

Alexion Reports Second Quarter 2016 Results

- Total Revenues of \$753 Million; Increased 18 Percent Year-on-Year; 23 Percent Volume Increase Year-on-Year-

- Soliris[®] (eculizumab) Revenue Growth Driven by Steady Number of New Patients with PNH and aHUS Treated Globally -

- Strong Strensiq[®] (asfotase alfa) Launch Continues in Initial Countries -

- Kanuma[®] (sebelipase alfa) Launch Progresses with Newly Identified Patients Starting on Treatment -

- Eculizumab Phase 3 REGAIN Data in Refractory gMG Presented at the ICNMD Congress -

- ALXN1210 Phase 1/2 Data Showed Rapid and Sustained Reductions in LDH in All Patients with PNH Treated with Once-Monthly Dosing -

- SBC-103 Phase 1/2 Data on MRI and Neurocognitive Assessments Consistent With Potential Dose-Dependent Disease Stabilization at Six Months in Patients with MPS IIIB -

- GAAP EPS of \$0.51 Per Share; Non-GAAP EPS of \$1.13 Per Share, Which Reflects a Reduction of \$0.12 Per Share Attributable to the Modification of Reported Non-GAAP Income Tax Expense -

NEW HAVEN, Conn.--(BUSINESS WIRE)-- Alexion Pharmaceuticals, Inc. (NASDAQ: ALXN) today announced financial results for the second quarter of 2016. Total revenues grew to \$753 million, an 18 percent increase, compared to \$636 million for the same period in 2015. In the second quarter, the negative impact of currency on total revenue was 3 percent or \$18 million, net of hedging activities, compared to the same quarter last year. On a GAAP basis, diluted earnings per share (EPS) for the second quarter of 2016 was \$0.51 per share, compared to \$0.83 per share in the second quarter of 2015. Non-GAAP diluted EPS for the second quarter 2016 was \$1.13 per share, reflecting a reduction of \$0.12 per share attributable to the modification non-GAAP diluted EPS would have been reported at \$1.25 per share (Table 2). Non-GAAP diluted EPS was \$1.30 per share in the second quarter 2015, reflecting a reduction of \$0.14 per share attributable to the tax modification.

Alexion has modified the definition of its non-GAAP income tax expense to align with the Compliance & Disclosure Interpretations (C&DIs) issued by the U.S. Securities and Exchange Commission (SEC) on May 17, 2016, and has reflected this modification in 2015 and 2016 non-GAAP interim period results. Alexion's modified definition no longer includes the cash tax benefits the Company realizes during the year from net operating losses and income tax credits, and now includes other deferred taxes. The modification does not change the amount of cash taxes the Company will pay in 2016, or in the future, or have any impact on cash flow. A reconciliation of GAAP to non-GAAP financial results (Table 2) and supplemental effective tax rate information for financial guidance (Table 6) are provided later in the press release.

"In Q2 2016, we delivered strong financial performance as we served an increasing number of patients with PNH, aHUS, HPP and LAL-D. We are pleased with the sustained growth in our core Soliris business, the strong launch of Strensiq, and the continued progress with our Kanuma launch," said David Hallal, Chief Executive Officer of Alexion. "In the second half of 2016, we will continue to leverage our rare disease expertise to reach more patients with Soliris, Strensiq and Kanuma while advancing multiple milestones in our robust pipeline."

Second Quarter 2016 Financial Highlights

- Soliris[®] (eculizumab) net product sales were \$701 million, compared to \$636 million in Q2 2015, representing a 10 percent increase. Soliris volume increased 15 percent year-on-year.
- Strensiq[®] (asfotase alfa) net product sales were \$45 million.
- Kanuma[®] (sebelipase alfa) net product sales were \$6 million.
- GAAP R&D expense was \$179 million, compared to \$132 million in the same quarter last year. Non-GAAP R&D expense was \$165 million, compared to \$117 million in the same quarter last year.

- GAAP SG&A expense was \$232 million, compared to \$221 million in the same quarter last year. Non-GAAP SG&A expense was \$200 million, compared to \$169 million in the same quarter last year.
- GAAP diluted EPS was \$0.51 per share, compared to \$0.83 per share in the same quarter last year. Non-GAAP diluted EPS was \$1.13 per share, reflecting a reduction of \$0.12 per share attributable to the modification of reported non-GAAP income tax expense, compared to \$1.30 per share, reflecting a reduction of \$0.14 per share attributable to the modification of non-GAAP income tax expense in the same quarter last year. GAAP and non-GAAP EPS in the second quarter of 2016 includes the impact of a full quarter of Synageva operations, shares issued for the acquisition and interest expense on related borrowings.

Product and Pipeline Updates

Complement Portfolio

- Eculizumab- Refractory Generalized Myasthenia Gravis (gMG): Data from the REGAIN study, a single, multinational, placebo-controlled Phase 3 trial of eculizumab in patients with refractory gMG, were presented at the International Congress on Neuromuscular Diseases (ICNMD) meeting. Alexion expects to provide an update on discussions with regulators by the end of the year.
- Eculizumab- Relapsing Neuromyelitis Optica Spectrum Disorder (NMOSD): Alexion expects to complete enrollment this year in the PREVENT study, a single, multinational, placebo-controlled Phase 3 trial of eculizumab in patients with relapsing NMOSD.
- Eculizumab- Delayed Graft Function (DGF): Enrollment is complete in the PROTECT study, a single, multinational, placebo-controlled Phase 3 trial of eculizumab in the prevention of DGF, and data are expected in the second half of 2016.
- ALXN1210: New data from the Phase 1/2 study of ALXN1210, a highly innovative longer-acting C5 antibody, in patients with paroxysmal nocturnal hemoglobinuria (PNH) were presented at the European Hematology Association (EHA) Congress. Alexion expects to present additional PNH data later this year. Alexion also expects to initiate a clinical program with ALXN1210 in patients with atypical hemolytic uremic syndrome (aHUS) later this year. The European Commission granted Orphan Drug Designation (ODD) to ALXN1210 for the treatment of patients with PNH.
- ALXN1007: New data from the Phase 2 study of ALXN1007, a complement inhibitor that targets C5a, in patients with graft-versus-host disease involving the lower gastrointestinal tract (GI-GVHD) were presented at EHA and Alexion is now evaluating higher doses of ALXN1007 in patients with GI-GVHD.

Metabolic Portfolio

- SBC-103: New Phase 1/2 data of SBC-103, a recombinant form of the NAGLU enzyme, in patients with mucopolysaccharidosis IIIB, or MPS IIIB, were presented at the International Symposium on MPS and Related Diseases meeting. Alexion has now completed the planned dose escalation, with all patients now randomized to either a 5 mg/kg or 10 mg/kg dose. A natural history study to characterize the course of disease progression in patients with MPS IIIB is ongoing.
- cPMP Replacement Therapy (ALXN1101): Alexion is enrolling patients in a pivotal study to evaluate ALXN1101 in neonates with Molybdenum Cofactor Deficiency (MoCD) Type A. A study to characterize the natural history of MoCD type A was completed in Q2.

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

Alexion is reiterating its total revenue and Soliris guidance ranges provided on the first quarter of 2016 earnings call on April 28, 2016, and based on the strength of the Strensiq launch is increasing its Metabolic revenue guidance to \$200 to \$220 million. Alexion is reiterating its non-GAAP operating expense guidance and is updating its non-GAAP tax rate and non-GAAP EPS guidance. Alexion is also issuing 2016 GAAP financial guidance.

2016 financial guidance is as follows:

	GAAP Guidance	Updated Non-GAAP Guidance	Prior Non-GAAP Guidance
Total revenues	\$3,050 to \$3,100 million	\$3,050 to \$3,100 million	Low end of \$3,050 to \$3,100 million
Soliris revenues	\$2,835 to \$2,875 million	\$2,835 to \$2,875 million	\$2,835 to \$2,875 million
Metabolic revenues	\$200 to \$220 million	\$200 to \$220 million	\$180 to \$200 million
Cost of sales	8% to 9%	8% to 9%	8% to 9%
Research and development expense	\$708 to \$779 million	High end of \$650 to \$680 million	High end of \$650 to \$680 million
Selling, general and administrative expense	\$883 to \$935 million	High end of \$760 to \$790 million	High end of \$760 to \$790 million
Interest expense	\$100 million	\$100 million	\$100 million
Effective tax rate	32% to 34%	15.5% to 16.5% (1)	7% to 8%
Earnings per share	\$1.91 to \$2.26	\$4.50 to \$4.65	Low end of \$5.00 to \$5.20
Diluted shares outstanding	228 million	230 million	230 million

Alexion's 2016 financial guidance is based on current foreign exchange rates net of hedging activities, and does not include the effect of business combinations, license and collaboration agreements, asset acquisitions, intangible asset impairments, changes in fair value of contingent consideration or restructuring activity that may occur after the day prior to the date of this press release.

(1) Alexion has modified the definition of its non-GAAP income tax expense. The modified definition no longer includes the cash tax benefits the Company realizes during the year from net operating losses and income tax credits, and now includes other deferred taxes. The modification does not change the amount of cash taxes the Company will pay in 2016, or in the future, or have any impact on cash flow. Refer to the reconciliation of GAAP to non-GAAP financial guidance (Table 3) and the supplemental effective tax rate information for financial guidance (Table 6) provided later in the press release.

Conference Call/Webcast Information:

Alexion will host a conference call/audio webcast to discuss matters mentioned in this release. The call is scheduled for today, July 28, at 10:00 a.m., Eastern Time. To participate in this call, dial 888-505-4328 (USA) or 719-325-2344 (International), passcode 3353485 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), passcode 3353485. The audio webcast can be accessed on the Investor page of Alexion's website at: 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 press 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 March 31, 2016 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 press 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, upfront and milestone payments related to licenses and collaborations and adjustments to income tax expense. 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 Reconciliations of GAAP to non-GAAP Financial Results and GAAP to non-GAAP 2016 Financial Guidance for explanations of the amounts adjusted to arrive at non-GAAP net income and non-GAAP earnings per share amounts for the three and six month periods ended June 30, 2016 and 2015 and projected twelve months ended December 31, 2016.

(Tables Follow)

ALEXION PHARMACEUTICALS, INC. TABLE 1: CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (in thousands, except per share amounts) (unaudited)

		nths ended ne 30		hs ended e 30
	2016	2015	2016	2015
Net product sales	\$752,546	\$ 635,983	\$1,452,971	\$1,236,316
Other revenue	570	227	1,183	227
Total revenues	753,116	636,210	1,454,154	1,236,543
Cost of sales	60,627	52,007	119,613	121,406
Operating expenses:				
Research and development	179,311	131,693	355,601	352,773
Selling, general and administrative	231,802	221,383	464,363	408,499
Amortization of purchased intangible assets	80,055	-	160,149	-
Change in fair value of contingent consideration	5,186	4,044	(9,614)	16,023
Acquisition-related costs	974	29,777	2,313	29,777
Restructuring expenses	455	16,224	1,177	23,276
Total operating expenses	497,783	403,121	973,989	830,348
Operating income	194,706	181,082	360,552	284,789
Other income and expense:				
Investment income	1,872	2,226	3,423	5,110
Interest expense	(23,793)	(3,971)	(47,683)	(4,622)

Foreign currency loss	(2,820)	(2,045)	(2,729)	(1,040)			
Income before income taxes	169,965	177,292	313,563	284,237			
Income tax expense	55,022	7,077	106,454	22,699			
Net income	\$ 114,943	\$ 170,215	\$ 207,109	\$ 261,538			
Earnings per common share							
Basic	\$ 0.51	\$ 0.84	\$ 0.92	\$ 1.30			
Diluted	\$ 0.51	\$ 0.83	\$ 0.92	\$ 1.29			
Shares used in computing earnings per common share							
Basic	224,089	202,234	224,593	200,806			

Diluted

ALEXION PHARMACEUTICALS, INC. TABLE 2: RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL RESULTS (in thousands, except per share amounts) (unaudited)

225,756

204,546

226,328

203,302

	Three months ended June 30			Six months ended June 30				
		2016	2015		2016		. <u> </u>	2015
GAAP net income	\$	114,943	\$	170,215	\$	207,109	\$	261,538
Before tax adjustments:								
Cost of sales:								
Share-based compensation		2,078		1,344		5,481		2,753
Fair value adjustment on inventory acquired (1)		1,326		-		1,857		-
Research and development expense:								
Share-based compensation		14,394		13,329		29,579		24,413
Upfront and milestone payments related to licenses								
and collaborations		-		1,750		3,050		114,250
Selling, general and administrative expense:								
Share-based compensation		31,507		52,327		69,808		82,631
Amortization of purchased intangible assets (2)		80,055		-		160,149		-
Change in fair value of contingent consideration (3)		5,186		4,044		(9,614)		16,023
Acquisition-related costs (4)		974		29,777		2,313		29,777
Restructuring expenses		455		16,224		1,177		23,276
Adjustments to income tax expense (5)		6,843		(20,172)		14,499		(27,880)
Non-GAAP net income	\$	257,761	\$	268,838	\$	485,408	\$	526,781
CAAD corrigge per abara diluted	¢	0.51	¢	0.92	¢	0.02	¢	1.00
GAAP earnings per share - diluted	\$	0.51	\$	0.83	\$	0.92	\$	1.29
Non-GAAP earnings per share - diluted (6)	\$	1.13	\$	1.30	\$	2.12	\$	2.56
Shares used in computing diluted earnings per share								
(GAAP)	_	225,756		204,546		226,328		203,302
Shares used in computing diluted earnings per share (non-GAAP)		228,212		206,934		228,720		205,488

- (1) Inventory fair value adjustment associated with the amortization of Kanuma inventory step-up related to the purchase accounting for Synageva.
- (2) In the third quarter of 2015, the Company initiated amortization of its purchased intangible assets due to the regulatory approvals for Strensiq and Kanuma.
- (3) In the first quarter of 2016, the Company realized a change in fair value of contingent consideration due to changes in the likelihood of payments for contingent consideration associated with our prior business combinations.
- (4) The following table summarizes acquisition-related costs:

	Т	Three months ended June 30			Six months ended June 30			
	20	016		2015		2016		2015
Acquisition-related costs:								
Transaction costs	\$	-	\$	26,799	\$	375	\$	26,799
Integration costs		974		2,978		1,938		2,978
	\$	974	\$	29,777	\$	2,313	\$	29,777

- (5) Alexion's modified non-GAAP income tax expense definition includes the tax effect of pre-tax adjustments to GAAP net income, intercompany transactions with our captive foreign partnership which would become due and payable only upon liquidation of a substantial portion of our non-US business interests, and share based compensation deductions not included in GAAP tax expense.
- (6) Alexion has modified its non-GAAP income tax expense definition. The following table is provided for informational purposes only, during the period of the modification, and will not be included in future earnings releases.

	Three months ended June 30			Six months ended June 30				
		2016		2015	2	2016		2015
Non-GAAP earnings per share - diluted Reduction attributable to the modified definition of non-	\$	1.13	\$	1.30	\$	2.12	\$	2.56
GAAP income tax expense	\$	0.12	\$	0.14	\$	0.24	\$	0.16
	\$	1.25	\$	1.44	\$	2.36	\$	2.72

ALEXION PHARMACEUTICALS, INC. TABLE 3: RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL GUIDANCE (in millions, except per share amounts) (unaudited)

	Twelve months ended December 31, 2016					
Low		High				
\$	435	\$	515			
	12		5			
		Low \$ 435	Low H \$ 435 \$			

Fair value adjustment on inventory acquired Research and development expense:	5	2
Share-based compensation	73	55
Upfront and milestone payments related to licenses and collaborations	26	3
Selling, general and administrative expense:		
Share-based compensation	145	123
Amortization of purchased intangible assets	320	320
Change in fair value of contingent consideration	(2)	(2)
Acquisition-related costs	2	2
Restructuring expenses	2	1
Adjustments to income tax expense	17	46
Non-GAAP net income guidance	\$ 1,035	\$ 1,070
Diluted GAAP earnings per share	\$ 1.91	\$ 2.26
Diluted Non-GAAP earnings per share	\$ 4.50	\$ 4.65
Shares used in computing diluted earnings per share guidance (GAAP)	 228	 228
Shares used in computing diluted earnings per share guidance (non-GAAP)	 230	 230

ALEXION PHARMACEUTICALS, INC.

TABLE 4: REVENUES (in thousands) (unaudited)

	Tł	Three months ended June 30			Six months ended June 30				
		2016		2015	2016	2015			
Soliris	\$	701,009	\$	635,983	\$1,365,665	\$1,236,316			
Strensiq		45,141		-	78,383	-			
Kanuma		6,396		-	8,923	-			
Total net product sales		752,546		635,983	1,452,971	1,236,316			
Royalty revenue		570		227	1,183	227			
Total other revenue		570		227	1,183	227			
Total revenues	\$	753,116	\$	636,210	\$1,454,154	\$1,236,543			

ALEXION PHARMACEUTICALS, INC. TABLE 5: CONDENSED CONSOLIDATED BALANCE SHEETS (in thousands) (unaudited)

	•	June 30 2016		cember 31 2015	
Cash and cash equivalents	\$	597,550	\$	1,010,111	
Marketable securities		582,501		374,904	
Trade accounts receivable, net		609,297		532,832	
Inventories		329,847		289,874	
Prepaid expenses and other current assets		242,014		208,993	
Property, plant and equipment, net		825,301		697,025	
Intangible assets, net		4,547,762		4,707,914	
Goodwill		5,037,444		5,047,885	

Other assets Total assets	257,631 \$13,029,347	228,343 \$ 13,097,881
Accounts payable and accrued expenses	\$ 436,267	\$ 460,708
Deferred revenue	53,422	20,504
Current portion of long-term debt	79,136	166,365
Other current liabilities	89,637	62,038
Long-term debt, less current portion	3,171,092	3,254,536
Facility lease obligation	196,439	151,307
Contingent consideration	109,565	121,424
Deferred tax liabilities	570,074	528,990
Other liabilities	124,376	73,393
Total liabilities	4,830,008	4,839,265
Total stockholders' equity	8,199,339	8,258,616
Total liabilities and stockholders' equity	\$13,029,347	\$ 13,097,881

ALEXION PHARMACEUTICALS, INC.

TABLE 6: SUPPLEMENTAL EFFECTIVE TAX RATE INFORMATION FOR FINANCIAL GUIDANCE - FOR INFORMATION PURPOSES ONLY

(unaudited)

	Twelve months ended December 31, 2016				
	High	Low			
GAAP income tax expense as a percentage of GAAP pre-tax income	34%	32%			
Tax effect of pre-tax adjustments to GAAP net income	(6.5%)	(4.5%)			
Tax effect of intercompany transactions (1) Share-based compensation deductions not	(11.0%)	(11.0%)			
included in GAAP tax expense		(1.0%)			
Non-GAAP income tax expenses as a percentage of non -GAAP pre-tax income	16.5%	15.5%			
Effect of other tax attributes (2)	(8.5%)	(8.5%)			
Cash taxes as a percentage of non-GAAP pre-tax income (3)	8.0%	7.0%			

- (1) Primarily related to deferred tax resulting from intercompany transactions with our captive foreign partnership. This deferred tax expense is not correlated to income before income taxes and would become due and payable only upon liquidation of a substantial portion of our non-US business interests.
- (2) Primarily related to deferred tax expense attributable to the utilization of acquired Synageva net operating losses and tax credits. We expect to substantially utilize these losses and credits prior to the fiscal year ending December 31, 2018.
- (3) Represents the amount of income taxes accrued during the period that will be due and payable in cash in connection with Alexion's income tax returns for the period as a percentage of non-GAAP pre-tax income.

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