

SEATTLE GENETICS INC /WA
Form 10-Q
November 07, 2014
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2014

OR

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

For the transition period from _____ to _____

Commission file number 0-32405

SEATTLE GENETICS, INC.

(Exact name of registrant as specified in its charter)

Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-Q

Delaware
(State or other jurisdiction of
incorporation or organization)

91-1874389
(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 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

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

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

Table of Contents

Seattle Genetics, Inc.

Quarterly Report on Form 10-Q

For the Quarter Ended September 30, 2014

INDEX

	Page
<u>PART I. FINANCIAL INFORMATION (Unaudited)</u>	
Item 1. <u>Condensed Consolidated Financial Statements</u>	3
<u>Condensed Consolidated Balance Sheets</u>	3
<u>Condensed Consolidated Statements of Comprehensive Loss</u>	4
<u>Condensed Consolidated Statements of Cash Flows</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	11
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	20
Item 4. <u>Controls and Procedures</u>	21
<u>PART II. OTHER INFORMATION</u>	
Item 1A <u>Risk Factors</u>	21
Item 6. <u>Exhibits</u>	37
<u>SIGNATURES</u>	38
<u>EXHIBIT INDEX</u>	39

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

Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-Q

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

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

Table of Contents**Seattle Genetics, Inc.****Condensed Consolidated Statements of Comprehensive Loss****(Unaudited)****(In thousands, except per share amounts)**

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

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

Table of Contents**Seattle Genetics, Inc.****Condensed Consolidated Statements of Cash Flows****(Unaudited)****(In thousands)**

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

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

Table of Contents

Seattle Genetics, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Basis of presentation and summary of significant accounting policies

Basis of presentation

The accompanying unaudited condensed consolidated financial statements reflect the accounts of Seattle Genetics, Inc. and its wholly-owned subsidiary, Seattle Genetics UK, Ltd. (collectively "Seattle Genetics" or the "Company"). The condensed consolidated balance sheet data as of December 31, 2013 were derived from audited financial statements not included in this quarterly report on Form 10-Q. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission, or SEC, and generally accepted accounting principles in the United States of America, or GAAP, for unaudited condensed consolidated financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. The accompanying unaudited condensed consolidated financial statements reflect all adjustments consisting of normal recurring adjustments which, in the opinion of management, are necessary for a fair statement of the Company's financial position and results of its operations, as of and for the periods presented. Management has determined that the Company operates in one segment: the development and sale of pharmaceutical products on its own behalf or in collaboration with others.

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

These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and accompanying notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2013, as filed with the SEC.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results could differ from those estimates. The results of the Company's operations for the three and nine month periods ended September 30, 2014 are not necessarily indicative of the results to be expected for the full year.

Non-cash investing activities

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

Revenue recognition

The Company's revenues are comprised of ADCETRIS® net product sales, amounts earned under its collaboration and licensing agreements and royalties. Revenue recognition is predicated upon persuasive evidence of an agreement existing, delivery of products or services being rendered, amounts payable being fixed or determinable, and collectibility being reasonably assured.

Net product sales

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

Government-mandated rebates and chargebacks: The Company has entered into a Medicaid Drug Rebate Agreement, or MDRA, with the Centers for Medicare & Medicaid Services. This agreement provides for a rebate based on covered purchases of ADCETRIS. Medicaid rebates

Edgar Filing: SEATTLE GENETICS INC /WA - Form 10-Q

are invoiced to the Company by the various state programs. The Company estimates Medicaid rebates based on a third-party study of the payer mix for ADCETRIS, information on utilization by Medicaid-eligible patients who received assistance through SeaGen Secure®, the Company's patient assistance program, and experience to date. The Company has also completed a Federal Supply Schedule, or FSS, agreement under which certain U.S. government purchasers receive a discount on eligible purchases of ADCETRIS. The Company has entered into a Pharmaceutical Pricing Agreement with the Secretary of Health and Human Services, which enables certain entities that qualify for government pricing under the Public Hea