

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): October 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 October 24, 2012, Alexion Pharmaceuticals, Inc. issued a press release relating to its results of operations and financial conditions for the quarter ended September 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, costs associated with acquisitions, taxes that are not payable in cash, taxes related to acquisition structuring, impact of intellectual property settlements and intangible asset impairments. 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 October 24, 2012 relating to its results of operations and financial conditions for the quarter ended September 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: October 24, 2012

ALEXION PHARMACEUTICALS, INC.

By: /s/ Michael V. Greco

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 THIRD QUARTER 2012 RESULTS

- *Soliris[®] (eculizumab) Net Product Sales Increased 44% to \$294.1 Million -*
- *Continued Steady Growth of Soliris in PNH -*
- *aHUS Launch Progresses With New Patients Starting on Soliris -*
- *Guidance Revised Upward for Revenues and Non-GAAP EPS -*
- *Encouraging Eculizumab Phase 2 Data in NMO Presented at the ANA Meeting -*

Third Quarter 2012 Financial Highlights:

- Q3 2012 revenues increased 44 percent to \$294.1 million, compared to \$204.0 million in Q3 2011
- Q3 2012 GAAP net income increased 41 percent to \$92.2 million, or \$0.46 per share, compared to GAAP net income of \$65.6 million, or \$0.34 per share, in Q3 2011
- Q3 2012 non-GAAP net income increased 66 percent to \$120.7 million, or \$0.60 per share, compared to non-GAAP net income of \$72.6 million, or \$0.37 per share, in Q3 2011

CHESHIRE, Conn., October 24, 2012 -- Alexion Pharmaceuticals, Inc. (NASDAQ: ALXN) (Alexion or the Company) today announced financial results for the three and nine months ended September 30, 2012. Alexion reported net product sales of Soliris[®] (eculizumab) of \$294.1 million in the third quarter of 2012, compared to \$204.0 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.

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

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, taxes related to acquisition structuring, impact of intellectual property settlements and intangible asset impairments. A full reconciliation of non-GAAP results is included later in this press release.

Third Quarter 2012 Non-GAAP Financial Results:

The Company reported non-GAAP net income of \$120.7 million, or \$0.60 per share, in the third quarter of 2012, compared to non-GAAP net income of \$72.6 million, or \$0.37 per share, in the third quarter of 2011.

As noted above, non-GAAP EPS in Q3 2012 excludes the \$0.13 per share net benefit attributable to the intellectual property settlement and intangible asset impairment that occurred in Q3 2012. Non-GAAP EPS in Q3 2011 excludes the \$0.09 per share benefit attributable to tax credits.

Alexion's non-GAAP operating expenses for Q3 2012 were \$130.9 million, compared to \$103.5 million for Q3 2011. Non-GAAP research and development (R&D) expenses for Q3 2012 were \$50.6 million, compared to \$34.1 million for Q3 2011. Non-GAAP selling, general and administrative (SG&A) expenses for Q3 2012 were \$80.3 million, compared to \$69.5 million for Q3 2011.

Third Quarter 2012 GAAP Financial Results:

Alexion reported GAAP net income of \$92.2 million, or \$0.46 per share, in the third quarter of 2012, compared to GAAP net income of \$65.6 million, or \$0.34 per share, in the third quarter of 2011.

On a GAAP basis, operating expenses for Q3 2012 were \$171.6 million, compared to \$114.5 million for Q3 2011. GAAP R&D expenses for Q3 2012 were \$54.3 million, compared to \$36.6 million for Q3 2011. GAAP SG&A expenses were \$90.0 million for Q3 2012, compared to \$77.6 million for Q3 2011. Q3 2012 GAAP results were negatively impacted by a \$26.3 million impairment of an intangible asset related to a previously acquired pre-clinical age-related macular degeneration (AMD) program. Q3 2012 GAAP results were positively impacted by the terms of a patent settlement and license agreement, for which the Company recognized a gain of \$53.4 million in cost of sales, net of the effect of an upfront payment. During Q3 2011, the Company recorded a GAAP tax benefit from the impact of tax credits of \$16.3 million.

Balance Sheet:

As of September 30, 2012, the Company had \$905.5 million in cash and cash equivalents, compared to \$806.2 million at June 30, 2012. The Company also reduced total debt to \$161.0 million at September 30, 2012 from \$228.0 million at June 30, 2012.

"In the third quarter, a substantial number of new patients with PNH started on Soliris in our core territories and new countries, while Soliris therapy also commenced for a growing number of

new patients with aHUS,” said Leonard Bell, M.D., Chief Executive Officer of Alexion. “In the final quarter of 2012, we will drive to serve an increasing number of patients with PNH and aHUS while accelerating our eight lead development programs with five highly innovative therapeutic candidates. Our steadfast focus across our global organization will continue to bring life-transforming innovation to more patients with severe and 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.

Ultra-Rare Disease Programs With Eculizumab

- **Nephrology: STEC-HUS and Kidney Transplant:** Data from the full cohort of 198 enrolled patients in the Company-sponsored Shiga-toxin-producing *E. coli* hemolytic uremic syndrome (STEC-HUS) trial will be presented at the American Society of Nephrology (ASN) meeting on November 3rd. Separately, enrollment is ongoing in Company-sponsored, multi-national, living-donor and deceased-donor kidney transplant trials in patients at elevated risk of Acute Humoral Rejection (AHR) also known as antibody mediated rejection.
- **Neurology: NMO and MG:** Data from the investigator-initiated Phase 2 clinical trial of eculizumab in severe and relapsing neuromyelitis optica (NMO) were presented at the American Neurological Association (ANA) meeting earlier this month. The study met its primary efficacy endpoint with high degrees of both clinical and statistical significance. Clinically and statistically significant improvements were also observed in key secondary endpoints. Separately, Alexion continues to work 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:** The natural history study in infants with hypophosphatasia (HPP), an ultra-rare, inherited and life-threatening metabolic disease, is on-going.
- **cPMP Replacement Therapy:** The Company expects to complete pre-IND toxicology studies in early 2013 required to commence clinical studies in normal volunteers with its cPMP replacement therapy for the treatment of patients with Molybdenum Cofactor Deficiency Type A, a severe, ultra-rare and genetic metabolic disorder that is fatal in newborns.
- **ALXN1102/ALXN1103:** Enrollment continues in a Phase I study to characterize the mechanism of action and develop initial safety data for ALXN1102 and ALXN1103, intravenous and sub-cutaneous versions, respectively, of one of Alexion's novel complement inhibitors.
- **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 therapeutic candidate in healthy volunteers.

2012 Financial Guidance:

Alexion today announced that it is raising its 2012 revenue guidance from the previous range of \$1.110 to \$1.125 billion, now to the higher and narrower range of \$1.120 to \$1.130 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 decreased from the previous range of \$360 to \$370 million, now to \$345 to \$355 million. 2012 non-GAAP R&D guidance is being reduced from the previous range of \$220 to \$230 million, now to the lower range of \$210 to \$220 million. 2012 guidance for cost of sales is being reduced from approximately 12 percent to approximately 11 percent. Guidance for the Company's non-GAAP tax rate is being reduced from the previous range of 8 to 10 percent, now to the lower and narrower range of 7 to 8 percent. Guidance for 2012 non-GAAP earnings per share is being raised, from the previous range of \$1.78 to \$1.88 per share, now to the higher and narrower range of \$1.99 to \$2.04 per share. Shares outstanding are expected to be approximately 204 million in the fourth quarter and 201 million for the full year.

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, October 24, at 10:00 a.m., Eastern Time. To participate in this call, dial 888-211-4495 (USA) or 913-312-9330 (International), confirmation code 4576472 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 719-457-0820 (International), confirmation code 4576472. 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 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, 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 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 June 30, 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.

In addition to financial information prepared in accordance with GAAP, this news release also contains non-GAAP financial measures that we believe, 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. 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 Net Income for explanations of the amounts adjusted to arrive at non-GAAP net income and non-GAAP earnings per share amounts for the three and nine month periods ended September 30, 2012 and 2011.

(Tables Follow)

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

	Three months ended		Nine months ended	
	September 30		September 30	
	2012	2011	2012	2011
Net product sales	\$ 294,136	\$ 204,047	\$ 813,588	\$ 555,872
Cost of sales	33,186	23,369	93,067	64,342
Gain on intellectual property settlement	(53,377)	—	(53,377)	—
Total cost of sales	<u>(20,191)</u>	<u>23,369</u>	<u>39,690</u>	<u>64,342</u>
Operating expenses:				
Research and development	54,280	36,567	159,323	103,023
Selling, general and administrative	89,957	77,572	272,054	221,609
Impairment of acquired in-process research and development	26,300	—	26,300	—
Acquisition-related costs	1,071	340	19,759	11,442
Total operating expenses	<u>171,608</u>	<u>114,479</u>	<u>477,436</u>	<u>336,074</u>
Operating income	142,719	66,199	296,462	155,456
Interest and other income (expense)	(1,954)	(522)	(6,165)	134
Income before income taxes	<u>140,765</u>	<u>65,677</u>	<u>290,297</u>	<u>155,590</u>
Income tax provision	48,586	107	116,446	28,445
Net income	<u>\$ 92,179</u>	<u>\$ 65,570</u>	<u>\$ 173,851</u>	<u>\$ 127,145</u>
Earnings per common share				
Basic	<u>\$ 0.48</u>	<u>\$ 0.36</u>	<u>\$ 0.92</u>	<u>\$ 0.70</u>
Diluted	<u>\$ 0.46</u>	<u>\$ 0.34</u>	<u>\$ 0.88</u>	<u>\$ 0.66</u>
Shares used in computing earnings per common share				
Basic	<u>193,353</u>	<u>183,706</u>	<u>189,219</u>	<u>182,805</u>
Diluted	<u>201,142</u>	<u>192,161</u>	<u>197,635</u>	<u>191,267</u>

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

	Three months ended		Nine months ended	
	September 30		September 30	
	2012	2011	2012	2011
GAAP net income	\$ 92,179	\$ 65,570	\$ 173,851	\$ 127,145
Share-based compensation expense (1)	14,015	11,261	40,322	34,426
Acquisition-related costs (2)	1,071	340	19,759	11,442
Non-cash taxes (3)	40,550	(4,597)	74,207	12,608
Tax related to acquisition structuring (3)	—	—	21,812	—
Gain on intellectual property settlement (4)	(53,377)	—	(53,377)	—
Impairment of acquired in-process research and development asset (5)	26,300	—	26,300	—
Non-GAAP net income	<u>\$ 120,738</u>	<u>\$ 72,574</u>	<u>\$ 302,874</u>	<u>\$ 185,621</u>
Shares used in computing diluted earnings per share (GAAP)	201,142	192,161	197,635	191,267
Shares used in computing diluted earnings per share (non-GAAP)	202,377	193,889	198,953	193,041
GAAP earnings per share - diluted	<u>\$ 0.46</u>	<u>\$ 0.34</u>	<u>\$ 0.88</u>	<u>\$ 0.66</u>
Non-GAAP earnings per share - diluted	<u>\$ 0.60</u>	<u>\$ 0.37</u>	<u>\$ 1.52</u>	<u>\$ 0.96</u>

- (1) The following table summarizes the share-based compensation expense for each expense category in our condensed consolidated statements of operations:

	Three months ended		Nine months ended	
	September 30		September 30	
	2012	2011	2012	2011
Share-based compensation expense:				
Cost of sales	\$ 664	\$ 645	\$ 1,939	\$ 1,762
Research and development	3,643	2,511	10,373	7,489
Selling, general and administrative	9,708	8,105	28,010	25,175
	<u>\$ 14,015</u>	<u>\$ 11,261</u>	<u>\$ 40,322</u>	<u>\$ 34,426</u>

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

	Three months ended		Nine months ended	
	September 30		September 30	
	2012	2011	2012	2011
Acquisition-related costs:				
Transaction and separation costs	\$ 1,509	\$ —	\$ 15,114	\$ 10,047
Contingent consideration	(542)	236	4,333	1,117
Amortization of purchased technology	104	104	312	278
	<u>\$ 1,071</u>	<u>\$ 340</u>	<u>\$ 19,759</u>	<u>\$ 11,442</u>

- (3) Non-cash taxes represent the adjustment for GAAP tax expense that is not payable in cash due to the utilization of our US net operating losses.

In the third quarter of 2011, we elected to claim foreign tax and orphan drug credits resulting in a tax benefit of \$16,300. The non-cash tax adjustment for the periods ended September 30, 2011 include these tax benefits which were recognized in the GAAP tax provision and were not received in cash.

The tax provision for the nine months ended September 30, 2012 also includes tax expense of \$21,812 related to the structuring of the Enobia acquisition.

- (4) In October 2012, we entered into a settlement and license agreement which included an upfront payment. The Company recognized a gain of \$53,377 in cost of sales which was the result of a reversal of a portion of the accrued liability, net of the effect of the upfront payment.
- (5) During the three months ended September 30, 2012, we recorded an impairment of an acquired in-process research and development asset of \$26,300 related to a preclinical AMD program.

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

	September 30,	December 31,
	2012	2011
Cash and cash equivalents	\$ 905,526	\$ 540,865
Trade accounts receivable, net	311,369	244,288
Inventories, net	90,049	81,386
Deferred tax assets, current	19,177	19,132
Other current assets	84,270	55,599
Property, plant and equipment, net	165,047	165,852
Deferred tax assets, noncurrent	14,509	103,868
Intangibles assets, net	648,306	91,604
Goodwill	253,839	79,639
Other noncurrent assets	13,516	12,518
Total assets	\$ 2,505,608	\$ 1,394,751
Accounts payable and accrued expenses	\$ 269,847	\$ 199,653
Current portion of long-term debt	48,000	—
Other current liabilities	44,095	28,132
Long-term debt	113,000	—
Contingent consideration	139,453	18,120
Other noncurrent liabilities	18,778	14,354
Total liabilities	633,173	260,259
Total stockholders' equity	1,872,435	1,134,492
Total liabilities and stockholders' equity	\$ 2,505,608	\$ 1,394,751