ALEXION PHARMACEUTICALS INC
Form 10-Q
May 10, 2007
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FORM 10-Q

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

x Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the quarterly period ended March 31, 2007

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 is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer x Accelerated filer ¨ Non-accelerated filer ¨

Indicate by check mark whether the registrant is a shell company (as defined in rule 12b-2 of the Act)

Yes ¨ No x

Common Stock, $0.0001 par value	**36,417,203**
Class	**Outstanding at May 4, 2007**

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ALEXION PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

(In Thousands, except per share amounts)

(Unaudited)

	March 31, 2007	December 31, 2006
Assets		
Current Assets		
Cash and cash equivalents	$ 136,992	$ 166,826
Marketable securities	46,695	49,728
Trade accounts receivable, net of allowance of $0 at March 31, 2007	1,173	
Inventories	3,113	2,314
Prepaid expenses and other current assets	5,067	3,973
Prepaid manufacturing costs	13,935	
Total Current Assets	206,975	222,841
Property, plant and equipment, net	54,592	39,135
Goodwill, net	19,954	19,954
Prepaid manufacturing costs		13,935
Restricted cash	22,248	33,594
Other assets	3,968	4,078
Total Assets	$ 307,737	$ 333,537
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 8,761	$ 10,939
Accrued expenses	13,705	16,228
Deferred revenue		588
Current portion of obligations under capital lease	68	67
Total Current Liabilities	22,534	27,822
Obligations under capital lease	264	283
Deferred revenue, less current portion		4,755
Mortgage loan	26,000	26,000
Convertible notes	150,000	150,000
Total Liabilities	198,798	208,860
Stockholders' Equity		
Preferred stock, $.0001 par value; 5,000 shares authorized, no shares issued or outstanding		
Common Stock, $.0001 par value; 145,000 shares authorized; 36,302 and 35,568 shares issued at March 31, 2007 and December 31, 2006, respectively	4	4
Additional paid-in capital	780,083	763,691
Treasury Stock, at cost, 57 shares at March 31, 2007 and December 31, 2006, respectively	(1,260)	(1,260)
Accumulated other comprehensive loss	(205)	(177)
Accumulated deficit	(669,683)	(637,581)

Total Stockholders' Equity	108,939	124,677
Total Liabilities and Stockholders' Equity	$ 307,737	$ 333,537

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

and Comprehensive Loss

(In Thousands, except per share amounts)

(Unaudited)

	Three months ended March 31,	
	2007	**2006**
Revenues		
Product revenues, net	$ 974	$
Contract research revenues	5,343	768
Total revenues, net	6,317	768
Costs and Expenses		
Cost of product revenues	85	
Research and development	21,219	21,214
General and administrative	19,838	8,146
Total costs and expenses	41,142	29,360
Operating loss	(34,825)	(28,592)
Other Income and Expense		
Investment income	2,769	1,963
Interest expense	(700)	(688)
Other expense	(27)	
Loss before state tax benefit	(32,783)	(27,317)
State Tax Benefit	90	90
Net Loss	$ (32,693)	$ (27,227)
Other Comprehensive Income/Loss		
Foreign currency translation	(52)	(27)
Unrealized gains on marketable securities	24	8
Comprehensive Loss	$ (32,721)	$ (27,246)
Net loss per share basic and diluted	$ (0.92)	$ (0.88)
Shares used in computing basic and diluted net loss per common share	35,361	30,991

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

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ALEXION PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Cash Flows

(In Thousands)

(Unaudited)

	Three months ended March 31,	
	2007	**2006**
Cash flows from operating activities:		
Net loss	$ (32,693)	$ (27,227)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization	873	881
Share-based compensation expense	4,980	3,166
Changes in operating assets and liabilities		
Accounts receivable	(1,173)	
Inventories	(799)	
Prepaid expenses and other assets	(1,094)	1,167
Accounts payable	(2,178)	(2,545)
Accrued expenses	(1,933)	(3,211)
Deferred revenue	(5,343)	(326)
Net cash used by operating activities	(39,360)	(28,095)
Cash flows from investing activities:		
Purchase of marketable securities	(43,157)	(231,085)
Proceeds from maturity or sale of marketable securities	46,214	222,597
Purchase of property, plant and equipment	(16,219)	(477)
Release of restricted cash	11,346	
Net cash used by investing activities	(1,816)	(8,965)
Cash flows from financing activities:		
Payment on capital leases	(18)	
Net proceeds from issuance of common stock	11,412	5,405
Net cash provided by financing activities	11,394	5,405
Effect of exchange rate changes	(52)	(27)
Net change in cash and cash equivalents	(29,834)	(31,682)
Cash and cash equivalents at beginning of period	166,826	43,629
Cash and cash equivalents at end of period	$ 136,992	$ 11,947

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

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ALEXION PHARMACEUTICALS, INC.

Notes to Condensed Consolidated Financial Statements

(in thousands, except share and per share amounts)

1. Basis of Presentation

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 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, 2006. 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, 2007, the results of our operations for the three months ended March 31, 2007 and 2006, and our cash flows for the three months ended March 31, 2007 and 2006. The December 31, 2006 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, 2006 included in our Annual Report on Form 10-K.

The financial position and results of operations of our foreign subsidiaries are measured using the local currency as the functional currency. Assets and liabilities of each subsidiary have been translated at end of period exchange rates, and related revenues and expenses have been translated at weighted average exchange rates with the resulting translation gain or loss recorded in accumulated other comprehensive income. Transaction gains and losses are included in other expense.

The results of operations for the three months ended March 31, 2007 are not necessarily indicative of the results to be expected for the full year.

During the three month period ended March 31, 2007, we established three new entities to support our planned growth and preparation for commercialization. Alexion Pharma Italy Srl, a simplified joint stock company, is registered under the laws of Italy and is wholly owned by Alexion Holding B.V. Alexion Pharma Germany GmbH, a simplified joint stock company, is registered under the laws of Germany and is wholly owned by Alexion Holding B.V. Alexion Pharma Spain S.L., a simplified joint stock company, is registered under the laws of Spain and is wholly owned by Alexion Holding B.V. There were no material transactions that occurred in the newly formed entities during the three month period ending March 31, 2007.

2. Revenue

Principal sources of revenue are product sales and contract research revenues from research and development support payments. We have applied the following principles in recognizing revenue:

Product Revenues, net

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. All revenues from product sales are recorded net of applicable provisions for distribution fees. The distribution fee represents handling fees and third-party carrier costs.

In Europe, we have entered into an agreement with a distributor to distribute Soliris (eculizumab) under pre-approval programs existing in certain European countries. As commercial approval, or marketing authorization, for Soliris had not been granted by the European Medicines Agency, or EMEA, in the three months ending March 31, 2007, all sales in Europe to date have been made on a named-patient or pre-approval basis. For revenue recognition purposes, our distributor is considered the final customer. For the three months ended March 31, 2007, we realized net sales of Soliris totaling $974.

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(in thousands, except share and per share amounts)

Distributor Fees

We have adopted the provisions set forth in EITF Issue No. 01-09, Accounting for Consideration given by a Vendor to a Customer (including a Reseller of a Vendor s Products) , which specifies that cash consideration (including a sales incentive) given by a vendor to a customer is presumed to be a reduction of the selling prices of the vendor s products or services and, therefore, should be characterized as a reduction of revenue. That presumption is overcome and the consideration should be characterized as a cost incurred if, and to the extent that, both of the following conditions are met: (1) the vendor receives, or will receive, an identifiable benefit (goods or services) in exchange for the consideration; and (2) the vendor can reasonably estimate the fair value of the benefit received.

We record fees paid to our distributors for their logistical, distribution and similar services as a reduction of product revenue.

Amounts collected from customers and remitted to governmental authorities, which are primarily comprised of value-added taxes (VAT) in foreign jurisdictions, are presented on a net basis in our income statement, in that taxes billed to customers are not included as a component of net product sales, as per Emerging Issues Task Force (EITF) Issue No. 06-3, *How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement* .

Contract Research Revenue

Procter & Gamble Pharmaceuticals Collaboration

In January 1999, we and Procter & Gamble Pharmaceuticals, or P&G, entered into an exclusive collaboration to develop and commercialize pexelizumab. We granted P&G an exclusive license to our intellectual property related to pexelizumab, with the right to sublicense.

In December 2001, we and P&G entered into a binding memorandum of understanding, or MOU, pursuant to which the January 1999 collaboration was revised. We and P&G agreed, as per the MOU, to share concurrently 50% of the ongoing U.S. pre-production and development manufacturing costs for pexelizumab as well as any acute myocardial infarction or coronary artery bypass graft Phase III clinical trial costs.

We had recognized a non-refundable up-front license fee of $10,000 related to the P&G collaboration as revenue over 17 years, representing the average of the remaining patent lives of the underlying technologies at the time the payment was received in fiscal 1999. We recorded this payment as deferred revenue.

During 2006, we completed a final Phase III trial of pexelizumab. After reviewing results from that trial, we along with P&G, determined not to pursue further development of pexelizumab. Effective March 30, 2007, we and P&G mutually agreed to terminate the collaboration agreement. As we have no further obligations under the agreement, the remaining portion of the $10,000 non-refundable up-front license fee, or $5,343, was recognized as revenue.

3. Inventories

Inventories are stated at the lower of cost or estimated realizable value. Cost is computed using standard cost, which approximates actual cost, on a first-in, first-out, or FIFO, basis. We periodically analyze our inventory levels, and write down inventory that has become obsolete, inventory that has a cost basis in excess of its estimated realizable value and inventory in excess of expected sales requirements to cost of product revenues. Expired inventory is disposed of and the related costs are written off to cost of product revenues. Additionally, we may be required to expense previously capitalized inventory that fails to meet commercial sale specifications.

At March 31, 2007, our inventory consists entirely of finished goods. We submitted a Marketing Authorization Application, or MAA, in the European Union and a Biologics License Application, or BLA, in the United States in September 2006. In March 2007, we received approval of

Soliris from the U.S. Food and Drug Administration, or FDA. We have launched Soliris in the U.S., and anticipate European Union approval in 2007. As of March 31, 2007 the carrying value of our inventory did not include any costs associated with products that have not yet received regulatory approval.

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(in thousands, except share and per share amounts)

Soliris currently has an estimated shelf life of up to 42 months and, based on our sales forecasts, we expect the carrying value of the Soliris inventory, and prepaid manufacturing costs to be fully realized.

Our products are subject to strict quality control and monitoring which we perform throughout the manufacturing process. Periodically, certain batches or units of product may no longer meet quality specifications or may expire. In certain instances, we may write-down, to net realizable value, commercial inventory that did not meet quality specifications or that became obsolete due to dating expiration. Based on this review, there are no write-downs against the value of our inventory, as of March 31, 2007.

4. Cost of Product Revenues

Our policy is to capitalize inventory costs associated with our products subsequent to the filing of a BLA, but prior to regulatory approval, when, based on management s judgment, future commercialization is considered probable and the future economic benefit is expected to be realized, which is customary in our industry. At the point of sale, we recognize costs of product revenues which include the cost of inventory sold and estimated royalties payable to third parties. Product sold during the three months ended March 31, 2007 under the named-patient program was previously expensed prior to submission of our BLA, and therefore is not included in the cost of product revenues during this period. For the three months ended March 31, 2007, our cost of product revenues consists entirely of estimated royalties owed to third parties related to the sale and commercial manufacture of Soliris.

5. Exit Activities

In December 2006, we initiated an integration plan at our subsidiary, Alexion Antibody Technologies, Inc., to consolidate certain functions and operations, including the termination of all Alexion Antibody personnel, closure of Alexion Antibody facilities, and impairment of equipment in that facility. These costs have been recognized as liabilities and were included in general and administrative expenses for the year ended December 31, 2006. The following table summarizes the liabilities established for exit activities as of December 31, 2006 and subsequent cash payments and revision of estimates made during the three month period ended March 31, 2007:

	Employee Related Benefits	Facility Lease Costs	Other Exit Activities	Total Exit Activities
Balance at December 31, 2006	$ 5,358	$ 1,147	$ 539	7,044
Revision of estimate	93			93
Payments in 2007	(5,379)	(175)		(5,554)
Balance at March 31, 2007	$ 73	$ 972	$ 539	$ 1,584

6. Accounting for Share-Based Compensation

A summary of the status of our stock option plans at March 31, 2007 and changes during the three months then ended is presented in the table and narrative below:

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(in thousands, except share and per share amounts)

	Options	Weighted-Average Exercise Price
Options outstanding at December 31, 2006	5,372,463	