## **UNITED STATES**

## SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

**CURRENT REPORT** 

PURSUANT TO SECTION 13 OR 15(D) OF THE

THE SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): July 25, 2012

## ALEXION PHARMACEUTICALS, INC.

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(Exact name of registrant as specified in its charter)

Delaware 000-27756 13-3648318
-----(State or other jurisdiction of (Commission (I.R.S. Employer of incorporation or organization) File Number) 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

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):

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o 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 25, 2012, Alexion Pharmaceuticals, Inc. issued a press release relating to its results of operations and financial condition for the quarter ended June 30, 2012. 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, or GAAP, and non-GAAP financial measures. The non-GAAP financial measures exclude share-based compensation expenses, taxes not payable in cash attributable to the utilization of US net operating losses, costs associated with acquisitions, and taxes related to acquisition structuring. 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. Alexion'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 25, 2012 relating to its results of operations and financial condition for the quarter ended June 30, 2012.

## 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.

Date: July 25, 2012

ALEXION PHARMACEUTICALS, INC.

By: <u>/s/ Michael V. Greco</u> Name: Michael V. Greco

Title: Associate General Counsel and

Corporate Secretary



#### **Contacts:**

Alexion Pharmaceuticals, Inc. Irving Adler Executive Director, Corporate Communications (203) 271-8210 Alexion Pharmaceuticals, Inc. Kim Diamond (Media) Director, Corporate Communications ((203) 439-9600

Rx Communications (Investors) Rhonda Chiger (917) 322-2569

## **ALEXION REPORTS SECOND QUARTER 2012 RESULTS**

- Soliris<sup>®</sup> (eculizumab) Net Product Sales Increased 48% to \$274.7 Million -

- Continued Steady Growth in PNH -
- aHUS Launch Advances with Addition of New Patients -
- Guidance Revised Upward for Revenues and Non-GAAP EPS -
- Pipeline Advances with 5 Innovative Compounds in 8 Severe and Ultra-Rare Disorders -

#### Second Quarter 2012 Financial Highlights:

- Q2 2012 revenues increased 48 percent to \$274.7 million, compared to \$185.7 million in Q2 2011
- Q2 2012 GAAP net income increased 4.4 percent to \$36.3 million, or \$0.18 per share, compared to GAAP net income of \$34.7 million, or \$0.18 per share, in Q2 2011; Q2 2012 GAAP net income included \$21.8 million of tax expense related to structuring of the Enobia acquisition
- Q2 2012 non-GAAP net income increased 66 percent to \$94.1 million, or \$0.47 per share, compared to non-GAAP net income of \$56.8 million, or \$0.29 per share, in Q2 2011

CHESHIRE, Conn., July 25, 2012 -- Alexion Pharmaceuticals, Inc. (NASDAQ: ALXN) (Alexion or the Company) today announced financial results for the three and six months ended June 30, 2012. Alexion reported net product sales of Soliris® (eculizumab) of \$274.7 million in the second quarter of 2012, compared to \$185.7 million for the same period in 2011.

Revenue performance for the quarter reflected steady additions of new patients with paroxysmal nocturnal hemoglobinuria (PNH) commencing Soliris therapy in Alexion's core territories of the US, Western Europe and Japan, as well as in new countries. Revenues were further augmented by an increasing number of new patients with atypical hemolytic uremic syndrome (aHUS) commencing Soliris treatment, as well as by \$3.3 million from shipments of Soliris that occurred in 2011.

Soliris is approved for patients with PNH in the US (2007), European Union (2007), Japan (2010) and other territories as the first and only treatment indicated for this ultra-rare, debilitating and life-threatening blood disease. Soliris is also approved as the first and only treatment for patients with aHUS, an ultra-rare, life-threatening, genetic disease, in the US (September 2011) and in the European Union (November 2011).

Alexion's non-GAAP operating results are equal to GAAP operating results adjusted for the impact of share-based compensation, costs associated with acquisitions, taxes that are not payable in cash (non-cash taxes) attributable to the utilization of US net operating losses, and taxes related to acquisition structuring. The following summary table is provided for investors' convenience:

## (in thousands, except per share amounts) (unaudited)

	Three months ended June 30			Six months ended June 30			
	2012		2011	 2012		2011	
Total revenues	\$ 274,719	\$	185,699	\$ 519,452	\$	351,825	
GAAP net income	\$ 36,258	\$	34,745	\$ 81,671	\$	61,575	
Share-based compensation	12,989		11,834	26,306		23,165	
Acquisition-related costs	4,911		1,104	18,688		11,102	
Non-cash taxes	18,103		9,095	33,657		17,205	
Tax related to acquisition structuring	21,812		_	21,812		_	
Non-GAAP net income	\$ 94,073	\$	56,778	\$ 182,134	\$	113,047	
Shares used in computing diluted earnings per share (GAAP)	197,051		191,187	195,832		190,790	
Shares used in computing diluted earnings per share (non-GAAP)	198,431		193,048	197,180		192,605	
GAAP earnings per share - diluted	\$ 0.18	\$	0.18	\$ 0.42	\$	0.32	
Non-GAAP earnings per share - diluted	\$ 0.47	\$	0.29	\$ 0.92	\$	0.59	

#### Second Quarter 2012 Non-GAAP Financial Results:

The Company reported non-GAAP net income of \$94.1 million, or \$0.47 per share, in the second quarter of 2012, compared to non-GAAP net income of \$56.8 million, or \$0.29 per share, in the second quarter of 2011.

Alexion's non-GAAP operating expenses for Q2 2012 were \$142.2 million, compared to \$102.6 million for Q2 2011. Non-GAAP research and development (R&D) expenses for Q2 2012 were \$56.3 million, compared to \$33.4 million for Q2 2011. Non-GAAP selling, general and administrative (SG&A) expenses for Q2 2012 were \$85.9 million, compared to \$69.2 million for Q2 2011.

#### **Second Quarter 2012 GAAP Financial Results:**

Alexion reported GAAP net income of \$36.3 million, or \$0.18 per share, in the second quarter of 2012, compared to GAAP net income of \$34.7 million, or \$0.18 per share, in the second quarter of 2011. Q2 2012 GAAP net income included \$21.8 million of tax expense related to the structuring of the Enobia acquisition.

On a GAAP basis, operating expenses for Q2 2012 were \$159.4 million, compared to \$114.9 million for Q2 2011. GAAP R&D expenses for Q2 2012 were \$59.6 million, compared to \$35.6 million for Q2 2011. GAAP SG&A expenses were \$94.9 million for Q2 2012, compared to \$78.2 million for Q2 2011.

## **Balance Sheet:**

As of June 30, 2012, the Company had \$806 million in cash and cash equivalents, compared to \$359 million at March 31, 2012. The Company raised net proceeds of \$462 million from the sale of 5,000,000 shares, announced on May 23, 2012, in connection with its inclusion in the S&P 500 Index. The Company also reduced total debt from \$355 million at March 31, 2012 to \$228 million at June 30, 2012.

"In the second quarter, we continued to provide Soliris to a substantial number of new patients with PNH, both in our core territories and in new countries, while also serving an increasing number of new patients with aHUS," said Leonard Bell, M.D., Chief Executive Officer of Alexion. "We also advanced our eight lead development programs which include five highly innovative biologics. In the second half of 2012, the global Alexion team will drive forward to serve more patients with PNH and aHUS around the world, and to bring life-transforming innovation to patients with additional severe and life-threatening ultra-rare disorders."

### **Research and Development Programs:**

Alexion currently has lead development programs underway with five highly innovative therapeutics, including eculizumab (Soliris), which are being investigated across eight severe and ultra-rare disorders beyond PNH and aHUS.

## <u>Ultra-Rare Disease Programs With Eculizumab</u>

• Nephrology: STEC-HUS and Acute Humoral Kidney Rejection (AHR): The European Commission has granted orphan designation for eculizumab as a treatment for patients with STEC-HUS, a severe, ultra-rare, and life-threatening inflammatory disorder. Separately, enrollment continues in a Company-sponsored, multi-national, living-donor kidney transplant trial in patients at elevated risk of acute humoral rejection, also known as antibody mediated rejection, and the Company has initiated a deceased-donor kidney

transplant study with enrollment expected to begin later this year.

• **Neurology: NMO and MG:** Data from the investigator-initiated Phase 2 clinical trial of eculizumab in severe and refractory neuromyelitis optica (NMO) are expected to be presented at a scientific meeting in the second half of 2012. Alexion is also currently working with investigators to design the next clinical trial to evaluate eculizumab as a treatment for patients with severe and refractory myasthenia gravis (MG).

## Ultra-Rare Disease Programs With Highly Innovative Therapeutic Candidates Beyond Eculizumab

- **Asfotase Alfa:** During Q2, Alexion initiated its planned natural history study in infants with hypophosphatasia (HPP), an ultra-rare, inherited, and life-threatening metabolic disease.
- **cPMP Replacement Therapy:** The Company is conducting pre-IND toxicology studies with its cPMP replacement therapy for the treatment of patients with the severe, ultra-rare, and genetic, fatal metabolic disorder Molybdenum Cofactor Deficiency Type A.
- ALXN1102 (previously TT30): Enrollment continues in a Phase I study to characterize the mechanism of action and develop initial safety data for ALXN1102, a novel complement inhibitor.
- **ALXN1007:** Enrollment continues in a Phase I study of ALXN1007, a novel anti-inflammatory antibody, to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of this compound in healthy volunteers.

#### 2012 Financial Guidance:

Alexion today announced that it is raising its 2012 revenue guidance from the previous range of \$1.065 to \$1.085 billion now to the higher range of \$1.110 to \$1.125 billion. The upward revision reflects continued global growth of Soliris in PNH and growth from the ongoing launch of Soliris in aHUS. 2012 guidance for non-GAAP SG&A is being increased from the previous range of \$345 to \$355 million, now to \$360 to \$370 million, reflecting continued investment in the growth of the Company's global operations. Non-GAAP R&D guidance remains unchanged. Guidance for 2012 non-GAAP earnings per share is being raised, from the previous range of \$1.65 to \$1.75 per share, now to the higher range of \$1.78 to \$1.88 per share for the year. Shares outstanding are expected to be approximately 203 million in the third quarter and approximately 204 million in the fourth quarter. All other items of the 2012 financial guidance provided in the Company's press release of April 24, 2012 are being reiterated at this time.

## **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 25, 2012, at 10:00 a.m., Eastern Time. To participate in this call, dial 866-804-6925 (USA) or 857-350-1671 (International), confirmation code 13237521 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 12:00 p.m. Eastern Time. The replay number is 888-286-8010 (USA) or 617-801-6888 (International), confirmation code 42568134. The audio webcast can be accessed at www.alexionpharma.com.

### **About Soliris:**

Soliris is a first-in-class terminal complement inhibitor developed from the laboratory through regulatory approval and commercialization by Alexion. Soliris is approved in the US, European Union, Japan and other countries as the first and only treatment for patients with paroxysmal nocturnal hemoglobinuria (PNH), a debilitating, ultra-rare and life-threatening blood disorder, characterized by complement-mediated hemolysis (destruction of red blood cells). Soliris is indicated to reduce hemolysis. Soliris is also approved in the US and the European Union as the first and only treatment for patients with atypical hemolytic uremic syndrome (aHUS), a debilitating, ultra-rare and life-threatening genetic disorder characterized by complement-mediated thrombotic microangiopathy, or TMA (blood clots in small vessels). Soliris is indicated to inhibit complement-mediated TMA. The effectiveness of Soliris in aHUS is based on the effects on TMA and renal function. Prospective clinical trials in additional patients are ongoing to confirm the benefit of Soliris in patients with aHUS. Soliris is not indicated for the treatment of patients with Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HUS). For the breakthrough innovation in complement inhibition, Alexion and Soliris have received 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 including the full prescribing information on Soliris is available at www.soliris.net.

#### **About Alexion:**

Alexion Pharmaceuticals, Inc. is a biopharmaceutical company focused on serving patients with severe and ultra-rare disorders through the innovation, development and commercialization of life-transforming therapeutic products. Alexion is the global leader in complement inhibition and has developed and markets Soliris® (eculizumab) as a treatment for patients with PNH and aHUS, two debilitating, ultra-rare and life-threatening disorders caused by chronic uncontrolled complement activation. Soliris is currently approved in more than 40 countries for the treatment of PNH, and in the United States and the European Union for the treatment of aHUS. Alexion is evaluating other potential indications for Soliris and is developing four other highly innovative biotechnology product candidates, which are being investigated across eight severe and ultra-rare disorders beyond PNH and aHUS. This press release and further information about Alexion Pharmaceuticals, Inc. can be found at: www.alexionpharma.com.

#### [ALXN-E]

This news release contains forward-looking statements, including statements related to guidance regarding anticipated financial results for 2012, assessment of the Company's financial position and commercialization efforts, medical benefits and commercial potential for Soliris for PNH and aHUS and other potential indications, plans to pursue reimbursement approvals in the European Union and other countries, expansion of clinical and commercial operations to additional countries, medical and commercial potential of Alexion's complement-inhibition technology and other technologies, plans for clinical programs for each of our product candidates 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 for PNH and aHUS and other potential indications, delays in arranging satisfactory manufacturing capabilities and establishing commercial infrastructure, the possibility that results of clinical trials are not predictive of safety and efficacy results of Soliris in broader patient populations in the disease studied or other diseases, the risk that recent acquisitions will not result in short-term or long-term benefits, the possibility that current results of commercialization are not predictive of future rates of adoption of Soliris in PNH, aHUS or other diseases, 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 or continue to reimburse for the use of Soliris at acceptable rates or at all, the risk that estimates regarding the number of patients with PNH, aHUS or other disorders are inaccurate, and a variety of other risks set forth from time to time in Alexion's filings with the US 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, 2012 and in our other filings with the US 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 a duty arises under law.

(Tables Follow)

# ALEXION PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Three months ended June 30			Six months ended June 30				
	 2012		2011		2012		2011	
Net product sales	\$ 274,719	\$	185,699	\$	519,452	\$	351,825	
Cost of sales (1)	31,613		21,745		59,881		40,973	
Operating expenses:								
Research and development (1)	59,635		35,646		105,043		66,456	
Selling, general and administrative (1)	94,855		78,180		182,097		144,037	
Acquisition-related costs (2)	4,911		1,104		18,688		11,102	
Total operating expenses	 159,401	_	114,930		305,828		221,595	
Operating income	83,705		49,024		153,743		89,257	
Interest and other income (expense)	(1,983)		63		(4,212)		656	
Income before income taxes	 81,722		49,087	-	149,531		89,913	
Income tax provision (3)	45,464		14,342		67,860		28,338	
Net income	\$ 36,258	\$	34,745	\$	81,671	\$	61,575	
Earnings per common share								
Basic	\$ 0.19	\$	0.19	\$	0.44	\$	0.34	
Diluted	\$ 0.18	\$	0.18	\$	0.42	\$	0.32	
Shares used in computing earnings per common share								
Basic	188,575	_	182,962	_	187,129	_	182,347	
Diluted	 197,051		191,187		195,832		190,790	

(1) The following table summarizes 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			
	 2012 2011		2012		2011		
Share-based compensation expense:	 						
Cost of sales	\$ 672	\$	572	\$ 1,275	\$	1,117	
Research and development	3,381		2,245	6,730		4,978	
Selling, general and administrative	8,936		9,017	18,301		17,070	
	\$ 12,989	\$	11,834	\$ 26,306	\$	23,165	

Acquisition-related costs of \$4,911 during the quarter ended June 30, 2012 includes transaction and separation costs of \$2,840 for the Enobia (2) acquisition and adjustments to the fair value of contingent consideration of \$1,967 for Enobia and our prior acquisitions. Acquisition-related costs of \$1,104 during the quarter ended June 30, 2011 represents costs incurred related to the Taligen and Orphatec acquisitions.

The income tax provision for the three months ended June 30, 2012 includes \$18.1 million of expense that is not payable in cash due to the utilization (3) of our US net operating losses. The tax provision for this period also includes tax expense of \$21.8 million related to the structuring of the Enobia acquisition.

# ALEXION PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)
 (unaudited)

		June 30,		December 31,		
		2011				
Cash and cash equivalents	\$	806,210	\$	540,865		
Trade accounts receivable, net		282,722		244,288		
Inventories, net		94,108		81,386		
Deferred tax assets, current		19,127		19,132		
Other current assets		73,994		55,599		
Property, plant and equipment, net		164,568		165,852		
Deferred tax assets, noncurrent		66,430		103,868		
Intangibles assets, net		675,796		91,604		
Goodwill		255,405		79,639		
Other noncurrent assets		19,250		12,518		
Total assets	\$	2,457,610	\$	1,394,751		
Accounts payable and accrued expenses	\$	294,325	\$	202,093		
Current portion of long-term debt		48,000		_		
Other current liabilities		32,837		28,132		
Long-term debt		180,000		_		
Contingent consideration		139,995		18,120		
Other noncurrent liabilities		12,759		11,914		
Total liabilities		707,916		260,259		
Total stockholders' equity		1,749,694		1,134,492		
Total liabilities and stockholders' equity	\$	2,457,610	\$	1,394,751		