

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 24, 2014

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 July 24, 2014, Alexion Pharmaceuticals, Inc. issued a press release relating to its results of operations and financial conditions for the quarter ended June 30, 2014. 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 the impact of share-based compensation expense, acquisition-related costs, amortization of purchased intangible assets, upfront and milestone payments related to license and collaboration agreements, intangible asset impairments and non-cash taxes. 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 Alexion. 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 24, 2014 relating to its results of operations and financial conditions for the quarter ended June 30, 2014.

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 24, 2014

ALEXION PHARMACEUTICALS, INC.

By: /s/ Michael V. Greco

Name: Michael V. Greco

Title: Vice President of Law and Corporate Secretary



Alexion Reports Second Quarter 2014 Results

- Soliris® (eculizumab) Net Product Sales Increased 38 Percent to \$512.5 Million
- EU Marketing Authorization Application for Asfotase Alfa Accepted by EMA; Accelerated Assessment Granted -
 - Eculizumab MG Registration Trial Underway -
- Dosing Completed in Living-Donor and Deceased-Donor Eculizumab AMR Trials -
 - 2014 Guidance Increased for Revenue and Non-GAAP EPS -

Second Quarter 2014 Financial Highlights:

- Q2 2014 net product sales increased 38 percent to \$512.5 million, compared to \$370.1 million in Q2 2013.
- Q2 2014 GAAP net income increased 74 percent to \$166.5 million, or \$0.83 per share, compared to Q2 2013 GAAP net income of \$95.9 million, or \$0.48 per share.
- Q2 2014 non-GAAP net income increased 56 percent to \$229.1 million, or \$1.12 per share, compared to Q2 2013 non-GAAP net income of \$147.2 million, or \$0.73 per share.

CHESHIRE, Conn., July 24, 2014-- Alexion Pharmaceuticals, Inc. (NASDAQ: ALXN) today announced financial results for the three and six months ended June 30, 2014. The Company reported net product sales of Soliris® (eculizumab) of \$512.5 million in the second quarter of 2014, an increase of 38 percent from the same period in 2013. This increase in revenue reflected an unfavorable foreign exchange impact of one percent. Revenue performance for the quarter reflected steady additions of new patients with paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS) commencing Soliris treatment.

Alexion is serving patients with PNH and aHUS in nearly 50 countries. Both PNH and aHUS are severe and life-threatening ultra-rare disorders caused by chronic uncontrolled complement activation.

“In the second quarter of 2014, we served an increasing number of new patients with PNH and aHUS worldwide while simultaneously reaching several significant milestones across our pipeline, including the filing of our MAA for asfotase alfa for HPP in Europe, which has been accepted and granted accelerated assessment,” said Leonard Bell, M.D., Chief Executive Officer of Alexion. “During the quarter we also continued to execute on key initiatives to further improve operational and financial efficiencies across our global operations. Throughout 2014, we will remain focused on serving more patients with PNH and aHUS globally while also

advancing our lead development programs as we drive toward as many as seven additional launches through 2018.”

Second Quarter 2014 Financial Results:

Alexion's non-GAAP operating results are GAAP operating results adjusted for the impact of certain items described below. A full reconciliation of GAAP results to non-GAAP results is included later in this press release.

Second Quarter 2014 Non-GAAP Financial Results:

The Company reported non-GAAP net income of \$229.1 million, or \$1.12 per share, in the second quarter of 2014, compared to non-GAAP net income of \$147.2 million, or \$0.73 per share, in the second quarter of 2013.

Alexion's non-GAAP operating expenses for Q2 2014 were \$224.6 million, compared to \$174.5 million for Q2 2013. Non-GAAP research and development (R&D) expenses for Q2 2014 were \$85.1 million, compared to \$63.5 million for Q2 2013. Non-GAAP selling, general and administrative (SG&A) expenses for Q2 2014 were \$139.5 million, compared to \$111.0 million for Q2 2013.

Second Quarter 2014 GAAP Financial Results:

Alexion reported GAAP net income of \$166.5 million, or \$0.83 per share, in the second quarter of 2014, compared to GAAP net income of \$95.9 million, or \$0.48 per share, in the second quarter of 2013.

On a GAAP basis, operating expenses for Q2 2014 were \$254.0 million, compared to \$193.0 million for Q2 2013. GAAP R&D expenses for Q2 2014 were \$92.6 million, compared to \$68.6 million for Q2 2013. GAAP SG&A expenses were \$159.5 million for Q2 2014, compared to \$123.2 million for Q2 2013.

Balance Sheet:

As of June 30, 2014, the Company had \$1.59 billion in cash, cash equivalents and marketable securities compared to \$1.55 billion at March 31, 2014. During the quarter, the Company repurchased \$156.4 million of stock under its share repurchase program.

Research and Development Progress:

Alexion has development programs underway with highly innovative therapeutic candidates that have the potential to become first-in-class therapies for patients with severe and ultra-rare disorders.

Asfotase Alfa

- Alexion filed a marketing authorization application (MAA) for asfotase alfa, a targeted enzyme replacement therapy for the treatment of patients with hypophosphatasia (HPP), with the European Medicines Agency (EMA) which has been validated and granted accelerated assessment.

- The Company continues to add to the rolling Biologics License Application (BLA) submission with the U.S. Food and Drug Administration (FDA). Alexion received Breakthrough Therapy designation from the FDA for asfotase alfa in 2013.
- Additionally, a natural history study in juveniles with HPP is ongoing.

Ultra-Rare Disease Programs With Eculizumab

- **Transplant: Antibody-Mediated Rejection (AMR)** - Dosing has now been completed in the Company-sponsored, multinational living-donor kidney transplant trial in patients at elevated risk of AMR. Additionally, both enrollment and dosing have been completed in the expanded Company-sponsored, multinational deceased-donor kidney transplant trial in patients at elevated risk of AMR.
- **Transplant: Delayed Graft Function (DGF)** - Alexion is preparing to commence a single, multinational registration trial for the prevention of DGF in renal transplant patients.
- **Neurology: Neuromyelitis Optica (NMO)** - Enrollment and dosing are ongoing in a Company-sponsored single, multinational, placebo-controlled, registration trial in relapsing NMO.
- **Neurology: Myasthenia Gravis (MG)** - Enrollment and dosing are on-going in a single, multinational, placebo-controlled, registration trial in refractory MG.

Ultra-Rare Disease Programs with Additional Highly Innovative Therapeutics

- **cPMP Replacement Therapy (ALXN 1101)** - A natural history study in patients with molybdenum cofactor deficiency (MoCD) and a synthetic cPMP bridging study are both on-going. Alexion received Breakthrough Therapy designation for its cPMP replacement therapy in 2013, which is being developed for patients with MoCD Type A.
- **ALXN1007** - Alexion has commenced screening in a Phase 2 proof-of-concept study of ALXN1007, a novel anti-inflammatory antibody, in patients with antiphospholipid syndrome (APS).

2014 Financial Guidance

Alexion today announced that the Company is revising upward its revenue guidance for 2014 from the previous range of \$2.15 to \$2.17 billion, now to the higher range of \$2.18 to \$2.20 billion. Non-GAAP earnings per share is also being revised upward, from the previous range of \$4.75 to \$4.85, now to the higher range of \$4.95 to \$5.05 per share.

Alexion is reiterating the other elements of its 2014 financial guidance as provided in the press release issued on April 24, 2014.

Conference Call/Webcast Information:

Alexion will host a conference call/audio webcast to discuss matters mentioned in this release. The call is scheduled for today, July 24, at 10:00 a.m., Eastern Time. To participate in this call, dial 800-967-7137 (USA) or +1-719-325-2492 (International), passcode 6169176, 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 888-203-1112 (USA) or

+1-719-457-0820 (International), passcode 6169176. The audio webcast can be accessed on the Investor page of 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 U.S. (2007), European Union (2007), Japan (2010) 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 U.S. (2011), the European Union (2011), Japan (2013) and other countries 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 its effects on TMA and renal function. Soliris is not indicated for the treatment of patients with Shiga-toxin E. coli-related hemolytic uremic syndrome (STEC-HUS). For the breakthrough medical 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 U.S. prescribing information on Soliris, is available at www.soliris.net.

About Alexion

Alexion is a biopharmaceutical company focused on serving patients with severe and 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 nearly 50 countries for the treatment of PNH, and in nearly 40 countries for the treatment of aHUS. Alexion is evaluating other potential indications for Soliris in additional severe and ultra-rare disorders beyond PNH and aHUS, and is developing other highly innovative biotechnology product candidates across multiple therapeutic areas. This press release and further information about Alexion 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 2014, 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, medical and commercial potential of Alexion's complement-inhibition technology and other technologies, and plans for clinical programs for each of our product candidates. 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, interruptions or failures in the manufacture and supply of Soliris and our product candidates, progress in establishing and developing commercial infrastructure, failure to satisfactorily address the

issues raised by the FDA in the Warning Letter received by Alexion in March 2013, 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 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 possibility that clinical trials of our product candidates could be delayed or that additional research and testing is required by regulatory agencies, the adequacy of our pharmacovigilance and drug safety reporting processes, 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 diseases are inaccurate, and a variety of other risks set forth from time to time in Alexion's filings with the U.S. 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, 2014 and in our other filings with the U.S. 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.

In addition to financial information prepared in accordance with GAAP, this news release also contains non-GAAP financial measures that Alexion believes, when considered together with the GAAP information, provide investors and management with supplemental information relating to performance, trends and prospects that promote a more complete understanding of our operating results and financial position during different periods. The non-GAAP results exclude the impact of the following GAAP items: share-based compensation expense, acquisition-related costs, amortization of purchased intangible assets, upfront and milestone payments related to license and collaboration agreements, intangible asset impairments, and non-cash taxes. These non-GAAP financial measures are not intended to be considered in isolation or as a substitute for, or superior to, the financial measures prepared and presented in accordance with GAAP and should be reviewed in conjunction with the relevant GAAP financial measures. Please refer to the attached Reconciliation of GAAP to Non-GAAP Financial Results for explanations of the amounts adjusted to arrive at non-GAAP net income and non-GAAP earnings per share amounts for the three and six month periods ended June 30, 2014 and 2013.

Alexion Contacts:

Media:

Irving Adler, 203-271-8210
Executive Director, Corporate Communications

OR

Kim Diamond, 203-439-9600
Senior Director, Corporate Communications

Investors:

Elena Ridloff, 203-699-7722
Executive Director, Investor Relations

- TABLES FOLLOW -

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

	Three months ended		Six months ended	
	June 30		June 30	
	2014	2013	2014	2013
Net product sales	\$ 512,495	\$ 370,091	\$ 1,079,111	\$ 709,032
Cost of sales	39,626	39,377	72,565	74,646
Operating expenses:				
Research and development	92,554	68,563	284,011	143,099
Selling, general and administrative	159,477	123,189	288,768	232,015
Impairment of intangible asset	—	—	3,464	—
Acquisition-related costs	1,989	1,167	1,951	4,401
Amortization of purchased intangible assets	—	104	—	208
Total operating expenses	<u>254,020</u>	<u>193,023</u>	<u>578,194</u>	<u>379,723</u>
Operating income	218,849	137,691	428,352	254,663
Other income (expense)	<u>(203)</u>	<u>(428)</u>	<u>2,205</u>	<u>(659)</u>
Income before income taxes	218,646	137,263	430,557	254,004
Income tax provision	52,151	41,378	104,708	75,902
Net income	<u>\$ 166,495</u>	<u>\$ 95,885</u>	<u>\$ 325,849</u>	<u>\$ 178,102</u>
Earnings per common share				
Basic	<u>\$ 0.84</u>	<u>\$ 0.49</u>	<u>\$ 1.65</u>	<u>\$ 0.92</u>
Diluted	<u>\$ 0.83</u>	<u>\$ 0.48</u>	<u>\$ 1.62</u>	<u>\$ 0.90</u>
Shares used in computing earnings per common share				
Basic	<u>197,880</u>	<u>195,247</u>	<u>197,838</u>	<u>193,944</u>
Diluted	<u>201,524</u>	<u>199,299</u>	<u>201,715</u>	<u>198,096</u>

ALEXION PHARMACEUTICALS, INC.
RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL RESULTS
(in thousands, except per share amounts)
(unaudited)

	Three months ended		Six months ended	
	June 30		June 30	
	2014	2013	2014	2013
Net income reconciliation:				
GAAP net income	\$ 166,495	\$ 95,885	\$ 325,849	\$ 178,102
Share-based compensation expense	28,414	17,957	52,254	34,812
Acquisition-related costs (1)	1,989	1,167	1,951	4,401
Amortization of purchased intangible assets	—	104	—	208
Upfront and milestone payments related to license and collaboration agreements	—	—	101,925	3,000
Impairment of intangible asset	—	—	3,464	—
Non-cash taxes (2)	32,174	32,117	56,228	58,021
Non-GAAP net income	<u>\$ 229,072</u>	<u>\$ 147,230</u>	<u>\$ 541,671</u>	<u>\$ 278,544</u>
GAAP earnings per share - diluted	<u>\$ 0.83</u>	<u>\$ 0.48</u>	<u>\$ 1.62</u>	<u>\$ 0.90</u>
Non-GAAP earnings per share - diluted	<u>\$ 1.12</u>	<u>\$ 0.73</u>	<u>\$ 2.65</u>	<u>\$ 1.38</u>
Shares used in computing diluted earnings per share (GAAP)	<u>201,524</u>	<u>199,299</u>	<u>201,715</u>	<u>198,096</u>
Shares used in computing diluted earnings per share (non-GAAP)	<u>204,435</u>	<u>202,593</u>	<u>204,631</u>	<u>201,340</u>

	Three months ended		Six months ended	
	June 30		June 30	
	2014	2013	2014	2013
Cost of sales reconciliation:				
GAAP cost of sales	\$ 39,626	\$ 39,377	\$ 72,565	\$ 74,646
Share-based compensation expense	(964)	(717)	(1,847)	(1,592)
Non-GAAP cost of sales	<u>\$ 38,662</u>	<u>\$ 38,660</u>	<u>\$ 70,718</u>	<u>\$ 73,054</u>
Research and development reconciliation:				
GAAP research and development	\$ 92,554	\$ 68,563	\$ 284,011	\$ 143,099
Share-based compensation expense	(7,453)	(5,068)	(15,437)	(10,158)
Upfront and milestone payments related to license and collaboration agreements	—	—	(101,925)	(3,000)
Non-GAAP research and development	<u>\$ 85,101</u>	<u>\$ 63,495</u>	<u>\$ 166,649</u>	<u>\$ 129,941</u>
Selling, general and administrative reconciliation:				
GAAP selling, general and administrative	\$ 159,477	\$ 123,189	\$ 288,768	\$ 232,015
Share-based compensation expense	(19,997)	(12,172)	(34,970)	(23,062)
Non-GAAP selling, general and administrative	<u>\$ 139,480</u>	<u>\$ 111,017</u>	<u>\$ 253,798</u>	<u>\$ 208,953</u>
Income tax provision reconciliation:				
GAAP income tax provision	\$ 52,151	\$ 41,378	\$ 104,708	\$ 75,902
Non-cash taxes (2)	(32,174)	(32,117)	(56,228)	(58,021)
Non-GAAP income tax provision	<u>\$ 19,977</u>	<u>\$ 9,261</u>	<u>\$ 48,480</u>	<u>\$ 17,881</u>

(1) The following table summarizes acquisition-related costs:

	Three months ended		Six months ended	
	June 30,		June 30	
	2014	2013	2014	2013
Separately-identifiable employee costs	\$ —	\$ —	\$ —	\$ 248
Professional fees	—	—	—	775
Changes in fair value of contingent consideration	1,989	1,167	1,951	3,378
	<u>\$ 1,989</u>	<u>\$ 1,167</u>	<u>\$ 1,951</u>	<u>\$ 4,401</u>

(2) Non-cash taxes represents the adjustment from GAAP tax expense to the amount of taxes that are payable in cash in the current period.

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

	June 30,	December 31,
	2014	2013
Cash and cash equivalents	\$ 612,045	\$ 529,857
Marketable securities	982,317	984,994
Trade accounts receivable, net	440,699	421,752
Inventories	144,859	102,602
Deferred tax assets, current	50,281	41,432
Other current assets	111,105	106,220
Property, plant and equipment, net	273,326	201,109
Intangible assets, net	599,786	609,719
Goodwill	254,073	254,073
Deferred tax assets, noncurrent	7,417	3,394
Other noncurrent assets	77,902	62,544
Total assets	<u>\$ 3,553,810</u>	<u>\$ 3,317,696</u>
Accounts payable and accrued expenses	240,809	423,940
Current portion of long-term debt	48,000	48,000
Other current liabilities	128,892	110,489
Long-term debt, less current portion	33,500	65,000
Contingent consideration, noncurrent	108,232	106,744
Deferred tax liabilities, noncurrent	96	101,241
Other noncurrent liabilities	112,699	80,203
Total liabilities	<u>672,228</u>	<u>935,617</u>
Total stockholders' equity	2,881,582	2,382,079
Total liabilities and stockholders' equity	<u>\$ 3,553,810</u>	<u>\$ 3,317,696</u>