 228,001 9,565 5,780 \$ 243,346 | unrea gai \$ | 24 0 | unre los | (3) (1) | \$ 228,022 9,564 5,780 \$ 243,366 \$ 237,586 |

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

| | June 30, 2012 | Dec | cember 31, 2011 |
|--------------------------|------------------|-----|--------------------|
| Short-term investments | \$ 269,577 | \$ | 243,062 |
| Other non-current assets | 304 | | 304 |
| Total | \$ 269,881 | \$ | 243,366 |

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

| | Period of continuous unrealized loss | | | | |
|--------------------------|--------------------------------------|------------|------------------------|------------|--|
| | 12 month | is or less | Greater than 12 months | | |
| | | Gross | | Gross | |
| | Fair | unrealized | Fair | unrealized | |
| | value | losses | value | losses | |
| As of June 30, 2012 | | | | | |
| U.S. treasury securities | \$ 214,898 | \$ (23) | \$ NA | \$ NA | |
| Corporate obligations | 9,967 | (16) | NA | NA | |
| | | | | | |
| Total | \$ 224,865 | \$ (39) | \$ NA | \$ NA | |
| | • | | | | |
| As of December 31, 2011 | | | | | |
| U.S. treasury securities | \$ 80,234 | \$ (3) | \$ NA | \$ NA | |
| Corporate obligations | 4,571 | (1) | NA | NA | |
| | · | · í | | | |
| Total | \$ 84,805 | \$ (4) | \$ NA | \$ NA | |

4. Fair Value

The Company holds short-term available-for-sale securities that are measured at fair value which is determined on a recurring basis according to a fair value hierarchy that prioritizes the inputs and assumptions used, and the valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described as follows:

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.
- Level 2: Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly.

Level 3: Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable. The determination of a financial instrument s level within the fair value hierarchy is based on an assessment of the lowest level of any input that is significant to the fair value measurement. The Company considers observable data to be market data which is readily available, regularly distributed or updated, reliable and verifiable, not proprietary, and provided by independent sources that are actively involved in the relevant market.

Level 1 investments, which include investments that are valued based on quoted market prices in active markets, consisted of U.S. treasury securities. Level 2 investments, which include investments that are valued based on quoted prices in markets that are not active, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency, consisted of high-grade corporate obligations. Level 3 investments consisted of auction rate securities at December 31, 2011 that were sold in March 2012. The Company did not hold any level 3 investments as of June 30, 2012 and did not transfer any investments into or out of Levels 1, 2 and 3 during the six month period ended June 30, 2012.

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

| | Quoted prices | Fair value measurement using: | | |
|--|---|--|---|------------------------------------|
| | in active markets for identical assets (Level 1) | Other observable inputs (Level 2) | Significant unobservable inputs (Level 3) | Total |
| As of June 30, 2012 | | | | |
| Short-term investments: | | | | |
| U.S. Treasury securities | \$ 259,610 | \$ 0 | \$ 0 | \$ 259,610 |
| Corporate obligations | 0 | 9,967 | 0 | 9,967 |
| Other non-current assets - U.S. Treasury securities | 304 | 0 | 0 | 304 |
| Total | \$ 259,914 | \$ 9,967 | \$ 0 | \$ 269,881 |
| | | | | |
| | | Fair value me | asurement using: | |
| | Quoted prices in active markets for identical assets (Level 1) | Fair value mes Other observable inputs (Level 2) | Significant unobservable inputs (Level 3) | Total |
| As of December 31, 2011 | in active markets for identical assets (Level 1) | Other observable inputs | Significant unobservable inputs (Level 3) | |
| Cash equivalents - money market funds | in active markets for identical assets | Other observable inputs | Significant unobservable inputs | Total \$ 66 |
| Cash equivalents - money market funds Short-term investments: | in active markets for identical assets (Level 1) | Other observable inputs (Level 2) | Significant unobservable inputs (Level 3) | \$ 66 |
| Cash equivalents - money market funds Short-term investments: U.S. Treasury securities | in active markets for identical assets (Level 1) \$ 66 | Other observable inputs (Level 2) \$ 0 | Significant unobservable inputs (Level 3) | \$ 66 227,718 |
| Cash equivalents - money market funds Short-term investments: U.S. Treasury securities Corporate obligations | in active markets for identical assets (Level 1) \$ 66 227,718 | Other observable inputs (Level 2) \$ 0 0 9,564 | Significant unobservable inputs (Level 3) \$ 0 | \$ 66 227,718 9,564 |
| Cash equivalents - money market funds Short-term investments: U.S. Treasury securities Corporate obligations Auction rate securities | in active markets for identical assets (Level 1) \$ 66 227,718 0 0 | Other observable inputs (Level 2) \$ 0 0 9,564 0 | Significant unobservable inputs (Level 3) \$ 0 0 0 5,780 | \$ 66 227,718 9,564 5,780 |
| Cash equivalents - money market funds Short-term investments: U.S. Treasury securities Corporate obligations | in active markets for identical assets (Level 1) \$ 66 227,718 | Other observable inputs (Level 2) \$ 0 0 9,564 | Significant unobservable inputs (Level 3) \$ 0 | \$ 66 227,718 9,564 |

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

| | Fa | air |
|--|------|-------|
| | Va | lue |
| Balance as of December 31, 2011 | \$ 5 | ,780 |
| Sale of auction rate securities | (5 | ,825) |
| Realized gain on auction rate securities | | 45 |
| | | |
| Balance as of June 30, 2012 | \$ | 0 |

5. Inventories

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

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| | June 30, 2012 | ember 31, 2011 |
|-----------------|------------------|-------------------|
| Raw materials | \$ 23,782 | \$ 9,275 |
| Work in process | 1,475 | 173 |
| Finished goods | 440 | 21 |
| | | |
| Total | \$ 25,697 | \$ 9,469 |

The Company began capitalizing ADCETRIS inventory costs following accelerated approval by the FDA in August 2011. Prior to FDA approval, the Company expensed ADCETRIS production costs as a research and development expense. The Company does not capitalize manufacturing costs for any of its other product candidates. ADCETRIS inventory that is deployed into clinical, research or development use is charged to research and development expense when it is no longer available for use in commercial sales.

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, should, expect, plan, anticipate, project, believe, estimate, predict, potential, continue, the negative of terms like these or other comparable terminology, and other words or terms of similar meaning in connection with any discussion of future operating or financial performance. These statements are only predictions. All forward-looking statements included in this document are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Any or all of our forward-looking statements in this document may turn out to be wrong. Actual events or results may differ materially. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks, uncertainties and other factors. In evaluating these statements, you should specifically consider various factors, including the risks outlined under the caption Risk Factors set forth in Item 1A of Part II of this quarterly report on Form 10-Q, as well as those contained from time to time in our other filings with the SEC. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Overview

Seattle Genetics is a biotechnology company focused on the development and commercialization of monoclonal antibody-based therapies for cancer. In August 2011, the U.S. Food and Drug Administration, or FDA, granted accelerated approval of ADCETRIS®, or brentuximab vedotin, in two indications: (1) the treatment of patients with Hodgkin lymphoma after failure of autologous stem cell transplant, or ASCT, or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates, and (2) the treatment of patients with systemic anaplastic large cell lymphoma, or sALCL, after failure of at least one prior multi-agent chemotherapy regimen. There are no data available demonstrating improvement in patient-reported outcomes or survival with ADCETRIS.

ADCETRIS is an antibody-drug conjugate, or ADC, comprising an anti-CD30 monoclonal antibody attached by a protease-cleavable linker to a microtubule disrupting agent, monomethyl auristatin E (MMAE), utilizing our proprietary technology. We have a broad development strategy for ADCETRIS evaluating its potential application in earlier lines of therapy for patients with Hodgkin lymphoma and mature T-cell lymphoma, or MTCL, and in other CD30-positive malignancies. In addition, we have three clinical-stage ADC programs, which consist of SGN-75, ASG-5ME, and ASG-22ME, as well as several preclinical product candidates, including SGN-CD19A.

In December 2009, we entered into a collaboration agreement with Millennium: The Takeda Oncology Company, or Millennium, to develop and commercialize ADCETRIS. Under this collaboration, Seattle Genetics has retained commercial rights for ADCETRIS in the United States and its territories and in Canada, and Millennium has commercial rights in the rest of the world. We are in the process of seeking regulatory approval to market ADCETRIS in Canada for relapsed Hodgkin lymphoma and sALCL and we anticipate a review decision by Health Canada in early 2013. In June 2011, Millennium s Marketing Authorization Application, or MAA, seeking regulatory approval to market ADCETRIS for the treatment of relapsed Hodgkin lymphoma and relapsed ALCL in the European Union was accepted by the European Medicines Agency, or EMA, which is currently reviewing the application. In July 2012, Millennium received a positive recommendation from the EMA s Committee for Medicinal Products for Human Use, or CHMP, for the conditional marketing authorization of ADCETRIS for two indications: (1) the treatment of adult patients with relapsed or refractory CD30-positive Hodgkin lymphoma following ASCT or following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option, and (2) for the treatment of adult patients with relapsed or refractory sALCL. The European Commission, which has the authority to approve medicines for use in the European Union, generally follows the recommendations of the CHMP and typically renders a final decision within three months of the CHMP opinion. If the CHMP recommendation is formally adopted by the European Commission, ADCETRIS would be approved for marketing in all 27 member states of the European Union. Even if the European Commission provides conditional marketing authorization of ADCETRIS for the two indications, Millennium would be subject to post-marketing compliance requirements, including providing confirmatory evidence of clinical benefit by completing additional studies on a post-approval basis. We also have collaborations for our ADC technology with a number of biotechnology and pharmaceutical companies, including Abbott Biotechnology Ltd., or Abbott; Bayer Pharmaceuticals Corporation, or Bayer; Celldex Therapeutics, Inc., or Celldex; Daiichi Sankyo Co., Ltd., or Daiichi Sankyo; Genentech, Inc., a member of the Roche Group, or Genentech; GlaxoSmithKline LLC, or GSK; Millennium, Pfizer, Inc., or Pfizer, and PSMA Development Company LLC, a subsidiary of Progenics Pharmaceuticals Inc., or Progenics; as well as ADC co-development agreements with Agensys, Inc., an affiliate of Astellas Pharma, Inc., or Agensys, Genmab A/S, or Genmab, and Oxford BioTherapeutics Ltd., or OBT.

We began commercializing ADCETRIS in August 2011 and the commercial potential of ADCETRIS and our ability to realize that potential remains uncertain. Our success in commercializing ADCETRIS will require, among other things, effective sales, marketing, manufacturing, distribution, information systems and pricing strategies, as well as compliance with applicable laws and regulations. The FDA granted accelerated approval of ADCETRIS which means that we are, among other things, obligated to

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conduct specific post-approval clinical studies to confirm patient benefit as a condition of that approval. In addition, we intend to explore the use of ADCETRIS earlier in the treatment of Hodgkin lymphoma and sALCL and in other CD30-positive malignancies. In order to do this, we will be required to conduct additional extensive clinical studies and, if these studies are successful, we intend to seek additional regulatory approvals. We and Millennium recently initiated a phase III clinical trial of ADCETRIS in relapsed cutaneous T-cell lymphoma, or CTCL. In addition, we and Millennium plan to conduct two other phase III clinical trials of ADCETRIS, including a trial in front-line advanced stage Hodgkin lymphoma, and a trial in front-line MTCL, including sALCL, both of which are planned to start by late 2012 or early 2013. The FDA has agreed to two special protocol assessments, or SPAs, one for the ongoing CTCL trial and another for the planned Hodgkin lymphoma clinical trial. We have formed a collaboration with Ventana Medical Systems, Inc., a member of the Roche Group, or Ventana, under which Ventana will develop, manufacture and commercialize a molecular companion diagnostic test with the goal of identifying patients who might respond to treatment with ADCETRIS based on CD30 expression levels in their tissue specimens. A molecular companion diagnostic is not required for the current FDA-approved indications for ADCETRIS; however, we expect that a molecular companion diagnostic may be required by regulatory authorities to support regulatory approval of ADCETRIS in other CD30-positive malignancies. All of these activities will require substantial amounts of capital and may not ultimately prove successful. Further, our other product candidates are in relatively early stages of development. These product candidates will require significant further development, financial resources and personnel to obtain regulatory approval and develop into commercially viable products, if at all. Accordingly, over the next several years, we expect that we will incur substantial expenses, primarily as a result of activities related to the commercialization and continued development of ADCETRIS. We will also continue to invest in research, development and manufacturing of our other product candidates. Our commitment of resources to the continuing development, regulatory and commercialization activities for ADCETRIS and the research, continued development and manufacturing of our other product candidates may require us to raise substantial amounts of additional capital and our operating expenses will fluctuate as a result of such activities. In addition, we may incur significant milestone payment obligations as our product candidates progress through clinical trials towards potential commercialization.

Although we have begun to recognize revenue from ADCETRIS product sales in the United States, we are early in the product launch and our future ADCETRIS product sales will be difficult to predict from period to period. Our product sales revenue may vary significantly from period to period. However, we continue to anticipate that ADCETRIS net product sales will be in the range of \$140 million to \$150 million in 2012. We also expect that amounts earned from our collaboration agreements will continue to be an important source of our revenues and cash flows and we continue to expect that revenues from collaboration and license agreements in 2012 will be in the range of \$55 million to \$65 million. These revenues will be impacted by future development funding and the achievement of development and clinical milestones by our collaborators under our existing collaboration and license agreements, including, in particular, our ADCETRIS collaboration with Millennium, as well as entering into new collaboration and license agreements. Our results of operations may vary substantially from year to year and from quarter to quarter and, as a result, we believe that period to period comparisons of our operating results may not be meaningful and should not be relied upon as being indicative of our future performance.

Financial summary

Our revenues are generated from a combination of ADCETRIS sales, which we began in the United States during August 2011, collaboration and license agreements and royalties. Collaboration revenues reflect the earned amount of upfront technology access fees, milestone payments, reimbursement for support and materials supplied to our collaborators, and development cost-sharing under our product collaborations. Under our ADCETRIS collaboration with Millennium, we are entitled to receive royalties based on a percentage of Millennium s net sales in its territories ranging from the mid-teens to the mid-twenties based on sales volume. For the six months ended June 30, 2012, total revenues increased to \$97.1 million, compared to \$25.2 million for the same period in 2011. This increase primarily reflects our product sales of ADCETRIS during the 2012 period. For the six months ended June 30, 2012, total costs and expenses increased 18% to \$129.9 million, compared to \$110.0 million for the same period in 2011. This reflects increases in sales and marketing expenses, research and clinical development activities to explore additional potential applications of ADCETRIS and development costs associated with advancing our ADC product candidates as well as cost of sales for the 2012 period. As of June 30, 2012, we had \$330.3 million in cash, cash equivalents and short-term investments, and \$218.5 million in total stockholders—equity.

Results of operations

Three months and six months ended June 30, 2012 and 2011

Net product sales

Net product sales were \$34.7 million and \$69.2 million for the three and six months ended June 30, 2012, respectively. We began selling ADCETRIS in the United States in August 2011.

We sell ADCETRIS in the United States through a limited number of pharmaceutical distributors. Healthcare providers order ADCETRIS through these distributors. We receive orders from distributors and ship product directly to the healthcare provider. We record product sales upon delivery of the product to the healthcare provider at which time title and risk of loss pass. Product sales are

recorded net of estimated government-mandated rebates and chargebacks, distribution fees, product returns and other deductions. Reserves are established for these deductions and actual amounts incurred are offset against applicable reserves. We reflect these reserves as either a reduction in the related account receivable from the distributor, or as an accrued liability depending on the nature of the sales deduction. Sales reserves are based on management sestimates that consider payer mix in target markets, industry benchmarks and experience to date. These estimates involve a high degree of judgment and are periodically reviewed and adjusted as necessary.

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

Distribution fees, product returns and other deductions: Our distributors charge a fee for distribution services that they perform on our behalf. We are able to calculate the amount due for each distributor based on the amount of sales to each distributor and the negotiated fee. We allow for the return of product that is within 30 days of its expiration date or that is damaged. We estimated product returns based on historical industry information of return rates for other specialty pharmaceutical products. In addition, we considered our direct-ship distribution model, our belief that product is typically not held in the distribution channel, and the expected rapid use of the product by healthcare providers. We provide reimbursement and financial assistance to qualifying patients in the U.S. and its territories who meet various financial need criteria and are underinsured or cannot cover the cost of commercial coinsurance amounts through SeaGen Secure. Estimated contributions for commercial coinsurance are deducted from gross sales. These contributions are based on an analysis of expected plan utilization and are adjusted as necessary to reflect our actual experience.

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

| | Rebates and chargebacks | Distribution fees, product returns and other | Total |
|---|-------------------------------|--|----------|
| Balance as of December 31, 2011 | \$ 895 | \$ 1,036 | \$ 1,931 |
| Provision related to current period sales | 7,335 | 2,050 | 9,385 |
| Adjustment for prior period sales | (240) | 0 | (240) |
| Payments/credits for current period sales | (3,652) | (1,011) | (4,663) |
| Payments/credits for prior period sales | (102) | (689) | (791) |
| Balance as of June 30, 2012 | \$ 4,236 | \$ 1,386 | \$ 5,622 |

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

Collaboration and license agreement revenues

We use a time-based proportional performance model to recognize revenue over our performance obligation period and have adopted ASU 2009-13 entitled Multiple-Deliverable Revenue Arrangements, a consensus of the FASB Emerging Issues Task Force. Under this standard, payments received by us are recognized as revenue over the performance period of the collaboration. Collaboration and license agreements are evaluated to determine whether the multiple elements and associated deliverables can be considered separate units of accounting. To date, the deliverables under our collaboration and license agreements have not qualified as separate units of accounting. Accordingly, all amounts received or due, including any upfront payments, maintenance fees, milestone payments and reimbursement payments, are recognized as

revenue over the performance obligation periods of each agreement, which range from two to fourteen years for our current agreements. Following the completion of the performance obligation period, such amounts received or due will be recognized as revenue when collectibility is reasonably assured. The assessment of multiple element arrangements requires judgment in order to determine

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the appropriate point in time, or period of time, that revenue should be recognized. We believe that the period used in each agreement is a reasonable estimate of the performance obligation period of such agreement. We did not elect to adopt ASU 2010-17 entitled Milestone Method of Revenue Recognition which was available as a policy election beginning in the first quarter of 2011.

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

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

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

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

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

Initiation or completion of a phase III clinical trial. Generally, phase III clinical trials take two to six years to complete. Regulatory milestones in our collaborations may include the following types of events:

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

Receiving marketing approval in a major market, such as in the United States, Europe or Japan. Generally it takes up to three years after a marketing application is submitted to obtain full approval for marketing and pricing from the applicable regulatory agency. Commercialization milestones in our collaborations may include the following types of events:

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

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

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

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

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

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

| | Three months ended June 30, | | | Six months ended June 30, | | | |
|---|-----------------------------|-----------|--------|---------------------------|-----------|--------|--|
| | | | % | | | % | |
| Collaboration and license agreement revenue by collaborator (\$ in thousands) | 2012 | 2011 | Change | 2012 | 2011 | Change | |
| Millennium | \$ 7,214 | \$ 7,335 | (2%) | \$ 13,593 | \$ 14,562 | (7%) | |
| Agensys | 737 | 503 | 47% | 3,358 | 1,005 | 234% | |
| Abbott | 1,264 | 1,031 | 23% | 2,601 | 1,031 | 152% | |
| Pfizer | 1,128 | 1,000 | 13% | 2,253 | 2,000 | 13% | |
| Genentech | 1,357 | 1,462 | (7%) | 2,219 | 2,881 | (23%) | |
| Other | 1,194 | 1,723 | (31%) | 2,619 | 3,746 | (30%) | |
| | | | | | | | |
| Total | \$ 12,894 | \$ 13,054 | (1%) | \$ 26,643 | \$ 25,225 | 6% | |

Millennium ADCETRIS and ADC collaborations

Revenues earned under our ADCETRIS and ADC collaborations with Millennium represented 56% of our collaboration and license agreement revenues during both the three months ended June 30, 2012 and 2011, and 51% and 58% during the six months ended June 30, 2012 and 2011, respectively. The decrease in revenues from Millennium during the six months ended June 30, 2012 from the comparable period in 2011 primarily reflects lower revenue from our ADC collaboration during the 2012 period. The 2011 revenues include an exclusive license fee earned in the first quarter of 2011. Millennium revenues for the three months ended June 30, 2012 were comparable to the same period in 2011.

Under the ADCETRIS collaboration, we are entitled to receive progress- and sales-dependent milestone payments based on Millennium s achievement of certain events related to ADCETRIS, including potential approval of ADCETRIS by the European Commission for which Millennium is responsible. We are also entitled to tiered royalties at percentages starting in the mid-teens and escalating to the mid-twenties based on net sales of ADCETRIS within Millennium s licensed territories, subject to offsets for third party royalties paid by Millennium. Total future potential milestone payments to us under the ADCETRIS collaboration could total approximately \$230 million, of which up to approximately \$7 million relate to the achievement of development milestones, up to approximately \$158 million relate to the achievement of regulatory milestones and up to approximately \$65 million relate to the achievement of commercial milestones. To date, we have received a \$5 million milestone payment as a result of the acceptance of Millennium s MAA by the European Commission. In July 2012, Millennium received a positive recommendation from the EMA s CHMP for the conditional marketing authorization of ADCETRIS for two indications. The European Commission, which has the authority to approve medicines for use in the European Union, generally follows the recommendations of the CHMP and typically renders a final decision within three months of the CHMP opinion. If the CHMP recommendation is formally adopted by the European Commission, ADCETRIS would be approved for marketing in all 27 member states of the European Union and we will be entitled to a \$25 million milestone payment from Millennium. We recognize as collaboration revenue the \$60 million upfront collaboration payment, milestone payments and development cost reimbursement payments to us over the ten-year development period of the collaboration. We receive reimbursement funding from Millennium equal to one-half of the cost of joint development activities that are performed by us under the collaboration. To the extent that Millennium performs development activities under the collaboration, our development cost reimbursement payments from Millennium are reduced by half of those costs.

Collaboration and Co-Development Agreement with Agensys

Under this collaboration and co-development agreement, Agensys is conducting preclinical studies aimed at identifying ADC product candidates for multiple designated antigens. We are currently co-developing ASG-5ME and ASG-22ME, and we have the right to exercise a co-development option for one additional ADC product candidate upon Agensys—submission of an investigational new drug application, or IND, to the FDA. Agensys has the right to develop and commercialize the other ADC product candidates on its own, subject to paying us fees, milestones, royalties and support fees for research and development services and material provided under the agreement. Either party may opt out of co-development and profit-sharing in return for receiving milestones and royalties from the continuing party. Amounts received for product candidates being developed solely by Agensys will be recognized as revenue over the development term of the collaboration agreement using a time-based approach. Revenues attributable to the Agensys agreement increased during both the three and six months ended June 30, 2012 from the comparable period in 2011 due to a payment made to us in 2012 to exercise an exclusive license for an ADC product candidate.

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ADC collaboration agreements

We have active collaborations with nine additional companies to allow them to use our proprietary ADC technology. Under our ADC collaborations, which we enter into in the ordinary course of business, we receive or are entitled to receive upfront cash payments, progress-dependent milestones and royalties on net sales of products incorporating our ADC technology, as well as annual maintenance fees and support fees for research and development services and materials provided under the agreements. As of June 30, 2012, our ADC collaborations had generated over \$170 million, primarily in the form of upfront payments. Total milestone payments to us under our current ADC collaborations could approximate up to \$3.2 billion if all potential product candidates achieved all of the milestone events under all of our current ADC collaborations. Of this amount, approximately \$0.7 billion relates to the achievement of development milestones, approximately \$1.5 billion relates to the achievement of regulatory milestones and approximately \$1.0 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, our current ADC collaborations are at early stages of development. We have not received and do not expect to receive material milestone payments from any of our current ADC collaborators unless and until a product that incorporates our ADC technology enters late-stage clinical development and/or receives marketing approval from the FDA, if at all. Successfully developing a product candidate, obtaining regulatory approval and ultimately commercializing it is a significantly lengthy and highly uncertain process which entails a significant risk of failure. In addition, business combinations, changes in an ADC collaborator s business strategy and financial difficulties or other factors could result in an ADC collaborator abandoning or delaying development of its ADC product candidates. As such, the milestone payments associated with our ADC collaborations involve a substantial degree of risk to achieve and may never be received. Accordingly, we do not expect, and investors should not assume, that we will receive all of the potential milestone payments provided for under our ADC collaborations and it is possible that we may never receive any significant milestone payments under our ADC collaborations.

Genentech revenues decreased 7% to \$1.4 million during the three month period ended June 30, 2012 and 23% to \$2.2 during the six months ended June 30, 2012 from the comparable period in 2011 as a result of a decrease in milestone payments made to us in 2012 compared to the 2011 periods.

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

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

Our collaboration revenues are impacted by the term and duration of our collaboration and co-development agreements and by progress-dependent milestones, annual maintenance fees and reimbursement of materials and support services as our collaborators advance their ADC product candidates through the development process. Collaboration revenues may vary substantially from year to year and quarter to quarter depending on the progress made by our collaborators with their product candidates, the level of support we provide to our collaborators, the timing of milestones achieved, and our ability to enter into additional collaboration and co-development agreements. We expect our collaboration and license agreement revenues to increase in 2012 compared to 2011, primarily as a result of our ADCETRIS collaboration with Millennium. We have a significant balance of deferred revenue, representing prior payments from our collaborators that have not yet been recognized as revenue. This deferred revenue will be recognized as revenue in future periods using a time-based approach as we fulfill our performance obligations.

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Royalty Revenues and Cost of Royalty Revenues

We are entitled to receive a royalty on sales of ADCETRIS by Millennium in its territory, which is worldwide outside of the U.S. and its territories and Canada. Royalties payable to us are based on a percentage of Millennium s net sales in its territories at rates that range from the mid-teens to the mid-twenties, based on Millennium s sales volume. Royalty revenues also include the portion of royalties owed to our third party licensors on Millennium s sales of ADCETRIS, which is paid by Millennium. We recognize royalties as revenue when Millennium reports its sales activity to us, which is the quarter following the related sales. Royalty revenues recognized in 2012 relate to ADCETRIS sales by Millennium under its international named patient program. In July 2012, Millennium received a positive recommendation from the EMA s CHMP for the conditional marketing authorization of ADCETRIS. If the CHMP recommendation is formally adopted by the European Commission, ADCETRIS would be approved for marketing in all 27 member states of the European Union. Cost of royalty revenues reflects amounts owed to our third party licensors related to Millennium s sale of ADCETRIS in its territory. Millennium is responsible for paying such royalties on sales of ADCETRIS and is allowed to offset a portion of third party royalties from the royalty paid to us. We expect that royalty revenues and cost of royalty revenues will increase if the European Commission approves the MAA and Millennium commences commercial sales of ADCETRIS in the European Union.

Cost of Sales

ADCETRIS cost of sales includes manufacturing costs of product sold, third party royalty costs, amortization of technology license costs and distribution and other costs. We began capitalizing ADCETRIS manufacturing costs as inventory following the accelerated approval by the FDA in its two approved indications in August 2011. The cost of product manufactured prior to FDA approval was expensed as research and development expense as incurred and was combined with other research and development expenses. While we tracked the quantities of individual ADCETRIS product lots, we did not track pre-FDA approval manufacturing costs in our inventory system and therefore the manufacturing cost of ADCETRIS produced prior to FDA approval is not reasonably determinable. Most of the product produced prior to FDA approval is expected to be available for us to use commercially. We expect that our cost of sales as a percentage of sales will increase in future periods as product manufactured prior to FDA approval, and therefore fully expensed, is consumed. This cost benefit is expected to occur for at least the next year; however, the time period over which this reduced-cost inventory is consumed will depend on a number of factors, including the amount of future ADCETRIS sales, the ultimate use of this inventory in either commercial sales, clinical development or other research activities and the ability to utilize inventory prior to its expiration date. We expect, as this reduced-cost inventory is used, the percentage of total costs of sales for sales of ADCETRIS will increase into the teens.

Research and development

Our research and development expenses are summarized as follows:

| | Three months ended June 30, | | | Six months ended June 30, | | | |
|--|-----------------------------|-----------|--------|------------------------------|-----------|--------|--|
| | | % | | | | % | |
| | | | Change | | | Change | |
| Research and development (\$ in thousands) | 2012 | 2011 | | 2012 | 2011 | | |
| Research | \$ 3,723 | \$ 8,342 | (55%) | \$ 7,448 | \$ 11,829 | (37%) | |
| Development and contract manufacturing | 13,120 | 22,334 | (41%) | 27,261 | 33,126 | (18%) | |
| Clinical | 23,290 | 16,818 | 38% | 41,107 | 32,681 | 26% | |
| Share-based compensation expense | 2,622 | 2,149 | 22% | 5,426 | 4,441 | 22% | |
| Total research and development expenses | \$ 42,755 | \$ 49,643 | (14%) | \$ 81,242 | \$ 82,077 | (1%) | |

Research expenses decreased 55% to \$3.7 million in the second quarter and 37% to \$7.4 million for the six month period ended June 30, 2012 from the comparable periods in 2011. These decreases were primarily due to lower technology access fees incurred in the 2012 periods.

Development and contract manufacturing expenses decreased 41% to \$13.1 million in the second quarter and 18% to \$27.3 million for the six month period ended June 30, 2012 from the comparable periods in 2011. The decreases resulted primarily from lower ADCETRIS manufacturing costs which were expensed to research and development expense in the 2011 periods and capitalized as inventory in 2012.

Clinical expenses increased 38% to \$23.3 million in the second quarter and 26% to \$41.1 million for the six month period ended June 30, 2012 from the comparable periods in 2011. These increases reflect costs to develop a companion diagnostic test for identifying CD-30 positive diseases that might respond to treatment with ADCETRIS, expansion of our ADCETRIS clinical program and higher compensation costs due to an increase in our staffing levels.

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

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

| | Three months ended June 30, | | Six months ended June 30, | | Five years ended June 30, 2012 | |
|---------------------------------------|-----------------------------|-----------|------------------------------|-----------|-----------------------------------|---------|
| Development program (\$ in thousands) | 2012 | 2011 | 2012 | 2011 | | |
| ADCETRIS (Brentuximab vedotin) | \$ 12,643 | \$ 20,617 | \$ 20,353 | \$ 29,506 | \$ | 177,154 |
| ASG-22ME | 2,082 | 4,000 | 4,278 | 4,000 | | 10,717 |
| SGN-CD19A | 428 | 1,012 | 2,989 | 2,065 | | 14,269 |
| SGN-75 | 305 | 803 | 384 | 1,644 | | 12,623 |
| ASG-5ME | 207 | 648 | 356 | 1,040 | | 10,908 |
| | | | | | | |
| | 15,665 | 27,080 | 28,360 | 38,255 | | 225,671 |
| Other costs and overhead | 24,468 | 20,414 | 47,456 | 39,381 | | 393,344 |
| Share-based compensation expense | 2,622 | 2,149 | 5,426 | 4,441 | | 39,960 |
| | | | | | | |
| Total research and development | \$ 42,755 | \$ 49,643 | \$81,242 | \$82,077 | \$ | 658,975 |

Third-party costs for ADCETRIS decreased during both the three and six months ended June 30, 2012 from the comparable periods in 2011, primarily as a result of manufacturing costs which were expensed to research and development in the 2011 periods and capitalized as inventory in 2012. We began capitalizing ADCETRIS production costs as inventory following accelerated approval of ADCETRIS by the FDA in August 2011. However, ADCETRIS inventory that is deployed into clinical, research or development use is charged to research and development expense when it is no longer available for commercial use. These decreases were partially offset by increased clinical trial expenses resulting from our expanded clinical trials program for ADCETRIS.

In June 2011, we exercised an option under our agreement with Agensys to co-develop ASG-22ME. In addition to the payment of an option fee, we now co-fund fifty percent of the development costs of this program. ASG-22ME costs in 2012 reflect our share of development costs incurred during the period.

Third party costs for SGN-CD19A decreased during the three months ended June 30, 2012 and increased during the six months ended June 30, 2012 from the comparable periods in 2011. These changes reflect the timing of contract manufacturing and other activities in preparation for a planned IND filing in 2012 and potential clinical trials.

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

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

the number of patients required in our clinical trials;

the length of time required to enroll trial participants;

the number and location of sites included in the trials;

the costs of producing supplies of the product candidates needed for clinical trials and regulatory submissions;

the safety and efficacy profile of the product candidate;

the use of clinical research organizations to assist with the management of the trials; and

the costs and timing of, and the ability to secure, regulatory approvals.

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Furthermore, our strategy has included entering into collaborations with third parties. In these situations, the preclinical development or clinical trial process for a product candidate and the estimated completion date are largely under the control of that third party and not under our control. We cannot forecast with any degree of certainty which of our product candidates will be subject to future collaborations or how such arrangements would affect our development plans or capital requirements.

We anticipate that our total research and development expenses in 2012 will be comparable to 2011. Following the approval of ADCETRIS for commercial sale by the FDA, the costs associated with manufacturing ADCETRIS are now capitalized as inventory if it is available for commercial use rather than being charged to research and development expenses. This resulted in a decrease in research and development expenses for ADCETRIS related to those activities. This decrease in ADCETRIS manufacturing expense is expected to be offset by increased clinical trial expenses for ADCETRIS related to post-approval studies required to be conducted as a condition of accelerated approval and additional studies that are ongoing or that we expect to pursue to evaluate other potential uses of ADCETRIS. Certain ADCETRIS development activities, including some clinical studies will be conducted by Millennium, the costs of which will not be 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 our product candidates.