ALEXION PHARMACEUTICALS INC
Form 10-Q
August 07, 2008
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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 June 30, 2008

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, 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. (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 Act) Yes ¨ No x

Common Stock, $0.0001 par value	38,899,422
Class	**Outstanding at August 4, 2008**

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ALEXION PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

(in thousands, except per share amounts)	June 30, 2008	December 31, 2007
Assets		
Current Assets:		
Cash and cash equivalents	$ 106,101	$ 95,321
Marketable securities	1,696	10,433
Trade accounts receivable	56,138	46,278
Inventories	48,048	32,907
Prepaid manufacturing costs	5,388	13,775
Prepaid expenses and other current assets	10,759	6,640
Total current assets	228,130	205,354
Property, plant and equipment, net	119,387	104,280
Intangible assets, net	10,240	
Goodwill, net	19,954	19,954
Restricted cash	484	958
Other assets	994	3,811
Total assets	$ 379,189	$ 334,357
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable	$ 6,989	$ 9,072
Accrued expenses	35,819	28,324
Deferred revenue	2,044	41
Revolving credit facility	5,000	
Current portion of long-term debt obligation	4,500	
Current portion of capital lease obligations	284	272
Total current liabilities	54,636	37,709
Capital lease obligations, less current portion	355	499
Mortgage loan	44,000	44,000
Convertible notes	150,000	150,000
Long-term debt obligation, less current portion	2,500	
Other liabilities	900	593
Total liabilities	252,391	232,801
Commitments and contingencies (Note 15)		
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; 38,601 and 37,873 shares issued at June 30, 2008 and December 31, 2007, respectively	4	4
Additional paid-in capital	860,808	833,534
Treasury stock, at cost, 57 shares	(1,260)	(1,260)

Accumulated other comprehensive loss	(1,600)	(1,443)
Accumulated deficit	(731,154)	(729,279)
Total stockholders equity	126,798	101,556
Total liabilities and stockholders equity	$ 379,189	$ 334,357

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 June 30, 2008	Three months ended June 30, 2007	Six months ended June 30, 2008	Six months ended June 30, 2007
Revenues:				
Net product sales	$ 59,559	$ 9,756	$ 105,105	$ 10,731
Contract research revenues			95	5,343
Total revenues	59,559	9,756	105,200	16,074
Cost of sales	7,142	1,067	12,606	1,152
Operating expenses:				
Research and development	16,825	15,195	32,434	36,415
Selling, general and administrative	32,907	22,788	62,688	42,627
Total operating expenses	49,732	37,983	95,122	79,042
Operating income (loss)	2,685	(29,294)	(2,528)	(64,120)
Other income and expense:				
Investment income	604	2,158	1,371	4,928
Interest expense	(736)	(511)	(1,332)	(1,211)
Foreign currency gain (loss)	(335)	373	368	346
Income (loss) before income tax benefit	2,218	(27,274)	(2,121)	(60,057)
Income tax benefit	156	90	246	180
Net income (loss)	$ 2,374	$ (27,184)	$ (1,875)	$ (59,877)
Net income (loss) per share:				
Basic	$ 0.06	$ (0.75)	$ (0.05)	$ (1.68)
Diluted	$ 0.06	$ (0.75)	$ (0.05)	$ (1.68)
Weighted average common shares used to compute net income (loss) per common share:				
Basic	37,842	36,031	37,679	35,698
Diluted	39,495	36,031	37,679	35,698

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

(UNAUDITED)

(in thousands)	Six months ended June 30, 2008	2007
Cash flows from operating activities:		
Net loss	$ (1,875)	$ (59,877)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	3,569	1,946
Share-based compensation expense	11,891	10,320
Loss on disposal of property, plant and equipment	47	
Changes in operating assets and liabilities:		
Accounts receivable	(9,474)	(10,262)
Inventories	(14,615)	(12,646)
Prepaid expenses and other assets	6,238	(793)
Accounts payable and accrued expenses	5,059	(3,427)
Deferred revenue	2,057	(5,343)
Net cash provided by (used in) operating activities	2,897	(80,082)
Cash flows from investing activities:		
Purchases of marketable securities	(53,006)	(86,366)
Proceeds from maturity or sale of marketable securities	61,743	105,949
Purchases of property, plant and equipment	(17,079)	(38,705)
Purchase of technology rights	(3,000)	
Release of restricted cash	474	24,069
Net cash (used in) provided by investing activities	(10,868)	4,947
Cash flows from financing activities:		
Payments under capital lease obligations	(134)	(33)
Proceeds from revolving credit facility	5,000	
Debt issuance costs	(312)	
Net proceeds from issuance of common stock	14,098	21,250
Net cash provided by financing activities	18,652	21,217
Effect of exchange rate changes on cash	99	(144)
Net change in cash and cash equivalents	10,780	(54,062)
Cash and cash equivalents at beginning of period	95,321	166,826
Cash and cash equivalents at end of period	$ 106,101	$ 112,764

See Notes 6 and 12 for investing and financing non-cash disclosures

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. Business

Alexion Pharmaceuticals, Inc. (Alexion or the Company) is a biopharmaceutical company engaged in the discovery, development and delivery of biologic therapeutic products aimed at treating patients with severe and life-threatening disease states, including hematologic and neurologic diseases, transplant rejection, cancer and autoimmune disorders. Our marketed product Soliris® (eculizumab) is the first therapy approved for the treatment of patients with paroxysmal nocturnal hemoglobinuria, or PNH. We were incorporated in January 1992, and we began commercial sales of Soliris in the United States and in certain countries in Europe 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, 2007. 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 June 30, 2008, the results of our operations for the three and six months ended June 30, 2008 and 2007, and our cash flows for the six months ended June 30, 2008 and 2007. The December 31, 2007 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, 2007 included in our Annual Report on Form 10-K. The results of operations for the three and six months ended June 30, 2008 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 in stockholders equity. Foreign currency transaction gains and losses are included in the results of operations in other income and expense.

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

3. Revenue

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

To date, our product sales have consisted solely of Soliris. 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. 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 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 who supply physician office clinics, hospital outpatient clinics, infusion clinics or home health care providers. In some cases, 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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(in thousands, except share and per share amounts)

Through June 30, 2008, we have recorded revenue on sales for individual patients through named-patient programs outside the United States. The relevant authorities 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. In Europe, we have entered into transitional agreements with a distributor to distribute Soliris on a named-patient basis in specified European countries.

To date, actual refunds and returns have been negligible. Because of the pricing of Soliris, the limited number of patients, the short period from sale of product to patient i