



February 3, 2016

Alexion Reports Fourth Quarter and Full Year 2015 Results and Provides Financial Guidance for 2016

- Total Revenues of \$2.604 Billion; Increased 21% Year-on-Year; 29% Increase Year-on-Year on Constant Currency Basis -
 - Soliris[®] (eculizumab) Net Product Sales of \$2.590 Billion -
- Strensiq[®] (asfotase alfa) and Kanuma[™] (sebelipase alfa) Approved in the United States in Q4 with Launches Underway; Two Rare Pediatric Disease Priority Review Vouchers Granted -
- Completed Enrollment in MG and DGF Registration Programs with Eculizumab; Advanced NMOSD Registration Trial -
 - Completed Enrollment in Phase 1/2 Study of ALXN1210 in Patients with PNH -
- Six-Month Data from SBC-103 Phase 1/2 Study in Patients with MPS-IIIB to be Presented as Late-Breaker Abstract at *WORLDSymposium Meeting* -

NEW HAVEN, Conn.--(BUSINESS WIRE)-- Alexion Pharmaceuticals, Inc. (NASDAQ: ALXN) today announced financial results for the fourth quarter and full year of 2015. Total revenues for the full year of 2015 were \$2.604 billion compared to \$2.146 billion for the full year 2014, representing 21 percent revenue growth, excluding the impact of \$88 million in 2014 for reimbursement of shipments in prior years. In 2015, the negative impact of currency on total revenue was 8 percent, or \$165 million, net of hedging activities, compared to the prior year. Non-GAAP diluted earnings per share (EPS) for the full year of 2015 was \$4.99 per share, compared to \$5.21 per share in 2014. Full year 2014 non-GAAP EPS included \$0.37 per share related to reimbursement of shipments in prior years. On a GAAP basis, Alexion reported diluted EPS of \$0.67 per share for the full year 2015, compared to \$3.26 per share in 2014. Full year 2014 GAAP EPS included \$0.31 per share related to reimbursement of prior year shipments.

Total revenues in the fourth quarter were \$701 million, a 17 percent increase, compared to \$600 million from the same period in 2014. In the fourth quarter, the negative impact of currency on total revenue was 8 percent or \$45 million, net of hedging activities, compared to the same quarter last year. Non-GAAP diluted EPS for the fourth quarter of 2015 was \$1.13, compared to \$1.30 in the fourth quarter of 2014. On a GAAP basis, diluted EPS for the fourth quarter of 2015 was \$0.29 per share, compared to \$0.76 in the fourth quarter of 2014.

"2015 was a transformative year for Alexion as we grew our complement franchise, commenced building a premier metabolic franchise with the global approvals of two new therapies, and simultaneously advanced the most robust rare disease pipeline in biotech," said David Hallal, Chief Executive Officer of Alexion. "In 2016 we will continue to focus on serving an increasing number of patients with PNH and aHUS globally, executing on the global launches of Strensiq and Kanuma, and advancing our complement and metabolic pipeline programs to drive our future growth. We look forward to reporting on multiple milestones in our expanding development pipeline in 2016, including results from two registration trials, and our broad and innovative mid-stage development programs."

Full Year 2015 Financial Results

- | Soliris[®] (eculizumab) net product sales were \$2.590 billion compared to \$2.146 billion in 2014, excluding the impact of \$88 million in 2014 for reimbursement of shipments in prior years.
- | Strensiq[®] (asfotase alfa) net product sales were \$12 million.
- | Non-GAAP R&D expense was \$516 million compared to \$368 million for 2014. GAAP R&D expense was \$709 million compared to \$514 million for 2014.
- | Non-GAAP SG&A expense was \$706 million compared to \$556 million in 2014. GAAP SG&A expense was \$863 million compared to \$630 million in 2014.
- | Non-GAAP diluted EPS was \$4.99, compared to \$5.21 in 2014. Full year 2014 non-GAAP EPS included \$0.37 per share related to reimbursement of prior year shipments. On a GAAP basis, diluted EPS was \$0.67 per share compared to \$3.26 in 2014. Full year 2014 GAAP EPS included \$0.31 per share related to reimbursement of prior

year shipments.

- | As of December 31, 2015, Alexion held cash, cash equivalents and marketable securities of \$1.385 billion.

Fourth Quarter 2015 Financial Results

- | Soliris net product sales were \$689 million compared to \$600 million in the same quarter last year, despite continued currency headwinds as well as macroeconomic factors in Latin American countries.
- | Strensiq net product sales were \$11.6 million.
- | Non-GAAP R&D expense was \$155 million compared to \$108 million in the same quarter last year. GAAP R&D expense was \$191 million compared to \$129 million in the same quarter last year.
- | Non-GAAP SG&A expense was \$198 million compared to \$164 million in the same quarter last year. GAAP SG&A expense was \$242 million compared to \$184 million in the same quarter last year.
- | Non-GAAP diluted EPS was \$1.13, compared to \$1.30 in the same quarter last year. On a GAAP basis, diluted EPS was \$0.29 per share compared to \$0.76 in the same quarter last year.

Product and Pipeline Updates

Complement Portfolio

- | **Eculizumab- Myasthenia Gravis (MG):** Enrollment is complete in the REGAIN study, a single, multinational, placebo-controlled, registration trial of eculizumab in refractory MG, and preliminary data are expected in mid-2016.
- | **Eculizumab- Neuromyelitis Optica Spectrum Disorder (NMOSD):** Alexion expects to complete enrollment in the PREVENT study, a single, multinational, placebo-controlled, registration trial of eculizumab in relapsing NMOSD, in 2016.
- | **Eculizumab- Delayed Graft Function (DGF):** Enrollment is complete in the PROTECT study, a single, multinational DGF prevention registration trial with eculizumab, and preliminary data are expected in the second half of 2016.
- | **ALXN1210:** Alexion has completed enrollment in a Phase 1/2 clinical study of ALXN1210, its highly innovative longer-acting C5 antibody, in patients with paroxysmal nocturnal hemoglobinuria (PNH) and is enrolling patients in a Phase 2 PNH study. In the fourth quarter, Alexion reported data showing a rapid reduction of LDH in initial patients with PNH receiving ALXN1210. Alexion expects to initiate a clinical program in patients with atypical hemolytic uremic syndrome (aHUS) in 2016.
- | **ALXN1007:** Enrollment is ongoing in a Phase 2 proof-of-concept study of ALXN1007, a complement inhibitor that targets C5a, in patients with graft-versus-host disease involving the lower gastrointestinal tract (GI-GVHD). In the fourth quarter, Alexion reported interim Phase 2 data, showing an overall response rate at 28 days in patients with acute GI-GVHD.

Metabolic Portfolio

- | **Strensiq:** Strensiq was approved by the U.S. Food and Drug Administration (FDA) under Breakthrough Therapy Designation and Priority Review for the treatment of patients with perinatal-, infantile- and juvenile-onset hypophosphatasia (HPP) in the fourth quarter of 2015. Alexion received a Rare Pediatric Disease Priority Review Voucher with the FDA approval. Strensiq was also approved in the European Union and Japan in the third quarter of 2015.
- | **Kanuma™ (sebelipase alfa):** Kanuma was approved by the FDA under Breakthrough Therapy Designation and Priority Review for the treatment of patients of all ages with a diagnosis of lysosomal acid lipase deficiency (LAL-D) in the fourth quarter of 2015, and launched in the first quarter of 2016. Alexion received a Rare Pediatric Disease Priority Review Voucher with the FDA approval. Kanuma was also approved in the European Union in the third quarter of 2015.
- | **SBC-103:** Alexion is enrolling patients in a Phase 1/2 trial of SBC-103, a recombinant form of the NAGLU enzyme, in patients with mucopolysaccharidosis IIIB, or MPS IIIB or Sanfilippo B. In the fourth quarter, Alexion reported interim data showing a dose-dependent reduction in heparan sulfate levels in cerebral spinal fluid at 12 weeks in patients with MPS-IIIB. Six-month data will be presented as a late-breaker abstract at the *WORLD Symposium* meeting in March. Alexion has also completed enrollment in a natural history study of patients with MPS IIIB.
- | **cPMP Replacement Therapy (ALXN 1101):** Alexion has initiated a pivotal study to evaluate ALXN1101 in neonates with Molybdenum Cofactor Deficiency (MoCD) Type A. Alexion received Breakthrough Therapy designation for its cPMP replacement therapy.

Preclinical Portfolio

- Alexion has more than 30 diverse preclinical programs across a range of therapeutic modalities, with four of these programs expected to enter the clinic in 2016.

2016 Financial Guidance

On a non-GAAP basis, 2016 financial guidance is as follows:

	Constant Currency Guidance (1)	Foreign Exchange	Financial Guidance (2)
Total product revenues	\$3,170 to \$3,220 million	(\$120 million)	\$3,050 to \$3,100 million
Soliris revenues			\$2,900 to \$2,925 million
Metabolic franchise revenues			\$150 to \$175 million
Cost of sales			8% to 9%
Research and development expense			\$650 to \$680 million
Selling, general and administrative expense			\$760 to \$790 million
Interest expense			\$100 million
Effective tax rate			7% to 8%
Earnings per share	\$5.31 to \$5.51	(\$0.31)	\$5.00 to \$5.20
Diluted shares outstanding			230 million

(1) Constant currency revenues are based on actual foreign exchange rates realized in 2015.

(2) Financial guidance is based on forecasted results at current spot rate net of hedging activities.

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, February 3, at 10:00 a.m., Eastern Time. To participate in this conference call, dial 877-856-1968 (USA) or 719-325-4815 (International), passcode 1542166 shortly before 10:00 a.m. ET. A replay of the call will be available from 1:00 p.m. ET for a limited time by dialing 888-203-1112 (USA) or 719-457-0820 (International), passcode 1542166. The audio webcast can be accessed on the Investor page of <http://ir.alexionpharm.com>.

About Alexion

Alexion is a global biopharmaceutical company focused on developing and delivering life-transforming therapies for patients with devastating and rare disorders. Alexion developed and commercializes Soliris[®] (eculizumab), the first and only approved complement inhibitor to treat patients with paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS), two life-threatening ultra-rare disorders. As the global leader in complement inhibition, Alexion is strengthening and broadening its portfolio of complement inhibitors, including evaluating potential indications for eculizumab in additional severe and ultra-rare disorders. Alexion's metabolic franchise includes two highly innovative enzyme replacement therapies for patients with life-threatening and ultra-rare disorders, Strensiq[®] (asfotase alfa) to treat patients with hypophosphatasia (HPP) and Kanuma[™] (sebelipase alfa) to treat patients with lysosomal acid lipase deficiency (LAL-D). In addition, Alexion is advancing the most robust rare disease pipeline in the biotech industry, with highly innovative product candidates in 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 2016, assessment of the Company's financial position and commercialization efforts, medical benefits and commercial potential for Soliris, Strensiq and Kanuma, medical and commercial potential of each of Alexion's product candidates, launch expectations for Strensiq and Kanuma, and plans for clinical programs for 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 our products, delays, interruptions or failures in the manufacture and supply of our products and our product

candidates, progress in establishing and developing commercial infrastructure, failure to satisfactorily address matters raised by the FDA and other regulatory agencies, the possibility that results of clinical trials are not predictive of safety and efficacy results of our products 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 our products at acceptable rates or at all, risks regarding government investigations, including the SEC and DOJ investigations, the risk that estimates regarding the number of patients with PNH, aHUS, HPP and LAL-D are inaccurate, the risks of shifting foreign exchange rates, 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, 2015 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, fair value adjustment of inventory acquired, amortization of purchased intangible assets, changes in fair value of contingent consideration, acquisition-related costs, restructuring expenses, intangible asset impairments, upfront and milestone payments related to license and collaboration agreements, 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, 2015 and 2014.

(Tables Follow)

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	
	2015	2014	2015	2014
Net product sales	\$ 700,425	\$ 599,476	\$2,602,532	\$2,233,733
Other revenue	442	-	1,515	-
Total revenues	<u>700,867</u>	<u>599,476</u>	<u>2,604,047</u>	<u>2,233,733</u>
Cost of sales	57,626	49,439	233,089	173,862
Operating expenses:				
Research and development	191,035	129,110	709,472	513,782
Selling, general and administrative	241,576	183,776	862,595	630,209
Amortization of purchased intangible assets	79,976	-	116,584	-
Change in fair value of contingent consideration	18,550	10,041	64,257	20,295
Acquisition-related costs	3,358	-	39,210	-
Restructuring expenses	11,432	15,365	42,169	15,365
Impairment of intangible asset	-	8,050	-	11,514
Total operating expenses	<u>545,927</u>	<u>346,342</u>	<u>1,834,287</u>	<u>1,191,165</u>
Operating income	97,314	203,695	536,671	868,706

Other income and expense:

Investment income	1,442	2,196	8,519	8,373
Interest expense	(23,151)	(549)	(47,744)	(2,982)
Foreign currency gain (loss)	(1,059)	(1)	696	(1,990)
	<u>74,546</u>	<u>205,341</u>	<u>498,142</u>	<u>872,107</u>
Income before income taxes				
Income tax provision	7,942	52,009	353,757	215,195
Net income	<u>\$ 66,604</u>	<u>\$ 153,332</u>	<u>\$ 144,385</u>	<u>\$ 656,912</u>
Earnings per common share				
Basic	<u>\$ 0.30</u>	<u>\$ 0.77</u>	<u>\$ 0.68</u>	<u>\$ 3.32</u>
Diluted	<u>\$ 0.29</u>	<u>\$ 0.76</u>	<u>\$ 0.67</u>	<u>\$ 3.26</u>
Shares used in computing earnings per common share				
Basic	<u>225,472</u>	<u>198,676</u>	<u>213,431</u>	<u>198,103</u>
Diluted	<u>227,967</u>	<u>201,732</u>	<u>215,933</u>	<u>201,623</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	
	2015	2014	2015	2014
Net income reconciliation:				
GAAP net income	\$ 66,604	\$ 153,332	\$ 144,385	\$ 656,912
Share-based compensation expense	66,280	33,840	227,133	114,461
Fair value adjustment of inventory acquired (1)	91	-	91	-
Amortization of purchased intangible assets (2)	79,976	-	116,584	-
Change in fair value of contingent consideration	18,550	10,041	64,257	20,295
Acquisition-related costs (3)	3,358	-	39,210	-
Restructuring expenses (4)	11,432	15,365	42,169	15,365
Impairment of intangible asset	-	8,050	-	11,514
Upfront and milestone payments related to license and collaboration agreements	15,500	8,000	129,750	109,925
Non-cash taxes (5)	(1,864)	37,355	324,978	137,449
Non-GAAP net income	<u>\$ 259,927</u>	<u>\$ 265,983</u>	<u>\$ 1,088,557</u>	<u>\$ 1,065,921</u>
GAAP earnings per share - diluted	<u>\$ 0.29</u>	<u>\$ 0.76</u>	<u>\$ 0.67</u>	<u>\$ 3.26</u>
Non-GAAP earnings per share - diluted	<u>\$ 1.13</u>	<u>\$ 1.30</u>	<u>\$ 4.99</u>	<u>\$ 5.21</u>
Shares used in computing diluted earnings per share (GAAP)	<u>227,967</u>	<u>201,732</u>	<u>215,933</u>	<u>201,623</u>
Shares used in computing diluted earnings per share (non-GAAP)	<u>230,148</u>	<u>204,270</u>	<u>218,251</u>	<u>204,459</u>
Cost of sales reconciliation:				
GAAP cost of sales	\$ 57,626	\$ 49,439	\$ 233,089	\$ 173,862
Share-based compensation expense	(2,407)	(1,268)	(6,630)	(4,174)
Fair value adjustment of inventory acquired (1)	(91)	-	(91)	-

Non-GAAP cost of sales	\$ 55,128	\$ 48,171	\$ 226,368	\$ 169,688
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Research and development expense reconciliation:

GAAP research and development expense	\$ 191,035	\$ 129,110	\$ 709,472	\$ 513,782
Share-based compensation expense	(20,735)	(12,829)	(64,235)	(36,203)
Upfront and milestone payments related to license and collaboration agreements	(15,500)	(8,000)	(129,750)	(109,925)
Non-GAAP research and development expense	\$ 154,800	\$ 108,281	\$ 515,487	\$ 367,654

Selling, general and administrative expense reconciliation:

GAAP selling, general and administrative expense	\$ 241,576	\$ 183,776	\$ 862,595	\$ 630,209
Share-based compensation expense	(43,138)	(19,743)	(156,268)	(74,084)
Non-GAAP selling, general and administrative expense	\$ 198,438	\$ 164,033	\$ 706,327	\$ 556,125

Income tax provision reconciliation:

GAAP income tax provision	\$ 7,942	\$ 52,009	\$ 353,757	\$ 215,195
Non-cash taxes (5)	1,864	(37,355)	(324,978)	(137,449)
Non-GAAP income tax provision	\$ 9,806	\$ 14,654	\$ 28,779	\$ 77,746

(1) Inventory fair value adjustment associated with the amortization of Kanuma inventory step-up related to the purchase accounting for Synageva.

In the third quarter, the Company initiated amortization of its purchased intangible assets due to the regulatory (2) approvals for Strensiq and Kanuma.

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

	Three months ended December 31		Twelve months ended December 31	
	2015	2014	2015	2014
Acquisition-related costs:				
Transaction costs	\$ 156	\$ -	\$ 26,955	\$ -
Integration costs	3,202	-	12,255	-
	\$ 3,358	\$ -	\$ 39,210	\$ -

(4) In the fourth quarter 2015, restructuring expenses includes \$11.2 million related to exit costs associated with the US headquarters relocation to New Haven, CT. During the twelve months ended December 31, 2015 restructuring expenses of \$42.2 million includes \$17.6 million related to the European headquarters relocation, \$13.4 million resulting from the acquisition of Synageva, and \$11.2 million related to exit costs associated with the US headquarters relocation to New Haven, CT.

(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 the third quarter 2015, the Company recorded a \$315.6 million GAAP income tax expense resulting from a non-cash deferred income tax expense from the integration of Synageva. The deferred income tax expense resulted from the integration of Synageva assets into our captive partnership.

ALEXION PHARMACEUTICALS, INC.
REVENUES
(in thousands)
(unaudited)

Three months ended

Twelve months ended

	December 31		December 31	
	2015	2014	2015	2014
Soliris (1)	\$ 688,477	\$ 599,476	\$ 2,590,197	\$ 2,233,733
Strensiq	11,612	-	11,969	-
Kanuma	336	-	366	-
Total net product revenues	700,425	599,476	2,602,532	2,233,733
Royalty revenue	442	-	1,515	-
Total other revenue	442	-	1,515	-
Total revenues	\$ 700,867	\$ 599,476	\$ 2,604,047	\$ 2,233,733

(1) Included within the Soliris revenues for the twelve months ended December 31, 2014 is a reimbursement of \$88 million for shipments made in years prior to January 1, 2014 as a result of an agreement with the French government.

ALEXION PHARMACEUTICALS, INC.
NET PRODUCT REVENUES GEOGRAPHY
(in thousands)
(unaudited)

	Three months ended December 31		Twelve months ended December 31	
	2015	2014	2015	2014
United States	\$ 272,725	\$ 212,966	\$ 951,307	\$ 730,089
Europe (1)	221,622	197,644	840,465	836,134
Asia-Pacific	73,360	65,562	276,350	244,059
Other	132,718	123,304	534,410	423,451
Total net product revenues	\$ 700,425	\$ 599,476	\$ 2,602,532	\$ 2,233,733

(1) Included within the Europe revenues for the twelve months ended December 31, 2014 is a reimbursement of \$88 million for shipments made in years prior to January 1, 2014 as a result of an agreement with the French government.

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

	December 31, 2015	December 31, 2014
Cash and cash equivalents	\$ 1,010,111	\$ 943,999
Marketable securities	374,904	1,017,567
Trade accounts receivable, net	532,832	432,888
Inventories	289,874	176,441
Prepaid expenses and other current assets	217,628	225,134
Property, plant and equipment, net	697,025	392,248
Intangible assets, net	4,707,914	587,046
Goodwill	5,047,885	254,073
Other assets	255,057	172,566
Total assets	\$ 13,133,230	\$ 4,201,962
Accounts payable and accrued expenses	\$ 460,708	\$ 439,248
Deferred revenue	20,504	58,837
Current portion of long-term debt	175,000	48,000

Other current liabilities	62,038	60,655
Long-term debt, less current portion	3,281,250	9,500
Contingent consideration	121,424	116,425
Facility lease obligation	151,307	107,099
Deferred tax liabilities	528,990	7,046
Other liabilities	73,393	53,134
Total liabilities	<u>4,874,614</u>	<u>899,944</u>
Total stockholders' equity	<u>8,258,616</u>	<u>3,302,018</u>
Total liabilities and stockholders' equity	<u>\$ 13,133,230</u>	<u>\$ 4,201,962</u>

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