October 23, 2014

Alexion Reports Third Quarter 2014 Results

- Soliris® (eculizumab) Net Product Sales Increased 39 Percent to $555.1 Million -

- Steady Soliris PNH Growth Worldwide, aHUS Global Launch Progresses -

- Juvenile-Onset HPP Natural History Study Completed, Asfotase Alfa Rolling BLA Submission to Complete in Fourth Quarter -

- NDA for Asfotase Alfa in Japan Submitted -

- Clinical Development of the First Two Next-Generation Soliris Programs Initiated -

- 2014 Guidance Increased for Revenue and Non-GAAP EPS -

Third Quarter 2014 Financial Highlights:

- Q3 2014 net product sales increased 39 percent to $555.1 million, compared to $400.4 million in Q3 2013.
- Q3 2014 GAAP EPS increased 87 percent to $0.88 per share, compared to Q3 2013 GAAP EPS of $0.47 per share; Q3 2013 GAAP EPS included an expense of $0.10 per share related to both a license agreement and a litigation settlement.
- Q3 2014 non-GAAP EPS increased 53 percent to $1.27 per share, compared to Q3 2013 non-GAAP EPS of $0.83 per share.

CHESHIRE, Conn.--(BUSINESS WIRE)-- Alexion Pharmaceuticals, Inc. (NASDAQ:ALXN) today announced financial results for the three and nine months ended September 30, 2014. The Company reported net product sales of Soliris® (eculizumab) of $555.1 million in the third quarter of 2014, an increase of 39 percent from the same period in 2013. 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 third 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 NDA for asfotase alfa in Japan and the completion of the juvenile-onset HPP natural history study which enables us to complete our rolling BLA submission in the U.S.," said Leonard Bell, M.D., Chairman and Chief Executive Officer of Alexion. "Our third quarter performance underscores the significant opportunity we have to serve more patients with PNH and aHUS globally. While we remain focused on our initiatives to reach more patients in our current operations, we are also preparing for the global launch of asfotase alfa in 2015 and advancing our lead development programs as we drive toward as many as seven additional launches through 2018."

Third Quarter 2014 Financial Results:

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

Third Quarter 2014 Non-GAAP Financial Results:

The Company reported non-GAAP net income of $258.3 million, or $1.27 per share, in the third quarter of 2014, compared to non-GAAP net income of $167.9 million, or $0.83 per share, in the third quarter of 2013.

Alexion's non-GAAP operating expenses for Q3 2014 were $231.0 million, compared to $178.8 million for Q3 2013. Non-GAAP research and development (R&D) expenses for Q3 2014 were $92.7 million, compared to $68.9 million for Q3 2013. Non-GAAP selling, general and administrative (SG&A) expenses for Q3 2014 were $138.3 million, compared to $109.9 million for Q3 2013.

Third Quarter 2014 GAAP Financial Results:

Alexion reported GAAP net income of $177.7 million, or $0.88 per share, in the third quarter of 2014, compared to GAAP net income of $93.8 million, or $0.47 per share, in the third quarter of 2013. Q3 2013 GAAP results included a decrease of $20.7 million, or $0.10 per share, related to expenses from both a license agreement and a litigation settlement.

On a GAAP basis, operating expenses for Q3 2014 were $266.6 million, compared to $213.8 million for Q3 2013. GAAP R&D expenses for Q3 2014 were $100.7 million, compared to $88.2 million for Q3 2013. GAAP SG&A expenses were $157.7 million for Q3 2014, compared to $122.9 million for Q3 2013.

Balance Sheet:

As of September 30, 2014, the Company had $1.78 billion in cash, cash equivalents and marketable securities compared to $1.59 billion at June 30, 2014. During the quarter, the Company repurchased $104.6 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 completed its natural history study in juvenile-onset hypophosphatasia (HPP), which enables the Company to complete its rolling Biologics License Application (BLA) submission for asfotase alfa with the U.S. Food and Drug Administration (FDA) in the fourth quarter. Alexion received Breakthrough Therapy designation from the FDA for asfotase alfa in 2013.
- Alexion submitted a New Drug Application (NDA) for asfotase alfa for patients with HPP to Japan's Ministry of Health, Labour and Welfare (MHLW) in October 2014.

Ultra-Rare Disease Programs With Eculizumab

- **Transplant: Antibody-Mediated Rejection (AMR)** - Alexion has completed enrollment and dosing in both the multinational living-donor and deceased-donor kidney transplant trials in patients at elevated risk of AMR.
- **Transplant: Delayed Graft Function (DGF)** - Alexion is enrolling patients in a single, multinational registration trial for the prevention of DGF in renal transplant patients.
- **Neurology: Neuromyelitis Optica (NMO)** - Enrollment is ongoing in a single, multinational, placebo-controlled, registration trial in relapsing NMO.
- **Neurology: Myasthenia Gravis (MG)** - Enrollment is ongoing in a single, multinational, placebo-controlled, registration trial in refractory MG.
- **Next-Generation Soliris Development Programs** - Alexion has initiated clinical development of the first two molecules in the Company's innovative portfolio of next-generation Soliris candidates.

Ultra-Rare Disease Programs with Additional Highly Innovative Therapeutics

- **cPMP Replacement Therapy (ALXN1101)** - A natural history study in patients with molybdenum cofactor deficiency (MoCD) Type A and a synthetic cPMP bridging study are both ongoing. 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 dosing in a Phase 2 proof-of-concept study of ALXN1007, a novel anti-inflammatory antibody, in patients with antiphospholipid syndrome (APS). Alexion has started site activation for another Phase 2 proof-of-concept study of ALXN1007 in patients with graft versus host disease involving the lower gastrointestinal tract (GI-GVHD), another severe and ultra-rare disorder.

2014 Financial Guidance

Alexion today announced that the Company is revising upward its revenue guidance for 2014 from the previous range of $2.18 to $2.20 billion, now to the higher range of $2.220 to $2.225 billion. Non-GAAP earnings per share guidance is also being revised upward, from the previous range of $4.95 to $5.05 per share, now to the higher range of $5.15 to $5.20 per share. Alexion is also forecasting a lower 2014 non-GAAP tax rate of approximately 7.5 percent, reduced from the previously announced rate of 8 to 9 percent.

Alexion is reiterating the other elements of its 2014 financial guidance as provided in the press release issued on July 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, October 23, at 10:00 a.m., Eastern Time. To participate in this call, dial 1-888-298-3457 (USA) or + 1-719-325-2209 (International), passcode 2636963, 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 1-888-203-1112 (USA) or +1-719-457-0820 (International), passcode 2636963. 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 some of the pharmaceutical industry's highest honors: the Prix Galien USA (2008, Best Biotechnology Product) and France (2009, Rare Disease Treatment).

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.

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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 regulatory correspondence, 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 strategic transactions 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 June 30, 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 nine month periods ended September 30, 2014 and 2013.

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

	Three months ended September 30		Nine months ended September 30	
	2014	**2013**	**2014**	**2013**
Net product sales	$555,146	$400,405	$1,634,257	$1,109,437
Cost of sales	51,858	42,177	124,423	116,823
Change in contingent liability from intellectual property settlement	-	9,181	-	9,181
Total cost of sales	51,858	51,358	124,423	126,004
Operating expenses:				
Research and development	100,661	88,209	384,672	231,308
Selling, general and administrative	157,665	122,886	446,433	354,901
Impairment of intangible asset	-	-	3,464	-
Acquisition-related costs	8,303	2,573	10,254	6,974
Amortization of purchased intangible assets	-	104	-	312
Total operating expenses	266,629	213,772	844,823	593,495
Operating income	236,659	135,275	665,011	389,938
Other income (expense)	(450)	(987)	1,755	(1,646)
Income before income taxes	236,209	134,288	666,766	388,292
Income tax provision	58,478	40,503	163,186	116,405
Net income	$177,731	$ 93,785	$ 503,580	$ 271,887
Earnings per common share				
Basic	$ 0.90	$ 0.48	$ 2.54	$ 1.40
Diluted	$ 0.88	$ 0.47	$ 2.50	$ 1.37
Shares used in computing earnings per common share				
Basic	198,052	195,662	197,910	194,520
Diluted	201,313	199,711	201,528	198,655

ALEXION PHARMACEUTICALS, INC.
RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL RESULTS

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

	Three months ended September 30		Nine months ended September 30	
	2014	**2013**	**2014**	**2013**
Net income reconciliation:				
GAAP net income	$177,731	$ 93,785	$ 503,580	$271,887
Share-based compensation expense	28,366	21,597	80,621	56,409
Acquisition-related costs (1)	8,303	2,573	10,254	6,974
Amortization of purchased intangible assets	-	104	-	312
Change in contingent liability from intellectual property settlement	-	9,181	-	9,181
Upfront and milestone payments related to license and collaboration agreements	-	11,500	101,925	14,500
Impairment of intangible asset	-	-	3,464	-
Non-cash taxes (2)	43,866	29,173	100,094	87,194
Non-GAAP net income	$258,266	$167,913	$ 799,938	$446,457
GAAP earnings per share - diluted	$ 0.88	$ 0.47	$ 2.50	$ 1.37
Non-GAAP earnings per share - diluted	$ 1.27	$ 0.83	$ 3.91	$ 2.21
Shares used in computing diluted earnings per share (GAAP)	201,313	199,711	201,528	198,655
Shares used in computing diluted earnings per share (non-GAAP)	203,992	202,988	204,417	201,886
Cost of sales reconciliation:				
GAAP cost of sales	$ 51,858	$ 51,358	$ 124,423	$126,004
Share-based compensation expense	(1,059)	(757)	(2,906)	(2,349)
Change in contingent liability from intellectual property settlement	-	(9,181)	-	(9,181)
Non-GAAP cost of sales	$ 50,799	$ 41,420	$ 121,517	$114,474
Research and development reconciliation:				
GAAP research and development	$100,661	$ 88,209	$ 384,672	$231,308
Share-based compensation expense	(7,936)	(7,803)	(23,374)	(17,961)
Upfront and milestone payments related to license and collaboration agreements	-	(11,500)	(101,925)	(14,500)
Non-GAAP research and development	$ 92,725	$ 68,906	$ 259,373	$198,847
Selling, general and administrative reconciliation:				
GAAP selling, general and administrative	$157,665	$122,886	$ 446,433	$354,901
Share-based compensation expense	(19,371)	(13,037)	(54,341)	(36,099)
Non-GAAP selling, general and administrative	$138,294	$109,849	$ 392,092	$318,802
Income tax provision reconciliation:				
GAAP income tax provision	$ 58,478	$ 40,503	$ 163,186	$116,405
Non-cash taxes (2)	(43,866)	(29,173)	(100,094)	(87,194)
Non-GAAP income tax provision	$ 14,612	$ 11,330	$ 63,092	$ 29,211

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

	Three months ended September 30		Nine months ended September 30	
	2014	**2013**	**2014**	**2013**
Acquisition-related costs:				
Separately-identifiable employee costs	$ -	$ -	$ -	$ 248
Professional fees	-	-	-	775
Changes in fair value of contingent consideration	8,303	2,573	10,254	5,951

$ 8,303	$ 2,573	$ 10,254	$ 6,974

(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)

	September 30, 2014	December 31, 2013
Cash and cash equivalents	$ 752,164	$ 529,857
Marketable securities	1,029,543	984,994
Trade accounts receivable, net	436,467	421,752
Inventories	140,044	102,602
Deferred tax assets, current	54,381	41,432
Other current assets	147,279	106,220
Property, plant and equipment, net	328,476	201,109
Intangible assets, net	597,260	609,719
Goodwill	254,073	254,073
Deferred tax assets, noncurrent	49,620	3,394
Other noncurrent assets	101,580	62,544
Total assets	$ 3,890,887	$ 3,317,696
Accounts payable and accrued expenses	$ 301,440	$ 423,940
Current portion of long-term debt	48,000	48,000
Other current liabilities	153,097	110,489
Long-term debt, less current portion	21,500	65,000
Contingent consideration, noncurrent	107,073	106,744
Deferred tax liabilties, noncurrent	4,971	101,241
Other noncurrent liabilities	131,767	80,203
Total liabilities	767,848	935,617
Total stockholders' equity	3,123,039	2,382,079
Total liabilities and stockholders' equity	$ 3,890,887	$ 3,317,696

Alexion:
Media
Irving Adler, 203-271-8210
Executive Director, Corporate Communications
or
Kim Diamond, 203-439-9600
Senior Director, Corporate Communications
or
Investors
Elena Ridloff, 203-699-7722
Executive Director, Investor Relations

Source: Alexion Pharmaceuticals, Inc.