ALEXION PHARMACEUTICALS INC
Form 10-Q
May 05, 2010
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the quarterly period ended March 31, 2010

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: 0-27756

Alexion Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**13-3648318**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

352 Knotter Drive, Cheshire, Connecticut 06410

(Address of principal executive offices) (Zip Code)

203-272-2596

(Registrant s telephone number, including area code)

N/A

(Former name, former address, and former fiscal year, if changed since last report)

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 (§ 232.405 of this chapter) 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 definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.:

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

Common Stock, $0.0001 par value	**89,585,562**
Class	**Outstanding at April 28, 2010**

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ALEXION PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)

(in thousands, except per share amounts)	March 31, 2010	December 31, 2009
Assets		
Current Assets:		
Cash and cash equivalents	$ 186,062	$ 157,172
Marketable securities	18,642	19,048
Trade accounts receivable, net	126,660	113,731
Inventories	55,552	40,885
Deferred tax assets	16,712	16,726
Prepaid expenses and other current assets	26,453	25,894
Total current assets	430,081	373,456
Property, plant and equipment, net	162,966	164,691
Intangible assets, net	27,414	28,589
Goodwill, net	19,954	19,954
Deferred tax assets	187,928	194,308
Other assets	7,420	5,403
Total assets	$ 835,763	$ 786,401
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable	$ 9,474	$ 11,530
Accrued expenses	67,533	71,657
Deferred revenue	3,240	1,652
Current portion of capital lease obligations	328	422
Other current liabilities	860	1
Total current liabilities	81,435	85,262
Capital lease obligations, less current portion	438	503
Convertible notes	8,918	9,918
Deferred tax liabilities	194	204
Other liabilities	2,303	2,158
Total liabilities	93,288	98,045
Commitments and contingencies (Note 14)		
Stockholders Equity:		
Preferred stock, $0.0001 par value; 5,000 shares authorized, no shares issued or outstanding		
Common stock, $0.0001 par value; 145,000 shares authorized; 90,048 and 89,097 shares issued at March 31, 2010 and December 31, 2009, respectively	5	5
Additional paid-in capital	1,114,549	1,093,933
Treasury stock, at cost	(2,676)	(2,676)
Accumulated other comprehensive income (loss)	10,628	(1,942)
Accumulated deficit	(380,031)	(400,964)

Total stockholders equity	742,475	688,356
Total liabilities and stockholders equity	$ 835,763	$ 786,401

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

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ALEXION PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share amounts)	Three months ended March 31, 2010	2009
Net product sales	$ 117,578	$ 81,267
Cost of sales	13,999	9,959
Operating expenses:		
Research and development	22,374	19,089
Selling, general and administrative	50,635	36,652
Total operating expenses	73,009	55,741
Operating income	30,570	15,567
Other income and expense:		
Investment income	250	303
Interest expense	(210)	(333)
Foreign currency loss	(537)	(393)
Income before income taxes	30,073	15,144
Income tax provision	9,139	638
Net income	$ 20,934	$ 14,506
Earnings per common share		
Basic	$ 0.24	$ 0.18
Diluted	$ 0.23	$ 0.16
Shares used in computing earnings per common share		
Basic	88,506	81,698
Diluted	92,090	90,645

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ALEXION PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)	Three months ended March 31, 2010	2009
Cash flows from operating activities:		
Net income	$ 20,934	$ 14,506
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation and amortization	3,842	3,024
Share-based compensation expense	8,104	7,926
Deferred taxes	6,333	
Marketable securities premium amortization	312	
Unrealized foreign currency loss	2,977	322
Unrealized loss on forward contracts	2,672	1,972
Loss on disposal of property, plant and equipment	63	24
Changes in operating assets and liabilities:		
Accounts receivable	(17,434)	(6,448)
Inventories	(12,755)	727
Prepaid expenses and other assets	9,105	(5,575)
Accounts payable and accrued expenses	(4,371)	(1,315)
Deferred revenue	1,710	766
Net cash provided by operating activities	21,492	15,929
Cash flows from investing activities:		
Purchases of marketable securities	(5,209)	
Proceeds from maturity or sale of marketable securities	5,250	
Purchases of property, plant and equipment	(2,317)	(6,406)
Purchase of technology rights		(12,500)
Increase in restricted cash		(67)
Net cash used in investing activities	(2,276)	(18,973)
Cash flows from financing activities:		
Payments on capital leases	(171)	(71)
Excess tax benefit from stock options	313	
Net proceeds from issuance of common stock	10,594	4,199
Net cash provided by financing activities	10,736	4,128
Effect of exchange rate changes on cash	(1,062)	(57)
Net change in cash and cash equivalents	28,890	1,027
Cash and cash equivalents at beginning of period	157,172	138,012
Cash and cash equivalents at end of period	$ 186,062	$ 139,039

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ALEXION PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

(in thousands, except per share amounts)

1. Business

Alexion Pharmaceuticals, Inc. (Alexion or the Company) is a biopharmaceutical company engaged in the discovery, development and commercialization of biologic therapeutic products aimed at treating patients with severe and life-threatening disease states, including hematologic, kidney, inflammatory and neurologic diseases, transplant rejection and cancer. Our marketed product Soliris® (eculizumab) is the first and only therapy approved for the treatment of patients with paroxysmal nocturnal hemoglobinuria, or PNH. We were incorporated in 1992 and began commercial sale of Soliris in 2007.

2. Basis of Presentation and Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. These accounting principles were applied on a basis consistent with those of the consolidated financial statements contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2009. In our opinion, the accompanying unaudited condensed consolidated financial statements contain all adjustments (consisting only of normal recurring adjustments) necessary to state fairly our financial position as of March 31, 2010 and the results of our operations and cash flows for the three months ended March 31, 2010 and 2009. The December 31, 2009 condensed consolidated balance sheet data was derived from audited financial statements but does not include all disclosures required by accounting principles generally accepted in the United States of America. These interim financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2009 included in our Annual Report on Form 10-K. The results of operations for the three months ended March 31, 2010 are not necessarily indicative of the results to be expected for the full year.

The financial statements of our subsidiaries with functional currencies other than the U.S. dollar are translated into U.S. dollars using period-end exchange rates for assets and liabilities, historical exchange rates for stockholders equity and weighted average exchange rates for operating results. Translation gains and losses are included in accumulated other comprehensive income (loss) in stockholders equity. Foreign currency transaction gains and losses are included in the results of operations in other income (expense).

The accompanying unaudited condensed consolidated financial statements include the accounts of Alexion Pharmaceuticals, Inc. and its subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

We have reclassified certain amounts for the prior period to conform to the current year presentation.

3. Revenue and Accounts Receivable

Revenue

Our principal source of revenue is product sales. We have applied the following principles in recognizing revenue:

We recognize revenue from product sales when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured and we have no further performance obligations. Revenue is recorded upon receipt of the product by the patients health-care provider, which is typically a hospital, physician s office, pharmacy or health care facility. Amounts collected from customers and remitted to governmental authorities, such as value-added taxes (VAT) in foreign jurisdictions, are presented on a net basis in the Company s statements of operations and do not impact net product sales.

In the United States, our customers are primarily specialty distributors and specialty pharmacies which supply physician office clinics, hospital outpatient clinics, infusion clinics or home health care providers. We also sell Soliris to government agencies. Outside the United States, our customers are primarily hospitals, hospital buying groups, pharmacies, other health care providers and distributors.

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(unaudited)

(in thousands, except per share amounts)

In addition to sales in countries where Soliris is commercially available, we have also recorded revenue on sales for individual patients through named-patient programs outside the United States. The relevant authorities or institutions in those countries have agreed to reimburse for product sold on a named-patient basis where Soliris has not received final approval for commercial sales.

Because of the pricing of Soliris, the limited number of patients, the short period from sale of product to patient infusion and the lack of contractual return rights, Soliris customers generally carry limited inventory. We monitor inventory within our distribution channel to determine whether deferral of sales is required. To date, actual refunds and returns have been negligible.

We record estimated rebates payable under governmental programs, including Medicaid in the United States and other programs in Europe, as a reduction of revenue at the time product sales are recorded. Our calculations related to these rebate accruals require an analysis of historical claim patterns and estimates of customer mix, to determine which sales will be subject to rebates and the amount of such rebates. We update our estimates and assumptions each period and record any necessary adjustments. Generally, the length of time between product sale and the processing and reporting of the rebates is three to six months. Upon review of historical rebate payments compared to our accruals, we revise our estimates of rebates payable, which may have an impact on revenue in the period in which the adjustment is made.

On March 23, 2010, healthcare reform legislation, which contains several provisions that impact rebates payable, was signed into law. The provisions in the legislation include an increase in the minimum Medicaid rebate percentages and an extension of the Medicaid rebate to managed care organizations that dispense drugs to Medicaid recipients. We have recorded estimated rebates payable according to legislative language. If the implementation provisions of this legislation change, we may revise our estimates of rebates payable, which may have an impact on revenue in the period in which the adjustment is made.

We record distribution and other fees paid to our customers as a reduction of revenue. These costs are typically known at the time of sale, resulting in minimal adjustments subsequent to the period of sale.

We record the effective portion of our cash flow hedges to revenue in the period in which the derivative contract is settled.

Accounts Receivable

Our European product sales to government-owned or supported customers in certain countries, including Greece, are subject to delays in payment due to government funding and reimbursement practices. Because these customers are government owned or supported, we may also be impacted by declines in sovereign credit ratings or by defaults in these countries.

To date, we have not experienced material losses with respect to the collection of our accounts receivable and believe that our accounts receivable, net of allowance, are collectible. However, a significant further decline in sovereign credit ratings or a default in Greece, or in other countries, may decrease the likelihood that we will collect these accounts receivable, resulting in a higher allowance for doubtful accounts and a corresponding decrease in revenue, and also may negatively impact our ability to recognize future revenue at the time of product delivery in these countries.

4. Inventories

Inventories are stated at the lower of cost or estimated realizable value. We determine the cost of inventory using the weighted average cost method.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)