

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): April 24, 2012

ALEXION PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
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)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- 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 April 24, 2012, Alexion Pharmaceuticals, Inc. issued a press release relating to its results of operations and financial conditions for the quarter ended March 31, 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, amortization of acquired intangible assets, and costs associated with acquisitions. 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 April 24, 2012 relating to its results of operations and financial conditions for the quarter ended March 31, 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: April 24, 2012

ALEXION PHARMACEUTICALS, INC.

By: /s/ Michael V. Greco

Name: Michael V. Greco

Title: Associate General Counsel and
Corporate Secretary

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Alexion Reports First Quarter 2012 Results

- Soliris® (eculizumab) Net Product Sales Increased 47 Percent Over Year-Ago Quarter to \$244.7 Million -
- Continued Steady Growth in PNH -
- aHUS Launch Progresses with Steady Addition of New Treated Patients -
- Guidance Revised Upward for 2012 Revenues and Non-GAAP EPS -

First Quarter 2012 Financial Highlights:

- Q1 2012 net product sales increased 47 percent to \$244.7 million, compared to \$166.1 million in Q1 2011.
- Q1 2012 GAAP net income increased 69 percent to \$45.4 million, or \$0.23 per share, compared to Q1 2011 GAAP net income of \$26.8 million, or \$0.14 per share.
- Q1 2012 non-GAAP net income increased 57 percent to \$88.1 million, or \$0.45 per share, compared to Q1 2011 non-GAAP net income of \$56.3 million, or \$0.29 per share.

CHESHIRE, Conn., April 24, 2012 -- Alexion Pharmaceuticals, Inc. (NASDAQ: ALXN) today announced financial results for the three months ended March 31, 2012. The Company reported net product sales of Soliris® (eculizumab) of \$244.7 million, an increase of 47 percent from the same period in 2011. Revenue performance for the quarter reflects steady additions of new patients with paroxysmal nocturnal hemoglobinuria (PNH) in Alexion's core territories of the US, Western Europe,

Japan and in other countries, augmented by a steady increase in new patients with atypical Hemolytic Uremic Syndrome (aHUS).

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, taxes that are not payable in cash (non-cash tax adjustment), amortization of acquired intangible assets, and costs associated with acquisitions. The non-cash tax adjustment represents the reduction in cash taxes attributable to the utilization of US net operating losses. The following summary table is provided for investors' convenience:

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

	Three months ended March 31	
	2012	2011
Total revenues	\$ 244,733	\$ 166,126
GAAP net income	\$ 45,413	\$ 26,830
Share-based compensation	13,318	11,331
Acquisition-related costs	13,673	9,928
Amortization of purchased intangibles	104	69
Non-cash tax adjustment	15,553	8,110
Non-GAAP net income	<u>\$ 88,061</u>	<u>\$ 56,268</u>
Shares used in computing diluted earnings per share (GAAP)	194,560	190,366
Shares used in computing diluted earnings per share (non-GAAP)	195,895	192,164
GAAP earnings per share - diluted	<u>\$ 0.23</u>	<u>\$ 0.14</u>
Non-GAAP earnings per share - diluted	<u>\$ 0.45</u>	<u>\$ 0.29</u>

First Quarter 2012 Non-GAAP Financial Results:

The Company reported non-GAAP net income of \$88.1 million, or \$0.45 per share, in the first quarter of 2012, compared to non-GAAP net income of \$56.3 million, or \$0.29 per share, in the first quarter of 2011.

Alexion's non-GAAP operating expenses for Q1 2012 were \$119.9 million, compared to \$85.9 million for Q1 2011. Non-GAAP research and development (R&D) expenses for Q1 2012 were \$42.1 million, compared to \$28.1 million for Q1 2011. Non-GAAP selling, general and administrative (SG&A) expenses for Q1 2012 were \$77.9 million, compared to \$57.8 million for Q1 2011.

First Quarter 2012 GAAP Financial Results:

Alexion reported GAAP net income of \$45.4 million, or \$0.23 per share, in the first quarter of 2012, compared to GAAP net income of \$26.8 million, or \$0.14 per share, in the first quarter of 2011.

On a GAAP basis, operating expenses for Q1 2012 were \$146.4 million, compared to \$106.7 million for Q1 2011. GAAP operating expenses included \$12.4 million of costs related to the acquisition of Enobia Pharma Corp. (Enobia), which closed during the quarter. GAAP R&D expenses for Q1 2012 were \$45.4 million, compared to \$30.8 million for Q1 2011. GAAP SG&A expenses were \$87.2 million for Q1 2012, compared to \$65.9 million for Q1 2011.

Balance Sheet:

As of March 31, 2012, the Company had \$359 million in cash, cash equivalents and marketable securities compared to \$541 million at the end of 2011. This change reflects positive cash flow from operations during the quarter and acquisition-related debt, offset by outflows for the purchase of Enobia.

"In the early months of 2012, we achieved steady growth in serving more patients with PNH and were also pleased to see a steady addition of new patients with aHUS starting on Soliris therapy," said Leonard Bell, M.D., Chief Executive Officer of Alexion. "As we look ahead to serving more patients with PNH and aHUS, we will simultaneously drive forward each of our eight lead development programs in which we are now investigating five highly innovative biologics as treatments for patients with severe and ultra-rare disorders."

Global Commercial Operations:

PNH

During Q1 2012, Alexion achieved steady quarter-on-quarter growth due to new patients with PNH who were started on Soliris therapy in the Company's core territories of the US, Western Europe and Japan, as well as new patients from a number of other countries where the Company is growing its presence.

aHUS

In the second full quarter of the US launch of Soliris for aHUS, a steady increase of new patients with aHUS commenced treatment with Soliris. Following approval by the European Commission in November 2011, Alexion expects to begin serving aHUS patients in initial European countries later in 2012.

Research and Development Progress:

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

Ultra-Rare Disease Programs With Eculizumab

- **Nephrology: STEC-HUS and Acute Humoral Kidney Rejection (AHR):**
The Company has completed dosing in its open-label study of eculizumab in patients with Shiga toxin *E. Coli* related Hemolytic Uremic Syndrome (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 antibody mediated rejection.
- **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 in the second half of 2012. Additional data from the Company's Phase 2 study in Myasthenia Gravis (MG) will be presented at the American Academy of Neurology annual meeting, being held April 21 to 28.

Ultra-Rare Disease Programs With Highly Innovative Therapeutics Beyond Eculizumab

- **Asfotase Alfa:** During Q1, Phase 2 data with asfotase alfa, the Company's highly innovative targeted enzyme replacement therapy in late-stage development for patients with the ultra-rare, inherited, and life-threatening metabolic disease hypophosphatasia (HPP), were published in the *New England Journal of Medicine*. The data showed that all patients treated with asfotase alfa had an objective response to therapy, with statistically significant decreases in enzyme substrates. The data also showed substantial skeletal healing in 90 percent of infants and young children treated with asfotase alfa. Key secondary endpoints, including improvement in cognitive development and motor and pulmonary function, were also achieved.

Also in Q1, data in juvenile patients were presented at the Sanford Burnham Rare Disease Day Symposium, showing that all patients treated with asfotase alfa had an objective response to therapy, with statistically significant decreases in enzyme substrates.

In addition, during Q1, a separate Phase 2 study of adult and adolescent patients presented at the American College of Medical Genetics meeting, showed that all patients who were treated with asfotase alfa had an objective response to therapy, with statistically significant decreases in enzyme substrates.

- **cPMP Replacement Therapy:** The Company has commenced 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 (formerly TT30):** Enrollment continues in a Phase I study to characterize the mechanism of action and develop initial safety data for ALXN1102. ALXN1102 is a unique

inhibitor of the alternative complement pathway with a mechanism of action different from Soliris.

- **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 \$1.04 to \$1.07 billion now to the higher and narrower range of \$1.065 to \$1.085 billion. The upward revision reflects continued global growth of Soliris in PNH and initial growth in aHUS.

With this increased revenue forecast, combined with control of expenses within previously guided ranges, the Company is also raising its guidance for 2012 non-GAAP earnings per share, from the previous range of \$1.60 to \$1.70 per share now to the higher range of \$1.65 to \$1.75 per share for the year. All other items of the 2012 financial guidance provided in the Company's press release of February 9, 2012 are being reiterated at this time.

Conference Call/Web Cast Information:

Alexion will host a conference call/audio web cast to discuss matters mentioned in this release. The call is scheduled for today, April 24, at 10:00 a.m., Eastern Time. To participate in this call, dial 800-299-9630 (USA) or 617-786-2904 (International), passcode 87393357, 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), passcode 38815409. 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 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). Alexion's breakthrough approach in complement inhibition has 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. This press release and further information about Alexion Pharmaceuticals, Inc. can be found at: www.alexionpharma.com.

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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, 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, progress in developing commercial infrastructure, and interest and acceptance regarding Soliris in the patient, physician and payor communities. 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 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 Securities and Exchange Commission, including but not limited to the risks discussed in Alexion's Annual Report on Form 10-K for the period ended December 31, 2011 and in our 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 a duty arises under law.

(Tables Follow)

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

	Three months ended	
	March 31	
	<u>2012</u>	<u>2011</u>
Net product sales	\$ 244,733	\$ 166,126
Cost of sales (1)	28,268	19,228
Operating expenses:		
Research and development (1)	45,408	30,810
Selling, general and administrative (1)	87,242	65,858
Acquisition-related costs (2)	13,673	9,928
Amortization of purchased intangibles	104	69
Total operating expenses	<u>146,427</u>	<u>106,665</u>
Operating income	70,038	40,233
Other income (expense)	<u>(2,229)</u>	<u>593</u>
Income before income taxes	67,809	40,826
Income tax provision	22,396	13,996
Net income	<u>\$ 45,413</u>	<u>\$ 26,830</u>
Earnings per common share		
Basic	<u>\$ 0.24</u>	<u>\$ 0.15</u>
Diluted	<u>\$ 0.23</u>	<u>\$ 0.14</u>
Shares used in computing earnings per common share		
Basic	<u>185,682</u>	<u>181,724</u>
Diluted	<u>194,560</u>	<u>190,366</u>

(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	
	March 31	
	2012	2011
Share-based compensation expense:		
Cost of sales	\$ 603	\$ 545
Research and development	3,349	2,733
Selling, general and administrative	9,366	8,053
	<u>\$ 13,318</u>	<u>\$ 11,331</u>

(2) Acquisition-related costs of \$13,673 during the quarter ended March 31, 2012 include transaction and separation costs of \$10,765 and adjustments to the fair value of contingent consideration of \$1,636 for the Enobia acquisition closed during the quarter. The remaining \$1,272 represents adjustments to the fair value of contingent consideration for previous acquisitions. Acquisition-related costs of \$9,928 during the quarter ended March 31, 2011 represents costs incurred related to the Taligen Therapeutics and Orphatec Pharmaceuticals acquisitions.

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

	March 31,	December 31,
	2012	2011
Cash, cash equivalents and marketable securities	\$ 359,388	\$ 540,865
Trade accounts receivable, net	267,397	244,288
Inventories, net	92,906	81,386
Deferred tax assets, current	19,048	19,132
Other current assets	73,195	55,599
Property, plant and equipment, net	165,763	165,852
Deferred tax assets, noncurrent	80,553	103,868
Intangibles assets, net	677,200	91,604
Goodwill	264,118	79,639
Other noncurrent assets	17,896	12,518
Total assets	<u>\$ 2,017,464</u>	<u>\$ 1,394,751</u>
Accounts payable and accrued expenses	\$ 222,886	\$ 202,093
Other current liabilities	130,791	28,132
Long term debt	247,000	—
Contingent consideration	138,028	18,120
Other noncurrent liabilities	65,479	11,914
Total liabilities	<u>804,184</u>	<u>260,259</u>
Total stockholders' equity	1,213,280	1,134,492
Total liabilities and stockholders' equity	<u>\$ 2,017,464</u>	<u>\$ 1,394,751</u>