SEATTLE GENETICS INC /WA
Form 10-Q
November 06, 2009
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 September 30, 2009

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

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

As of November 5, 2009, there were 100,531,889 shares of the registrant s common stock outstanding.

Table of Contents

Seattle Genetics, Inc.

For the quarter ended September 30, 2009

INDEX

Table of Contents

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, 2009	December 31, 2008
Assets		
Current assets		
Cash and cash equivalents	$ 72,060	$ 30,800
Short-term investments	194,417	64,379
Interest receivable	1,369	1,888
Accounts receivable	3,994	8,186
Prepaid expenses and other current assets	2,046	5,463
Total current assets	273,886	110,716
Property and equipment, net	12,465	10,996
Long-term investments	39,539	65,529
Other non-current assets	531	476
Total assets	$ 326,421	$ 187,717
Liabilities and Stockholders Equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 21,946	$ 15,879
Current portion of deferred revenue	27,866	24,341
Total current liabilities	49,812	40,220
Long-term liabilities		
Deferred revenue, less current portion	58,397	66,958
Deferred rent and other long-term liabilities	2,665	1,521
Total long-term liabilities	61,062	68,479
Commitments and contingencies		
Stockholders equity		
Preferred stock, $0.001 par value, 5,000 shares authorized; none issued		
Common stock, $0.001 par value, 150,000 shares authorized; 100,502 shares issued and outstanding at September 30, 2009 and 79,791 shares issued and outstanding at December 31, 2008	101	80
Additional paid-in capital	599,507	394,338
Accumulated other comprehensive loss	(473)	(1,378)
Accumulated deficit	(383,588)	(314,022)

Total stockholders equity	215,547	79,018
Total liabilities and stockholders equity	$ 326,421	$ 187,717

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

Table of Contents

Seattle Genetics, Inc.

Condensed Consolidated Statements of Operations

(Unaudited)

(In thousands, except per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
Revenues from collaboration and license agreements	$ 11,646	$ 8,079	$ 30,196	$ 25,168
Operating expenses				
Research and development	28,263	27,711	90,221	73,362
General and administrative	3,956	3,687	12,131	11,716
Total operating expenses	32,219	31,398	102,352	85,078
Loss from operations	(20,573)	(23,319)	(72,156)	(59,910)
Investment income, net	746	1,555	2,590	5,006
Net loss	$ (19,827)	$ (21,764)	$ (69,566)	$ (54,904)
Net loss per share basic and diluted	$ (0.21)	$ (0.27)	$ (0.79)	$ (0.70)
Shares used in computation of net loss per share basic and diluted	93,460	79,559	87,771	78,369

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

Table of Contents

Seattle Genetics, Inc.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(In thousands)

	Nine months ended September 30,	
	2009	**2008**
Operating activities		
Net loss	$ (69,566)	$ (54,904)
Adjustments to reconcile net loss to net cash used in operating activities		
Share-based compensation expense	8,489	7,400
Depreciation and amortization	2,414	2,488
Amortization on investments	2,851	1,035
Deferred rent and other long-term liabilities	1,144	968
Changes in operating assets and liabilities		
Interest receivable	519	(1,311)
Accounts receivable	4,192	(607)
Prepaid expenses and other current assets	3,417	(5,509)
Other non-current assets	(55)	
Accounts payable and accrued liabilities	6,067	5,209
Deferred revenue	(5,036)	8,238
Net cash used in operating activities	(45,564)	(36,993)
Investing activities		
Purchases of securities available for sale	(229,365)	(154,336)
Proceeds from maturities of securities available for sale	121,279	51,528
Proceeds from sales of securities available for sale	2,092	7,000
Purchases of property and equipment	(3,883)	(3,974)
Net cash used in investing activities	(109,877)	(99,782)
Financing activities		
Net proceeds from issuance of common stock	192,141	97,628
Proceeds from exercise of stock options and employee stock purchase plan	4,560	3,916
Net cash provided by financing activities	196,701	101,544
Net increase (decrease) in cash and cash equivalents	41,260	(35,231)
Cash and cash equivalents, at beginning of period	30,800	59,644
Cash and cash equivalents, at end of period	$ 72,060	$ 24,413

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

Table of Contents

Seattle Genetics, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. 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, 2008 was 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 for unaudited condensed consolidated financial information. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles 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 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 footnotes included in the Company s Annual Report on Form 10-K for the year ended December 31, 2008 as filed with the SEC.

The preparation of financial statements in conformity with generally accepted accounting principles in the United States of America requires management to make estimates and assumptions that affect the reported amounts. Actual results could differ from those estimates. The results of the Company s operations for the three- and nine-month periods ended September 30, 2009 are not necessarily indicative of the results to be expected for the full year.

The Company considered subsequent events through November 5, 2009, the date the financial statements were available for issuance. There were no subsequent events requiring recognition or disclosure in the financial statements.

2. Fair Value of Financial Instruments

The recorded amounts of certain financial instruments, including cash and cash equivalents, interest receivable, accounts receivable, accounts payable and accrued liabilities approximate fair value due to their relatively short maturities. Short-term and long-term investments that are classified as available-for-sale are recorded at fair value. See *Investments* below for a discussion of the methodology used to measure fair value.

3. Common Stock

In August 2009, the Company completed an underwritten public offering of 12,650,000 shares of its common stock at a price to the public of $10.75 per share, resulting in net proceeds of $128.2 million. In August 2009, an institutional investor and its affiliated entities that held privately-placed warrants to purchase an aggregate of 812,500 shares of the Company s common stock at an exercise per share price of $6.25 exercised the warrants under the net exercise provisions of the warrants. As a result, 395,214 shares of the Company s common stock were issued to the warrant holders upon exercise of the warrants on a net, or cashless, basis. In addition, the Company completed an underwritten public offering of 5,740,000 shares of its common stock in February 2009 resulting in net proceeds of $52.5 million, and a private offering of 1,178,163 shares of its common stock in May 2009 resulting in net proceeds of $11.5 million.

4. Concentration of Credit Risk

Cash, cash equivalents and investments are invested in accordance with the Company s investment policy. The policy includes guidelines for the investment of cash reserves and is reviewed periodically to minimize credit risk. Most of the Company s investments are not federally insured. The Company has not experienced any significant realized losses on its deposits of cash, cash equivalents and investments as a result of credit risk concentration. The Company does not require collateral on amounts due from its collaborators and is therefore subject to credit risk. The Company has not experienced any credit losses to date and does not consider an allowance for doubtful accounts to be necessary.

6

Table of Contents

Seattle Genetics, Inc.

Notes to Condensed Consolidated Financial Statements Continued

(Unaudited)

5. Recent Accounting Pronouncements

In October 2009, the Financial Accounting Standards Board (FASB) issued an accounting standards update entitled Multiple-Deliverable Revenue Arrangements, a consensus of the FASB Emerging Issues Task Force. This standard prescribes the accounting treatment for arrangements that contain multiple-deliverable elements and enables vendors to account for products or services (deliverables) separately rather than as a combined unit in certain circumstances. Prior to this standard, only certain types of evidence were acceptable for determining the selling price of the deliverables under an arrangement. If that evidence was not available, the deliverables were treated as a single unit of accounting. This updated standard expands the nature of evidence which may be used to determine the selling price of separate deliverables to include a vendor s best estimate. The FASB believes that this standard will allow companies to separate deliverables included in multiple-deliverable arrangements into more units of accounting than was previously possible. This standard is applicable to arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption is permitted; however, if the standard is adopted early, and the period of adoption is not the beginning of a company s fiscal year, the company will be required to apply the amendments retrospectively from the beginning of the company s fiscal year. The Company has not yet adopted this standard or determined the impact of this standard on its results of operations, cash flows and financial position.

Table of Contents

Seattle Genetics, Inc.

Notes to Condensed Consolidated Financial Statements Continued

(Unaudited)

6. Net Loss Per Share

Basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period. The Company excluded all warrants and options to purchase common stock from the calculation of diluted net loss per share as such securities are antidilutive for all periods presented. The following table presents the weighted-average number of shares that were excluded from the number of shares used to calculate basic and diluted net loss per share (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
Warrants to purchase common stock	1,651	1,925	1,833	1,925
Options to purchase common stock	9,758	8,007	9,339	7,679
Total	11,409	9,932	11,172	9,604

7. Comprehensive Loss

Comprehensive loss includes certain changes in equity that are excluded from net loss. Specifically, unrealized gains or losses in available-for-sale investments are included in comprehensive loss. Comprehensive loss and its components were as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
Net loss	$ (19,827)	$ (21,764)	$ (69,566)	$ (54,904)
Unrealized gain (loss) on securities available for sale	581	(1,477)	905	(2,218)
Comprehensive loss	$ (19,246)	$ (23,241)	$ (68,661)	$ (57,122)

8. Investments

Short-term and long-term investments consist of U.S. government and U.S. government agency securities, corporate notes, auction rate securities, or ARS, and taxable municipal bonds. 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 loss in stockholders equity. Investments in securities with maturities 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.

Table of Contents

Seattle Genetics, Inc.

Notes to Condensed Consolidated Financial Statements Continued

(Unaudited)

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

	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
September 30, 2009				
Corporate obligations	$ 39,449	$ 746	$ (35)	$ 40,160
Auction rate securities	14,450		(1,366)	13,084
U.S. government and agencies	168,192	149	(1)	168,340
Taxable municipal bonds	12,639	49	(15)	12,673
Total	$ 234,730	$ 944	$ (1,417)	$ 234,257
Contractual Maturities:				
Due in one year or less	$ 194,517			$ 194,718
Due in one to three years	25,763			26,455
Due in 2017	14,450			13,084
Total	$ 234,730			$ 234,257
Reported as:				
Short-term investments				$ 194,417
Long-term investments				39,539
Other non-current assets				301
Total				$ 234,257

As of September 30, 2009, certain of the Company s investment securities have a fair value that is less than the Company s amortized cost of the security and are therefore carried at an unrealized loss. The aggregate estimated fair value of the Company s investments with unrealized losses is 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, 2009				
Corporate obligations	$ NA	$ NA	$ 961	$ (35)
Auction rate securities	NA	NA	13,084	(1,366)
U.S. government and agencies	19,995	(1)	NA	NA
Taxable municipal bonds	3,498	(15)	NA	NA

Total	$ 23,493	$ (16)	$ 14,045	$ (1,401)

When the estimated fair value of a security is below its carrying value, the Company evaluates whether it is more likely than not that it will be required to sell the security before its anticipated recovery in market value and whether evidence indicating that the cost of the investment is recoverable within a reasonable period of time outweighs evidence to the contrary. The Company also evaluates whether or not it intends to sell the investment. If the impairment is considered to be other-than-temporary, the security is written down to its estimated fair value. In addition, the Company considers whether credit losses exist for any securities. A credit loss exists if the present value of cash flows expected to be collected is less than the amortized cost basis of the security. Other-than-temporary declines in estimated fair value and credit losses are charged against investment income. The Company has not deemed it necessary to record any charges related to other-than-temporary declines in the estimated fair values of its marketable debt securities or credit losses.

Realized gains and realized losses are included in investment income. Cost of investments for purposes of computing realized and unrealized gains and losses are based on the specific identification method. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Amortization of premiums and accretion of discounts are included in investment income. Interest and dividends earned on all securities are included in investment income.

Table of Contents

Seattle Genetics, Inc.

Notes to Condensed Consolidated Financial Statements Continued

(Unaudited)

As of September 30, 2009, the Company held ARS valued at $13.1 million that have failed at auction and are currently illiquid. Liquidity of these investments is subject to either a successful auction process, redemption of the investment, or a sale of the security in a secondary market. Each of the securities continues to pay interest according to the stated terms on a monthly basis. The interest rates on these ARS are no longer established based on an auction process but are established according to the terms of the issue. As of September 30, 2009, the interest rate of the ARS was set at the 30-day London Interbank Offering rate plus 225 basis points. The Company considers the market for these securities to be inactive and distressed. Accordingly, fair value for the ARS has been determined based on a probability-weighted discounted cash flow analysis. This analysis relies upon certain estimates, including the probability-weighted term to an orderly liquidation and the discount rate applied to future cash flows. The discount rate used to determine fair value is based on the observed comparable yield of securities with similar characteristics. Due to the expected time to a liquidation event, investments in ARS are presented as long-term investments in the accompanying condensed consolidated balance sheets.

Based on the Company s available cash, expected operating cash requirements and its belief that the holdings in ARS can be liquidated in approximately one to three years at par, the Company believes it is more likely than not that it has the ability to hold, and intends to hold, these investments until they recover substantially all of their cost basis. This belief is based on a current assessment of the Company s future operating plans and assessment of the individual securities and general market conditions. The Company periodically assesses this conclusion based on several factors, including the continued failure of future auctions, failure of the investment to be redeemed, further deterioration of the credit rating of the investment, market risk and other factors. Any such future reassessment that results in a conclusion that the unrealized losses on these investments are other than temporary would result in a write down in the fair value of these investments. Such a write down would be recognized in operating results.

The Company holds short term and long 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 following table presents the Company s available-for-sale securities 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

Available-for-sale securities at December 31, 2008	$ 301	$ 116,525	$ 13,383	$ 130,209
Available-for-sale securities at September 30, 2009	$ 171,730	$ 49,443	$ 13,084	$ 234,257

Level 1 investments, which include investments that are valued based on quoted market prices in active markets, include most U.S. government 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, include most high-grade corporate bonds, U.S. agency obligations, taxable municipal bonds and commercial paper. Level 3 investments consist of ARS and accounted for 6% of total investment securities measured at fair value as of September 30, 2009.

Table of Contents

Seattle Genetics, Inc.

Notes to Condensed Consolidated Financial Statements Continued

(Unaudited)

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

	Fair value
Balance as of December 31, 2008	$ 13,383
Unrealized loss reflected as a component of other comprehensive income	(299)
Balance as of September 30, 2009	$ 13,084

The Company recorded a net unrealized gain of $0.6 million for the three months ended September 30, 2009, and a $0.9 million net unrealized gain for the nine months ended September 30, 2009, in other comprehensive income.

9. Collaborative arrangements

Agensys

In January 2007, the Company entered into an agreement with Agensys, now a wholly-owned subsidiary of Astellas Pharma, to jointly research, develop and commercialize antibody-drug conjugates (ADCs) for the treatment of cancer. The collaboration encompasses combinations of the Company s ADC technology with antibodies developed by Agensys to proprietary cancer targets. Under the terms of the multi-year agreement, Agensys and the Company will jointly screen and select ADC product candidates to an initial target, ASG-5ME (formerly AGS-5), and will equally co-fund all development and commercialization costs and share equally in any profits of such ADC product candidates.

The Agensys collaboration agreement defines a mechanism for calculating the costs of co-development activities and for reimbursing the other party in order to maintain an equal sharing of development costs. Third-party costs are billed at actual cost and internal labor and support costs are billed at a contractual rate. Payments made by the Company to Agensys are included in research and development expense. Payments made by Agensys to the Company are reflected as a reduction in research and development expense. The following table summarizes research and development expenses incurred by the Company and payments made to, or received from, Agensys under the collaboration (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
Research and development expense using contractual rates	$ 1,071	$ 318	$ 2,967	$ 492
Reimbursement payable to Agensys	839	89	816	409
Total	$ 1,910	$ 407	$ 3,783	$ 901

Table of Contents

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. These statements relate to future events or our future financial performance. 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 oth 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 and uncertainties. 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

We are a clinical stage biotechnology company focused on the development and commercialization of monoclonal antibody-based therapies for the treatment of cancer and autoimmune disease. We initiated a pivotal trial of our lead product candidate, brentuximab vedotin (SGN-35), during the first quarter of 2009 for patients with relapsed or refractory Hodgkin lymphoma under a special protocol assessment (SPA) with the U.S. Food and Drug Administration (FDA). Brentuximab vedotin is empowered by our proprietary antibody-drug conjugate (ADC) technology comprising highly potent synthetic drugs and stable linkers for attaching the drugs to monoclonal antibodies. Patient enrollment on this clinical trial was completed in August 2009. In addition, we have three other product candidates in ongoing clinical trials: lintuzumab (SGN-33), dacetuzumab (SGN-40) and SGN-70. We completed patient enrollment in an ongoing phase IIb clinical trial of lintuzumab in February 2009 and expect data from this trial in the first half of 2010. Dacetuzumab is being developed under a worldwide collaboration with Genentech, Inc., a wholly-owned member of the Roche Group. In October 2009, we announced the discontinuation of our phase IIb clinical trial of dacetuzumab in combination with Rituxan (rituximab) plus ifosfamide, carboplatin and etoposide (R-ICE) chemotherapy for patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) based on a determination that the trial would be unlikely to meet its primary endpoint of superior complete response rate in the dacetuzumab combination arm as compared to the placebo combination arm. The trial was closed based upon a recommendation by the Independent Data Monitoring Committee following a pre-specified interim analysis. Under our dacetuzumab collaboration with Genentech, dacetuzumab is being evaluated in combination with other agents in four ongoing phase Ib clinical trials for the treatment of lymphoma and multiple myeloma.

We have collaborations for our ADC technology with a number of leading biotechnology and pharmaceutical companies, including Genentech, Inc., Bayer Pharmaceuticals Corporation, CuraGen Corporation, a subsidiary of CellDex, Progenics Pharmaceuticals, Inc., Daiichi Sankyo Co., Ltd., Millennium: The Takeda Oncology Company, a subsidiary of the Takeda Pharmaceutical Company Limited, and MedImmune, Inc., a subsidiary of AstraZeneca Inc. In addition, we have an ADC co-development agreement with Agensys Inc., a subsidiary of Astellas Pharma, Inc.

We do not currently have any commercial products for sale. While certain of our product candidates are advancing into later stages of development, such as brentuximab vedotin, significant further research and development, financial resources and personnel will be required to develop commercially viable products and obtain regulatory approvals. As of September 30, 2009, we had an accumulated deficit of $383.6 million. Over the next several years, we expect that we will incur substantial expenses, primarily as a result of activities related to the potential regulatory approval and commercialization of brentuximab vedotin, including preparation for commercial manufacturing. We also expect to continue to invest in research, development and manufacturing as we move towards potential commercialization of our other product candidates. Our commitment of resources to the potential regulatory approval and commercialization activities for brentuximab vedotin and the research and continued development and potential commercialization of our other product candidates will require substantial additional funds and resources, and our operating expenses will also likely increase 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. We expect that a substantial portion of our revenues for the next several years will be the result of the amortization of payments already received and that are expected to be received from Genentech under our dacetuzumab collaboration agreement. Until such time as we may commercialize a product candidate, our revenues will also depend on the achievement of development and clinical milestones under our existing collaboration and license agreements, particularly our dacetuzumab collaboration agreement with Genentech, 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 you should not rely on them as indicative of our future performance.

Financial summary

To date, we have generated revenues principally from our collaboration and license agreements. These revenues reflect upfront technology access fees, milestone payments and reimbursement for support and materials supplied to our collaborators. For the nine months ended September 30, 2009, revenues increased 20% to $30.2 million, compared to $25.2 million for the same period in 2008. For the nine months ended September 30, 2009, total operating expenses increased 20% to $102.4 million, compared to $85.1 million for the same period in 2008. Our net loss for the nine-month period ended September 30, 2009 was $69.6 million, or $0.79 per share, compared to $54.9 million, or $0.70 per share, for the same period in 2008. As of September 30, 2009, we had $306.0 million in cash, cash equivalents and short-term and long-term investments, and $215.5 million in total stockholders equity.

Table of Contents

Results of Operations

Three months and nine months ended September 30, 2009 and 2008

Revenues.

Revenues by collaborator are summarized as follows:

Collaboration and license agreement revenue ($ in thousands)	Three months ended September 30, 2009	2008	% change	Nine months ended September 30, 2009	2008	% change
Genentech	$ 8,512	$ 6,850	24%	$ 25,343	$ 20,488	24%
Daiichi Sankyo	481	354	36%	1,296	354	266%
Bayer	1,000	63	1,487%	1,221	981	24%
MedImmune	1,000	436	129%	1,100	1,316	(16)%
Millennium	357		N/A(1)	695		N/A(1)
CuraGen		50	(100)%	134	1,137	(88)%
Other	296	326	(9)%	407	892	(54)%
Total	$ 11,646	$ 8,079	44%	$ 30,196	$ 25,168	20%

(1) No amount in comparable period.

Genentech revenues increased 24% to $8.5 million in the third quarter of 2009 and 24% to $25.3 million for the first nine months of 2009 compared to the comparable periods in 2008. The increases primarily resulted from revenues earned under the dacetuzumab collaboration agreement with Genentech entered into in January 2007. Under the terms of this agreement, we perform research and development activities over the six-year development period of the agreement, the costs of which are reimbursed by Genentech. We are also entitled to receive milestones as dacetuzumab progresses through development and royalties on potential future product sales. The $60 million upfront payment received in 2007 and all reimbursement and milestone payments received by us are deferred and recognized as revenue over the development period of the agreement using a time-based method. Genentech revenues also reflect the earned portion of payments received under our ADC collaboration agreement with Genentech. Revenues attributable to our ADC collaboration agreement with Daiichi Sankyo increased during both the three- and nine-month periods of 2009 and reflect both the earned portion of a $4.0 million upfront payment received by us under our ADC collaboration that began in July 2008 and reimbursable support and research materials provided to Daiichi Sankyo by us. Revenues attributable to our ADC collaboration agreement with Bayer increased during both the three- and nine-month periods of 2009 reflecting revenue earned from a milestone payment received in the third quarter of 2009 related to an Investigational New Drug (IND) filing with the FDA for Bayer s ADC product candidate. Revenues attributable to our ADC collaboration agreement with MedImmune increased for the three-month period of 2009, reflecting a milestone payment received by us triggered by MedImmune s initiation of a phase I clinical trial of its ADC product candidate in the third quarter of 2009. MedImmune revenues decreased for the first nine months of 2009 compared to the comparable period in 2008 due to the completion of the research term of the agreement in late 2008. Revenues attributable to our ADC collaboration agreement with Millennium reflect both the earned portion of a $4.0 million upfront payment received by us under our ADC collaboration that began in March 2009 and reimbursable support and research materials provided to Millennium by us. Revenues attributable to our ADC collaboration agreement with CuraGen decreased during both the three- and nine-month periods of 2009 compared to the comparable periods in 2008 reflecting revenue earned from a milestone payment triggered by CuraGen s initiation of a phase II clinical trial of its ADC product candidate in the second quarter of 2008. There have been no milestone payments during the first nine months of 2009 under this collaboration agreement.

Our revenue is impacted by progress-dependent milestones, annual maintenance fees and reimbursement and support fees as our collaborators advance product candidates through the development process and the level of activity we perform under our dacetuzumab collaboration with Genentech. We expect that our collaboration and license agreement revenue will increase in 2009 compared to 2008. However, revenue may vary substantially from 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 agreements. We expect the level of future support we will provide under the dacetuzumab collaboration with Genentech to decrease as a result of the discontinuation of our phase IIb clinical trial of dacetuzumab in combination with R-ICE chemotherapy for patients with DLBCL. A significant portion of our

deferred revenue balance relates to our dacetuzumab collaboration with Genentech that is being recognized as revenue using a time-based approach through early 2013 as we fulfill our performance obligations under the dacetuzumab collaboration agreement.

Table of Contents

Research and development.

Our research and development expenses are summarized as follows:

Research and Development ($ in thousands)	Three months ended September 30, 2009	2008	% change	Nine months ended September 30, 2009	2008	% change
Research	$ 3,052	$ 3,431	(11)%	$ 9,353	$ 11,252	(17)%
Development and contract manufacturing	9,896	9,370	6%	33,525	22,078	52%
Clinical	13,433	13,410	0%	42,042	35,465	19%
Share-based compensation expense	1,882	1,500	25%	5,301	4,567	16%
Total research and development expenses	$ 28,263	$ 27,711	2%	$ 90,221	$ 73,362	23%

Research expenses decreased 11% to $3.1 million in the third quarter of 2009 and decreased 17% to $9.4 million in the first nine months of 2009 from the comparable periods in 2008. Research expenses have decreased in 2009, primarily reflecting lower personnel, lab supply and services costs in 2009. Development and contract manufacturing costs increased 6% to $9.9 million in the third quarter of 2009 and increased 52% to $33.5 million for the first nine months of 2009 from the comparable periods in 2008. The increases reflect increased manufacturing costs associated with supplying brentuximab vedotin for our clinical trials, including our pivotal trial in relapsed or refractory Hodgkin lymphoma initiated in the first quarter of 2009, and higher employee costs related to increased staffing levels. Clinical costs increased 19% to $42.0 million for the first nine months of 2009 from the comparable period in 2008. The increase resulted primarily from expanded clinical trial activities for brentuximab vedotin, as well as higher compensation costs related to an increase in staffing levels to support ongoing clinical trials. Share-based compensation expense increased 25% during the third quarter of 2009 and 16% during the first nine months of 2009 compared to the comparable periods in 2008. The increases were due to a larger number of optioned shares subject to expense recognition during the 2009 periods as a result of increased staffing levels and a higher average value per optioned share primarily attributable to increases in the weighted average stock price.

Certain amounts reported in comparable prior periods in the table above have been reclassified to conform with the current period presentation as it relates to the categorization of certain expenses.

The following table shows expenses incurred for preclinical study support, contract manufacturing for clinical supplies and clinical trial services provided by third parties as well as milestone payments for in-licensed technology for each of our product candidates. The table also presents other costs and overhead consisting of personnel, facilities and other costs not directly allocable to development programs:

Product Candidates ($ in thousands)	Three months ended September 30, 2009	2008	Nine months ended September 30, 2009	2008	Five years ended September 30, 2009
Brentuximab vedotin (SGN-35)	$ 7,315	$ 3,862	$ 23,605	$ 7,835	$ 49,030
Dacetuzumab (SGN-40)	2,781	4,002	11,094	12,021	45,078
Lintuzumab (SGN-33)	1,535	4,620	7,302	10,215	33,586
SGN-70	77	511	665	1,136	10,128
SGN-75	408	924	1,822	1,889	5,485
Total third-party costs	12,116	13,919	44,488	33,096	143,307
Other costs and overhead	14,265	12,292	40,432	35,699	188,370
Share-based compensation expense	1,882	1,500	5,301	4,567	20,202