# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# FORM 8-K

# **CURRENT REPORT**

PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): July 22, 2010

# **ALEXION PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware** (State or other jurisdiction of incorporation or organization) 000-27756 (Commission File Number) 13-3648318 (I.R.S. Employer Identification No.)

352 Knotter Drive, Cheshire, Connecticut 06410 (Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (203) 272-2596

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

D Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

D Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 2.02 Results of Operations and Financial Condition.

On July 22, 2010, Alexion issued a press release relating to its results of operations and financial condition for the quarter ended June 30, 2010. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

The attached press release contains both U.S. Generally Accepted Accounting Principles ("GAAP") and non-GAAP financial measures. The non-GAAP financial measures exclude share-based compensation expenses and taxes not payable in cash. Reconciliations between non-GAAP and GAAP financial measures are included in the press release set forth as Exhibit 99.1 furnished to this Form 8-K. The Company's management utilizes non-GAAP financial information to provide a useful measure of comparative operating performance of the Company. The non-GAAP financial measures are supplemental to and not a substitute for, measures of financial performance prepared in accordance with GAAP.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release issued by Alexion Pharmaceuticals, Inc. on July 22, 2010 relating to its results of operations and financial condition for the quarter ended June 30, 2010.

#### Signature

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

# ALEXION PHARMACEUTICALS, INC.

By: /s/ Thomas I.H. Dubin

Name: Thomas I. H. Dubin Title: Senior Vice President and Chief Legal Officer

Date: July 22, 2010



Contacts:

Alexion Pharmaceuticals, Inc. Irving Adler Sr. Director, Corporate Communications (203) 271-8210 Makovksy + Company (Media) Kristie Kuhl (212) 508-9642 Rx Communications (Investors) Rhonda Chiger (917) 322-2569

#### ALEXION REPORTS SECOND QUARTER 2010 RESULTS

- Continued Steady Addition of New Patients on Soliris® in U.S. and Europe -

- Reiterating Upward Revisions to 2010 Sales and Non-GAAP EPS Guidance Announced in June -

- Current aHUS Trials Fully Enrolled; Data Expected by Year-End -

# Second Quarter 2010 — Selected Highlights:

Financial:

- Soliris<sup>®</sup> (eculizumab) net product sales increased 36 percent to \$125.8 million in Q2 2010, compared to \$92.3 million in Q2 2009.
- Q2 GAAP net income increased 30 percent to \$21.8 million, or \$0.24 per share, compared to GAAP net income of \$16.8 million, or \$0.19 per share, in Q2 2009.
- Q2 non-GAAP net income increased 56 percent to \$36.9 million, or \$0.39 per share, compared to non-GAAP net income of \$23.8 million, or \$0.26 per share, in Q2 2009.

#### Development:

- Soliris received regulatory and reimbursement approvals in Japan.
- Enrollment completed in current clinical studies of Soliris as a treatment for patients with aHUS.
- Data presentations further support aHUS and transplant programs.

**Cheshire, CT, July 22, 2010** - Alexion Pharmaceuticals, Inc. (Nasdaq: ALXN) today announced financial results for the three and six months ended June 30, 2010.

#### Second Quarter 2010 Financial Results:

For the three months ended June 30, 2010, Alexion Pharmaceuticals, Inc. ("Alexion" or the "Company") reported total revenues of \$125.8 million from net product sales of Soliris<sup>®</sup> (eculizumab), compared to \$92.3 million in Q2 2009, reflecting ongoing steady additions of new patients in the U.S. and in European countries during the quarter.

Soliris is the only drug specifically indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH), an ultra-rare, debilitating and lifethreatening blood disorder. Soliris was approved by the U.S. Food and Drug Administration and the European Commission in 2007, and by Japan's Ministry of Health, Labour and Welfare (MHLW) in 2010.

Alexion's non-GAAP operating results are equal to its GAAP operating results less only share-based compensation and non-cash tax expense. Non-cash tax expense represents the reduction in cash taxes attributable to the utilization of U.S. net operating losses (NOL's). The following summary table is provided for investors' convenience.

(in thousands, except per share data) (unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Total revenues	\$125,834	\$92,256	\$243,412	\$ 173,523
GAAP net income	\$ 21,773	\$16,802	\$ 42,707	\$ 31,308
Share-based compensation	8,250	6,948	16,354	14,874
Non-cash tax expense	6,923		12,439	
Non-GAAP net income	\$ 36,946	\$23,750	\$ 71,500	\$ 46,182
Shares used in computing diluted earnings per share (GAAP)	92,575	90,159	92,340	89,975
Shares used in computing diluted earnings per share (Non-GAAP)	93,852	91,236	93,611	91,107
GAAP earnings per share - diluted	\$ 0.24	\$ 0.19	\$ 0.46	\$ 0.35
Non-GAAP earnings per share - diluted	\$ 0.39	\$ 0.26	\$ 0.76	\$ 0.51

# Second Quarter 2010 Non-GAAP Financial Results:

The Company reported non-GAAP net income for Q2 2010 of \$36.9 million, or \$0.39 per share, an increase of 56 percent compared to \$23.8 million, or \$0.26 per share, in Q2 2009. Non-GAAP earnings per share in Q2 2009 included a non-cash charge of \$3.4 million, or \$0.04 per share, associated with the exchange of convertible notes during the quarter.

Alexion's non-GAAP operating expenses for Q2 2010 were \$71.8 million, compared to \$54.0 million for Q2 2009. Non-GAAP research and development (R&D) expenses for Q2 2010 were \$21.7 million, compared to \$16.5 million for Q2 2009. The increase in R&D expenses primarily reflected the Company's expanded clinical development programs. Non-GAAP selling, general and administrative (SG&A) expenses for Q2 2010 were \$50.1 million, compared to \$37.6 million for Q2 2009. The increase in SG&A expenses primarily reflected costs associated with the expansion of the Company's operations worldwide.

#### Second Quarter 2010 GAAP Financial Results:

The Company reported GAAP net income for Q2 2010 of \$21.8 million, or \$0.24 per share, an increase of 30 percent compared to \$16.8 million, or \$0.19 per share, in Q2 2009. GAAP earnings per share in Q2 2009 included a non-cash charge of \$3.4 million, or \$0.04 per share, associated with the exchange of convertible notes during the quarter.

Alexion's GAAP operating expenses for Q2 2010 were \$79.8 million, compared to \$61.0 million for Q2 2009. GAAP R&D expenses for Q2 2010 were \$23.7 million, compared to \$18.3 million for Q2 2009. GAAP SG&A expenses were \$56.1 million for Q2 2010, compared to \$42.7 million for Q2 2009.

As of June 30, 2010, the Company had \$248.8 million in cash, cash equivalents and marketable securities, compared to \$204.7 million at March 31, 2010.

"Our achievements in the second quarter, including landmark accomplishments in Japan and impressive progress in our lead pipeline programs, reflect clinical benefits provided by the innovative complement-blockade technology of Soliris, and the continued strengthening of our growing global operations," said Leonard Bell, M.D., Chief Executive Officer of Alexion. "We look forward to the opportunity to serve more patients with PNH in the coming quarters, while progressing our aHUS and transplant programs to serve patients with other severe and ultra-rare disorders in the years ahead."

#### Second Quarter 2010 Research and Development Progress:

During the second quarter, Alexion made continued progress on advancing the development of Soliris as a treatment for patients suffering from additional rare and severe complement-mediated disorders. There are currently 12 clinical trials of Soliris underway in eight diseases, and the Company is increasingly focused on its two lead areas of nephrology and transplant.

#### PNH: Approvals and Continuing Research

On June 2, 2010, the Company announced that the launch of Soliris as a treatment for patients with PNH in Japan will begin in the third quarter of 2010, approximately three months earlier than expected, as a result of rapid actions by the MHLW. The MHLW approved the new drug application for Soliris in April and listed Soliris for reimbursement through Japan's National Health Insurance system in June.

On June 14, 2010, Alexion reported that data were presented at the 15th Congress of the European Hematology Association held in Barcelona, Spain, evaluating the substantial disease burden of PNH in patients enrolled in the International PNH Registry and, separately, in a South Korean PNH patient registry.

#### Nephrology: Atypical Hemolytic Uremic Syndrome (aHUS)

In April 2010, Alexion announced completion of enrollment in its current clinical studies to investigate Soliris as a treatment for patients with aHUS. The 26week trials include adult and adolescent patients in two cohorts: those who had been treated chronically with plasma therapy, and others who were resistant or intolerant to plasma therapy. Preliminary data from the trials are expected to be presented near the end of 2010. The Company expects to begin a trial in pediatric aHUS patients in the fall of 2010. Additional early clinical experience with Soliris as a treatment for patients with aHUS was recently presented at the Second International Conference on HUS-MPGN-PNH held in Innsbruck, Austria and summarized in an announcement by the Company on June 15, 2010.

#### Transplant: Acute Humoral Rejection (AHR)

Soliris is being investigated as a treatment for patients undergoing kidney transplant who are at elevated risk of antibody mediated rejection, also known as acute humoral rejection, or AHR. The Company is supporting investigator-initiated studies in elevated-risk kidney transplantation in the U.S. and Australia and is planning a company-sponsored controlled clinical trial using Soliris to prevent AHR in patients undergoing kidney transplant. This study is expected to commence in multiple centers toward the end of the year. Positive interim data on 16 patients from an investigator-initiated trial at the Mayo Clinic was presented at the American Transplant Congress in May 2010.

# Oncology Program: Trial Enrollment Completed

Enrollment is now completed in the Company's Phase I dose-escalation clinical study of samalizumab, its anti-CD200 antibody, in patients with treatment refractory chronic lymphocytic leukemia or multiple myeloma. The trial has enrolled approximately 25 patients.

# 2010 Financial Guidance:

The Company is reiterating its previously announced 2010 financial guidance, including the upward revisions in 2010 guidance for revenues and non-GAAP EPS, and the narrowing of 2010 guidance for non-GAAP operating expenses, which were announced on June 2, 2010.

In 2010, worldwide net product sales are expected to be within an upwardly revised range of \$515 to \$530 million, from the previous range of \$505 to \$520 million. Non-GAAP R&D expenses are anticipated to be in the range of \$95 to \$100 million and guidance for non-GAAP SG&A expenses have been narrowed from the previous range of \$185 to \$195 million to \$190 to \$195 million. As a result, 2010 guidance for non-GAAP operating expenses has been narrowed from the previous range of \$280 to \$295 million to \$285 to \$295 million. Cost of sales are anticipated to be in the range of 12 to 13 percent. The Company's share-based compensation expenses for the year are expected to be in a range of \$32 to \$34 million. The GAAP tax rate is expected to be in the range of 30 to 32 percent. The non-GAAP tax rate, which excludes non-cash tax expense, is expected to be in the range of 11 to 12 percent. Based on a forecast of 94 million fully diluted shares outstanding for 2010, Alexion is reiterating its non-GAAP earnings per share guidance in the upwardly revised range of \$1.63 to \$1.68, from the previous range of \$1.60 to \$1.65.

# **Conference Call/Web Cast Information**

Alexion will host a conference call/webcast to discuss matters mentioned in this release. The call is scheduled for today, July 22, 2010, at 10:00 a.m., Eastern Time. To participate in this call, dial 719-457-2642, confirmation code 4227999, shortly before 10:00 a.m., Eastern Time. A replay of the call will be available for a limited period following the call, beginning at 1:00 p.m., Eastern Time. The replay number is 719-457-0820, confirmation code 4227999. The audio webcast can be accessed at <u>www.alexionpharma.com</u>.

#### **About Soliris**

Soliris is a first-in-class terminal complement inhibitor developed from the laboratory through regulatory approval and commercialization by Alexion. Soliris has been approved in the U.S., European Union, Japan and other countries as the first treatment for patients with PNH, an ultra-rare, debilitating and life-threatening blood disorder defined by chronic hemolysis, or the destruction of red blood cells. Prior to these approvals, there were no therapies specifically available for the treatment of patients with PNH. Alexion's innovative approach to complement inhibition has received some of the pharmaceutical industry's highest honors: the 2008 Prix Galien USA Award for Best Biotechnology Product with broad implications for future biomedical research and the 2009 Prix Galien France Award in the category of Drugs for Rare Diseases. More information on Soliris is available at <u>www.soliris.net</u>.

#### **About Alexion**

Alexion Pharmaceuticals, Inc. is a biopharmaceutical company working to develop and deliver life-changing drug therapies for patients with serious and lifethreatening medical conditions. Alexion is engaged in the discovery, development and commercialization of therapeutic products aimed at treating patients with a wide array of severe disease states, including hematologic and kidney diseases, transplant, other inflammatory disorders, and cancer. Soliris is Alexion's first marketed product, and the Company is pursuing potential new indications for Soliris beyond PNH, as well as early-stage development of other antibody product candidates. This press release and further information about Alexion Pharmaceuticals, Inc. can be found at <u>www.alexionpharma.com</u>.

This press release includes certain non-GAAP financial measures that are adjusted from GAAP figures. Alexion believes that these non-GAAP financial measures, when considered together with the GAAP figures, can enhance an overall understanding of Alexion's past financial performance and its prospects for the future. The non-GAAP financial measures are included with the intent of providing both management and investors with a more complete understanding of underlying operational results and trends. In addition, these non-GAAP financial measures are among the primary indicators Alexion management uses for planning and forecasting purposes and for measuring the Company's performance.

These non-GAAP financial measures are not intended to be considered in isolation or as a substitute for GAAP figures. A reconciliation of GAAP to non-GAAP figures is included in this press release.

# [ALXN-E]

This news release contains forward-looking statements, including statements related to guidance regarding anticipated financial results for 2010, projected tax rates, assessment of the Company's financial position and commercialization efforts, including with respect to the expected commercial launch of Soliris in Japan, potential benefits and commercial potential for Soliris, potential of Alexion's complement-inhibition technology for treatment of diseases other than PNH; plans for clinical programs for Soliris in aHUS and other non-PNH indications and for samalizumab; and progress in developing commercial infrastructure. Forward-looking statements are subject to factors that may cause Alexion's results and plans to differ from those expected, including for example, decisions of regulatory authorities regarding marketing approval or material limitations on the marketing of Soliris, delays in arranging satisfactory manufacturing capabilities and establishing

commercial infrastructure, delays in developing or adverse changes in commercial relationships, the possibility that results of clinical trials are not predictive of safety and efficacy results of Soliris in broader patient populations, the possibility that initial results of commercialization are not predictive of future rates of adoption of Soliris, the risk that third parties will not agree to license any necessary intellectual property to Alexion on reasonable terms or at all, the risk that third party payors (including governmental agencies) will not reimburse for the use of Soliris at acceptable rates or at all, the risk that estimates regarding the number of patients with PNH or other disorders is inaccurate, and a variety of other risks set forth from time to time in Alexion's filings with the Securities and Exchange Commission, including but not limited to the risks discussed in Alexion's Quarterly Report on Form 10-Q for the period ended March 31, 2010 and in Alexion's other filings with the Securities and Exchange Commission. Alexion does not intend to update any of these forward-looking statements to reflect events or circumstances after the date hereof, except when duty arises under law.

(Tables Follow)

#### ALEXION PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (in thousands, except per share amounts) (unaudited)

	June	Three Months Ended June 30,		hs Ended 2 30,
	2010	2009	2010	2009
Net product sales	\$125,834	\$92,256	\$243,412	\$173,523
Cost of sales (1)	13,721	10,313	27,720	20,272
Operating expenses:				
Research and development (1)	23,690	18,288	46,064	37,377
Selling, general and administrative (1)	56,098	42,705	106,733	79,357
Total operating expenses	79,788	60,993	152,797	116,734
Operating income	32,325	20,950	62,895	36,517
Other income (expense)	(242)	339	(739)	(84)
Debt exchange expense		(3,395)		(3,395)
Income before income taxes	32,083	17,894	62,156	33,038
Income tax provision	10,310	1,092	19,449	1,730
Net income	\$ 21,773	\$16,802	\$ 42,707	\$ 31,308
Earnings per common share				
Basic	\$ 0.24	\$ 0.20	\$ 0.48	\$ 0.38
Diluted	\$ 0.24	\$ 0.19	\$ 0.46	\$ 0.35
Shares used in computing earnings per common share				
Basic	89,002	85,128	88,755	82,948
Diluted	92,575	90,159	92,340	89,975

(1) The following is the share-based compensation expense included in the respective captions of the condensed consolidated statements of operations above:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Share-based compensation expense:				
Cost of sales	\$ 250	\$ —	\$ 565	\$ —
Research and development	2,025	1,817	4,110	4,055
Selling, general and administrative	 5,975	5,131	11,679	10,819
Total share-based compensation expense	\$ 8,250	\$ 6,948	\$ 16,354	\$ 14,874

# ALEXION PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (in thousands) (unaudited)

	At		
	June 30, 2010	December 31, 2009	
Cash, cash equivalents and marketable securities	\$248,825	\$ 176,220	
Trade accounts receivable, net	127,023	113,731	
Inventories	57,747	40,885	
Deferred tax assets	16,816	16,726	
Other current assets	41,374	25,894	
Property, plant and equipment, net	161,871	164,691	
Deferred tax assets, noncurrent	181,095	194,308	
Other noncurrent assets	54,843	53,946	
Total assets	\$889,594	\$ 786,401	
Accounts payable and accrued expenses	\$ 84,730	\$ 83,187	
Other current liabilities	4,499	2,075	
Long term debt	3,718	9,918	
Other noncurrent liabilities	4,433	2,865	
Total liabilities	97,380	98,045	
Total stockholders' equity	792,214	688,356	
Total liabilities and stockholders' equity	\$889,594	\$ 786,401	