



January 29, 2015

Alexion Reports Fourth Quarter and Full Year 2014 Results and Provides Financial Guidance for 2015

- Soliris® (eculizumab) Net Product Sales Increased 44 Percent to \$2.234 Billion -
 - Soliris Net Product In-Year Sales Increased 38 Percent to \$2.146 Billion -
 - Steady Soliris PNH Growth Worldwide; aHUS Global Launch Progresses -
- Regulatory Submissions for Asfotase Alfa in the U.S., Europe and Japan Completed -
 - Three Eculizumab Registration Programs Enrolling in DGF, NMO and MG -
- Two Next-Generation Soliris Phase 1 Trials Underway with ALXN1210 and ALXN5500 -
- 17 Pre-clinical Development Programs Spanning Diverse Modalities and Therapeutic Areas -

Full Year 2014 Financial Highlights:

- 2014 net product sales increased 44 percent to \$2.234 billion, compared to \$1.551 billion in 2013. Excluding the impact of \$88 million for reimbursement of prior year shipments, 2014 net product sales increased 38 percent to \$2.146 billion.
- 2014 GAAP EPS increased to \$3.26 per share, compared to 2013 GAAP EPS of \$1.27 per share.
- 2014 non-GAAP EPS increased 69 percent to \$5.21 per share, compared to 2013 non-GAAP EPS of \$3.08 per share. Excluding \$0.37 per share related to reimbursement of prior year shipments, 2014 non-GAAP EPS increased 57 percent to \$4.84 per share.

Fourth Quarter 2014 Financial Highlights:

- Q4 2014 net product sales increased 36 percent to \$599 million, compared to \$442 million in Q4 2013.
- Q4 2014 GAAP EPS increased to \$0.76 per share, compared to a Q4 2013 GAAP net loss of \$0.10 per share.
- Q4 2014 non-GAAP EPS increased 49 percent to \$1.30 per share, compared to Q4 2013 non-GAAP EPS of \$0.87 per share.

CHESHIRE, Conn.--(BUSINESS WIRE)-- Alexion Pharmaceuticals, Inc. (NASDAQ:ALXN) today announced financial results for the quarter and year ended December 31, 2014. For the three months ended December 31, 2014, the Company reported net product sales of Soliris® (eculizumab) of \$599 million, compared to \$442 million for the same period in 2013. The year-on-year increase in Q4 net product sales of 36 percent 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 50 countries. Both PNH and aHUS are severe and life-threatening ultra-rare disorders caused by chronic uncontrolled complement activation.

"In 2014, we provided Soliris to an increasing number of patients with PNH and aHUS worldwide while simultaneously reaching several significant milestones across our pipeline. Most notably, we completed the regulatory submissions in the U.S., Europe and Japan for asfotase alfa as a potential treatment for patients with HPP, commenced registration trials for eculizumab in patients with DGF, NMO and MG, and initiated clinical development of our first two molecules from our next-generation Soliris portfolio," said Leonard Bell, M.D., Chairman and Chief Executive Officer of Alexion. "Throughout 2015, we will focus on serving more patients with PNH and aHUS globally while also preparing for the launch of asfotase alfa. At the same time, we will advance our lead development programs as we drive toward as many as seven potential new indications or product approvals through 2018."

Full Year 2014 GAAP Financial Results

Alexion reported GAAP net income of \$657 million, or \$3.26 per share, in 2014 compared to 2013 GAAP net income of \$253 million, or \$1.27 per share. Full year 2014 GAAP EPS included \$0.31 per share related to reimbursement of prior year shipments.

Alexion's GAAP operating expenses for the full year 2014 were \$1.191 billion, compared to \$846 million in 2013. GAAP research and development (R&D) expenses for 2014 were \$514 million, compared to \$317 million in 2013. GAAP selling, general and administrative (SG&A) expenses for 2014 were \$630 million, compared to \$490 million for the prior year.

Full Year 2014 Non-GAAP 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.

The Company reported non-GAAP net income of \$1.066 billion in 2014, or \$5.21 per share, compared to non-GAAP net income of \$624 million, or \$3.08 per share, in 2013. Full year 2014 non-GAAP EPS included \$0.37 per share related to reimbursement of prior year shipments.

Alexion's non-GAAP operating expenses for the full year 2014 were \$924 million, compared to \$719 million for 2013. Non-GAAP R&D expenses for 2014 were \$368 million, compared to \$279 million for the prior year. Non-GAAP SG&A expenses for 2014 were \$556 million, compared to \$441 million.

Fourth Quarter GAAP Financial Results

Alexion reported GAAP net income of \$153 million, or \$0.76 per share, in Q4 2014, compared to a GAAP net loss of \$19 million, or \$0.10 per share, in Q4 2013. Q4 2013 GAAP results were impacted by \$96 million, or \$0.48 per share, related to a non-cash tax expense associated with centralizing certain business operations.

On a GAAP basis, operating expenses for Q4 2014 were \$346 million, compared to \$252 million for Q4 2013. GAAP R&D expenses for Q4 2014 were \$129 million, compared to \$86 million for Q4 2013. GAAP SG&A expenses were \$184 million for Q4 2014, compared to \$135 million for Q4 2013.

Fourth Quarter Non-GAAP Financial Results

The Company reported non-GAAP net income of \$266 million, or \$1.30 per share, in Q4 2014, compared to non-GAAP net income of \$178 million, or \$0.87 per share, in Q4 2013.

Alexion's non-GAAP operating expenses for Q4 2014 were \$272 million, compared to \$202 million for Q4 2013. Non-GAAP R&D expenses for Q4 2014 were \$108 million, compared to \$80 million for Q4 2013. Non-GAAP SG&A expenses for Q4 2014 were \$164 million, compared to \$122 million for Q4 2013.

Balance Sheet

As of December 31, 2014, the Company had \$1.962 billion in cash, cash equivalents and marketable securities compared to \$1.515 billion at December 31, 2013.

Research and Development Progress:

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

Asfotase Alfa

- Alexion completed regulatory submissions in the United States, Europe and Japan for asfotase alfa for the treatment of hypophosphatasia (HPP).
- Alexion will initiate a clinical trial of asfotase alfa in adults with severe HPP.

Ultra-Rare Disease Programs With Eculizumab

- **Kidney Transplant: Antibody-Mediated Rejection (AMR)** - Alexion reported that the Phase 2 living-donor AMR prevention trial did not meet its primary endpoint. Deceased-donor Phase 2 trial data are expected in the second half of 2015. Alexion has announced plans to commence an AMR treatment trial.

- **Kidney Transplant: Delayed Graft Function (DGF)** - Alexion is enrolling patients in a single, multinational DGF prevention registration trial.
- **Neurology: Neuromyelitis Optica (NMO)** - Enrollment and dosing are ongoing in a single, multinational, placebo-controlled, registration trial in relapsing NMO.
- **Neurology: Myasthenia Gravis (MG)** - Enrollment and dosing are ongoing in a single, multinational, placebo-controlled, registration trial in refractory MG.
- **Next-Generation Soliris Development Programs** - Alexion initiated clinical development of ALXN1210 and ALXN5500, the first two molecules in the Company's innovative portfolio of next-generation Soliris candidates.

Ultra-Rare Disease Programs with Additional Highly Innovative Therapeutics

- **ALXN1007** - Alexion commenced dosing in two Phase 2 proof-of-concept studies of ALXN1007, a novel anti-inflammatory antibody, in patients with graft versus host disease involving the lower gastrointestinal tract (GI-GVHD) and antiphospholipid syndrome (APS), two severe, auto-immune diseases with potentially life-threatening complications.
- **cPMP Replacement Therapy (ALXN1101)** - A synthetic cPMP bridging study in patients with molybdenum cofactor deficiency (MoCD) Type A is ongoing and enrollment in a natural history study is also ongoing. Alexion received Breakthrough Therapy designation for its cPMP replacement therapy.

2015 Financial Guidance

In 2015, worldwide net product sales are expected to be within a range of \$2.55 to \$2.6 billion, which includes an approximately negative 5 percent, or \$135 million, foreign exchange impact compared to 2014 exchange rates. Non-GAAP earnings per share for the year are expected to be \$5.60 to \$5.80, which includes an approximately \$0.30 negative foreign exchange impact compared to 2014 exchange rates. 2015 guidance is based on current exchange rates remaining unchanged.

On a non-GAAP basis, 2015 financial guidance is as follows:

Cost of sales	8% to 9% of net product sales
Research and development	\$440 to \$470 million
Selling, general and administrative	\$620 to \$650 million
Effective tax rate	7% to 9%
Diluted shares outstanding	205 million

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, January 29, at 10:00 a.m., Eastern Time. To participate in this call, dial 1-800-768-6569 (USA) or +1-785-830-7992 (International), passcode 6130985, 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 6130985. The audio webcast can be accessed on the Investor page of Alexion's website at: <http://ir.alexionpharm.com>.

About Soliris® (eculizumab)

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) to reduce hemolysis. PNH is 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 U.S. (2011), European Union (2011), Japan (2013) and other countries as the first and only treatment for patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy, or TMA (blood clots in small vessels). aHUS is a debilitating, ultra-rare and life-threatening genetic disorder characterized by complement-mediated TMA. 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.alexion.com.

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This news release contains forward-looking statements, including statements related to guidance regarding anticipated financial results for 2015, 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, commercial potential associated with the expected launch of asfotase alfa in 2015, 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 or asfotase alfa for HPP, 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 September 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, restructuring expense, 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 twelve month periods ended December 31, 2014 and 2013.

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

	Three months ended		Twelve months ended	
	December 31		December 31	
	2014	2013	2014	2013
Net product sales	\$ 599,476	\$ 441,909	\$2,233,733	\$1,551,346
Cost of sales	49,439	51,552	173,862	168,375
Change in contingent liability from intellectual property settlements	-	-	-	9,181
Total cost of sales	49,439	51,552	173,862	177,556

Operating expenses:				
Research and development	129,110	85,785	513,782	317,093
Selling, general and administrative	183,776	134,819	630,209	489,720
Acquisition-related costs	10,041	(1,945)	20,295	5,029
Impairment of intangible assets	8,050	33,521	11,514	33,521
Restructuring expenses	15,365	-	15,365	-
Amortization of purchased intangible assets	-	105	-	417
Total operating expenses	<u>346,342</u>	<u>252,285</u>	<u>1,191,165</u>	<u>845,780</u>
Operating income	203,695	138,072	868,706	528,010
Other income (expense)	<u>1,646</u>	<u>(95)</u>	<u>3,401</u>	<u>(1,741)</u>
Income before income taxes	205,341	137,977	872,107	526,269
Income tax provision	52,009	156,969	215,195	273,374
Net income (loss)	<u>\$ 153,332</u>	<u>\$ (18,992)</u>	<u>\$ 656,912</u>	<u>\$ 252,895</u>
Earnings (loss) per common share				
Basic	<u>\$ 0.77</u>	<u>\$ (0.10)</u>	<u>\$ 3.32</u>	<u>\$ 1.29</u>
Diluted	<u>\$ 0.76</u>	<u>\$ (0.10)</u>	<u>\$ 3.26</u>	<u>\$ 1.27</u>
Shares used in computing earnings (loss) per common share				
Basic	<u>198,676</u>	<u>196,430</u>	<u>198,103</u>	<u>195,532</u>
Diluted	<u>201,732</u>	<u>196,430</u>	<u>201,623</u>	<u>199,712</u>

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

	Three months ended		Twelve months ended	
	December 31		December 31	
	<u>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
Net income reconciliation:				
GAAP net income (loss)	\$153,332	\$ (18,992)	\$ 656,912	\$ 252,895
Share-based compensation expense	33,840	19,794	114,461	76,203
Acquisition-related costs (1)	10,041	(1,945)	20,295	5,029
Upfront and milestone payments related to license and collaboration agreements (2)	8,000	-	109,925	14,500
Impairment of intangible assets (3)	8,050	33,521	11,514	33,521
Restructuring expenses (4)	15,365	-	15,365	-
Amortization of purchased intangible assets	-	105	-	417
Change in contingent liability from intellectual property settlements	-	-	-	9,181
Non-cash taxes (5)	37,355	145,266	137,449	232,460
Non-GAAP net income	<u>\$265,983</u>	<u>\$ 177,749</u>	<u>\$1,065,921</u>	<u>\$ 624,206</u>
GAAP earnings (loss) per share - diluted	<u>\$ 0.76</u>	<u>\$ (0.10)</u>	<u>\$ 3.26</u>	<u>\$ 1.27</u>
Non-GAAP earnings per share - diluted	<u>\$ 1.30</u>	<u>\$ 0.87</u>	<u>\$ 5.21</u>	<u>\$ 3.08</u>

Shares used in computing diluted earnings (loss) per share (GAAP)	<u>201,732</u>	<u>196,430</u>	<u>201,623</u>	<u>199,712</u>
Shares used in computing diluted earnings per share (non-GAAP)	<u>204,270</u>	<u>203,586</u>	<u>204,459</u>	<u>202,943</u>
Cost of sales reconciliation:				
GAAP cost of sales	\$ 49,439	\$ 51,552	\$ 173,862	\$ 177,556
Share-based compensation expense	(1,268)	(865)	(4,174)	(3,214)
Change in contingent liability from intellectual property settlements	-	-	-	(9,181)
Non-GAAP cost of sales	<u>\$ 48,171</u>	<u>\$ 50,687</u>	<u>\$ 169,688</u>	<u>\$ 165,161</u>
Research and development reconciliation:				
GAAP research and development	\$129,110	\$ 85,785	\$ 513,782	\$ 317,093
Share-based compensation expense	(12,829)	(5,944)	(36,203)	(23,905)
Upfront and milestone payments related to license and collaboration agreements (2)	(8,000)	-	(109,925)	(14,500)
Non-GAAP research and development	<u>\$108,281</u>	<u>\$ 79,841</u>	<u>\$ 367,654</u>	<u>\$ 278,688</u>
Selling, general and administrative reconciliation:				
GAAP selling, general and administrative	\$183,776	\$ 134,819	\$ 630,209	\$ 489,720
Share-based compensation expense	(19,743)	(12,985)	(74,084)	(49,084)
Non-GAAP selling, general and administrative	<u>\$164,033</u>	<u>\$ 121,834</u>	<u>\$ 556,125</u>	<u>\$ 440,636</u>
Income tax provision reconciliation:				
GAAP income tax provision	\$ 52,009	\$ 156,969	\$ 215,195	\$ 273,374
Non-cash taxes (5)	(37,355)	(145,266)	(137,449)	(232,460)
Non-GAAP income tax provision	<u>\$ 14,654</u>	<u>\$ 11,703</u>	<u>\$ 77,746</u>	<u>\$ 40,914</u>

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

	Three months ended		Twelve months ended	
	December 31		December 31	
	2014	2013	2014	2013
Acquisition-related costs:				
Separately-identifiable employee costs	\$ -	\$ -	\$ -	\$ 248
Professional fees	-	-	-	775
Changes in fair value of contingent consideration	10,041	(1,945)	20,295	4,006
	<u>\$ 10,041</u>	<u>\$ (1,945)</u>	<u>\$ 20,295</u>	<u>\$ 5,029</u>

(2) In December 2014, the Company entered into an agreement that provides an option to purchase drug products for clinical development and commercialization. The Company recorded research and development expense for an upfront payment of \$8 million.

(3) During the three and twelve months ended December 31, 2014, the Company recorded impairment charges related to early stage development assets.

(4) In October 2014, the Company announced plans to move its European headquarters from Lausanne to Zurich, Switzerland. As a result of this action, the Company recorded restructuring expense of \$15 million during the three months ended December 31, 2014 related to employee costs.

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

(in thousands)
(unaudited)

	December 31, 2014	December 31, 2013
Cash and cash equivalents	\$ 943,999	\$ 529,857
Marketable securities	1,017,567	984,994
Trade accounts receivable, net	432,888	421,752
Inventories	176,441	102,602
Deferred tax assets, current	35,733	41,432
Other current assets	189,401	106,220
Property, plant and equipment, net	392,248	201,109
Intangible assets, net	587,046	609,719
Goodwill	254,073	254,073
Deferred tax assets, noncurrent	34,939	3,394
Other noncurrent assets	137,627	62,544
Total assets	\$ 4,201,962	\$ 3,317,696
Accounts payable and accrued expenses	\$ 439,248	\$ 423,940
Current portion of long-term debt	48,000	48,000
Other current liabilities	119,492	110,489
Long-term debt, less current portion	9,500	65,000
Contingent consideration, noncurrent	116,425	106,744
Deferred tax liabilities, noncurrent	7,046	101,241
Other noncurrent liabilities	160,233	80,203
Total liabilities	899,944	935,617
Total stockholders' equity	3,302,018	2,382,079
Total liabilities and stockholders' equity	\$ 4,201,962	\$ 3,317,696

ALEXION PHARMACEUTICALS, INC.
NET PRODUCT SALES BY SIGNIFICANT GEOGRAPHIC REGION
(in thousands, except per share amounts)
(unaudited)

	Twelve months ended December 31		
	2014	2013	% Variance
United States	\$ 730,089	\$ 561,405	30%
Europe (1)	836,134	514,987	62%
Asia Pacific	244,059	203,538	20%
Other	423,451	271,416	56%
Total net product sales	<u>\$2,233,733</u>	<u>\$1,551,346</u>	<u>44%</u>

(1) In March 2014, we entered into an agreement with the French government which positively impacted prospective reimbursement of Soliris and also provided for reimbursement for shipments made in years prior to January 1, 2014. As a result of the agreement, in the first quarter of 2014, we recognized \$88 million of net product sales from Soliris in France relating to years prior to January 1, 2014.

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

Investors

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

Source: Alexion Pharmaceuticals, Inc.

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