October 29, 2015

Alexion Reports Third Quarter 2015 Results

- Soliris® (eculizumab) Net Product Sales of $665.4 Million; Increased 20% Year-on-Year Despite 9% Currency Headwinds; 29% Volume Increase Year-on-Year -

- 2015 Non-GAAP EPS Guidance Increased to $4.92 to $4.97 -

-Strensiq™ (asfotase alfa) Approved in the United States, European Union, Japan and Canada for Hypophosphatasia (HPP) -

- Kanuma™ (sebelipase alfa) Approved in the European Union for Lysosomal Acid Lipase Deficiency (LAL-D) -

- Completed Enrollment in Registration Trial of Eculizumab in Refractory MG and Progressed Registration Trials in Relapsing NMO and DGF -

- Advanced Complement and Metabolic Pipelines, Including ALXN 1210 and SBC-103 -

CHESHIRE, Conn.--(BUSINESS WIRE)-- Alexion Pharmaceuticals, Inc. (NASDAQ:ALXN) today announced financial results for the third quarter of 2015. Total revenues grew to $666.6 million, a 20 percent increase, compared to $555.1 million for the same period in 2014, despite 9 percent currency headwinds. Results for the third quarter of 2015 reflect results of Synageva's operations for the first full quarter following the close of the stock and cash acquisition on June 22, 2015. Non-GAAP diluted earnings per share (EPS) for the third quarter of 2015 were $1.16, compared to $1.27 in the third quarter of 2014. On a GAAP basis, net loss for the third quarter of 2015 was $0.81 per share, impacted by $315.6 million, or $1.39 per share, related to a non-cash deferred income tax expense resulting from the integration of Synageva, compared to diluted GAAP EPS of $0.88 in the third quarter of 2014.

"The third quarter of 2015 was a landmark quarter for Alexion as we firmly established our leadership in serving patients with rare and devastating diseases by diversifying our commercial portfolio, advancing the most robust rare disease pipeline in biotech, and continuing to deliver long-term value creation," said David Hallal, Chief Executive Officer of Alexion. "In the remaining months of 2015, we will continue to grow our core Soliris business in PNH and aHUS, focus on our launches of Strensiq and Kanuma, and will report on several R&D catalysts that are expected in the fourth quarter."

Third Quarter 2015 Financial Highlights

- Total revenues were $666.6 million compared to $555.1 million in the same quarter last year. Soliris net product sales were $665.4 million, and total net product sales were $665.8. A breakdown of total revenues is included later in this press release.
- Non-GAAP R&D expense was $146.6 million compared to $92.7 million in the same quarter last year. GAAP R&D expense was $165.7 million compared to $100.7 million in the same quarter last year.
- Non-GAAP SG&A expense was $182.0 million compared to $138.3 million in the same quarter last year. GAAP SG&A expense was $212.5 million compared to $157.7 million in the same quarter last year.
- Non-GAAP effective tax rate was 0.5 percent compared to 5.4 percent in the same quarter last year.
- Non-GAAP diluted EPS was $1.16, compared to $1.27 in the same quarter last year. On a GAAP basis, net loss was $0.81 per share compared to diluted EPS of $0.88 in the same quarter last year. Q3 2015 GAAP net loss was impacted by $315.6 million, or $1.39 per share, related to a non-cash deferred income tax expense resulting from the integration of Synageva.
- As of September 30, 2015, Alexion held cash, cash equivalents and marketable securities of $1.5 billion.

Product and Pipeline Updates

Complement Portfolio

- **Neurology- 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 is expected in mid-2016.

- **Neurology- Neuromyelitis Optica (NMO):** Alexion expects to complete enrollment in the PREVENT study, a single, multinational, placebo-controlled, registration trial of eculizumab in relapsing NMO, in 2016.
- **Kidney Transplant- Delayed Graft Function (DGF):** Alexion expects to complete enrollment in the PROTECT study, a single, multinational DGF prevention registration trial with eculizumab, in the fourth quarter.
- **Kidney Transplant- Antibody-Mediated Rejection (AMR):** Researchers will present updated 1-year data from a single-arm Phase 2 study of eculizumab in the prevention of acute AMR in sensitized deceased-donor kidney transplant recipients at the American Society of Nephrology meeting.
- **ALXN 1210:** Alexion is completing the Phase 1 multiple ascending dose study of ALXN1210, its lead next-generation Soliris molecule, and expects to initiate a proof-of-concept study with ALXN 1210 in patients with paroxysmal nocturnal hemoglobinuria (PNH) in the fourth quarter.
- **ALXN 1007:** Enrollment and dosing are ongoing in a Phase 2 proof-of-concept study in patients with graft-versus-host disease involving the lower gastrointestinal tract (GI-GVHD), a severe, autoimmune disease with potentially life-threatening complications. Alexion expects to have interim data from the GI-GVHD study in the fourth quarter.

Metabolic Portfolio

- **Strensiq™ (asfotase alfa):** Strensiq was approved by the U.S. Food and Drug Administration under Breakthrough Therapy Designation and Priority Review for the treatment of patients with perinatal-, infantile- and juvenile-onset hypophosphatasia (HPP). Strensiq was also approved in the European Union, Japan and Canada.
- **Kanuma™ (sebelipase alfa):** Kanuma was approved in the European Union for the treatment of patients of all ages with lysosomal acid lipase deficiency (LAL-D). The regulatory processes for Kanuma in the U.S. and Japan are ongoing. The FDA granted Breakthrough Therapy designation for Kanuma for LAL-D presenting in infants and accepted the BLA for Priority Review.
- **SBC-103:** A Phase 1/2 trial of SBC-103, an enzyme replacement therapy being investigated for patients with mucopolysaccharidosis IIIB, or MPS IIIB or Sanfilippo B, is ongoing and preliminary data are expected in the fourth quarter of 2015. Alexion completed enrollment in a natural history study of patients with MPS IIIB.
- **cPMP Replacement Therapy (ALXN 1101):** Alexion completed planned enrollment in the synthetic cPMP bridging study and the natural history study in patients with molybdenum cofactor deficiency (MoCD) Type A. The Company plans to initiate a pivotal study with ALXN 1101 in the fourth quarter. Alexion received Breakthrough Therapy designation for its cPMP replacement therapy in 2013.

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.

2015 Financial Guidance

Alexion expects 2015 total revenues to be at the lower end of our previously guided range of $2.6 billion to $2.62 billion, primarily due to macroeconomic factors in Latin American countries. 2015 revenue guidance includes an approximately negative 6 percent, or $160 million, foreign exchange impact compared to 2014 exchange rates. Alexion continues to forecast strong volume growth of 28 percent for the full year 2015 compared to 2014.

Alexion is increasing 2015 non-GAAP EPS guidance to the range of $4.92 to $4.97 per share, from the previous range of $4.70 to $4.80 per share.

Updated 2015 non-GAAP financial guidance is as follows:

	Revised Guidance	Prior Guidance
Cost of sales	8% to 9% of net product sales	8% to 9% of net product sales
Research and development expense	$500 to $510 million	$520 to $540 million
Selling, general and administrative expense	$700 to $710 million	$690 to $710 million
Interest expense	$55 million	$55 million
Effective tax rate	3% to 4 %	3% to 4 %
Diluted shares outstanding	219 million	219 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, October 29, at 10:00 a.m., Eastern Time. To participate in this conference call, dial 877-876-9176 (USA) or 785-424-1667 (International), passcode 582738 shortly before 10:00 a.m. ET. A replay of the call will be available for a limited time by dialing 888-203-1112 (USA) or 719-457-0820 (International), passcode 582738. 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 (LAD). 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.

[ALXN-E]

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, Strensiq and Kanuma, medical and commercial potential of Alexion's complement-inhibition technology and other technologies, commercial potential of Strensiq and Kanuma, including launch expectations, 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 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 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, 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, 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, amortization of purchased intangible assets, 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 nine month periods ended September 30, 2015 and 2014.

(Tables Follow)

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	
	2015	2014	2015	2014
Net product sales	$ 665,791	$555,146	$1,902,107	$1,634,257
Other revenue	846	-	1,073	-
Total revenues	666,637	555,146	1,903,180	1,634,257
Cost of sales	54,057	51,858	175,463	124,423
Operating expenses:				
Research and development	165,664	100,661	518,437	384,672
Selling, general and administrative	212,520	157,665	621,019	446,433
Amortization of purchased intangible assets	36,608	-	36,608	-
Acquisition-related costs	35,759	8,303	81,559	10,254
Restructuring expenses	7,461	-	30,737	-
Impairment of intangible asset	-	-	-	3,464
Total operating expenses	458,012	266,629	1,288,360	844,823
Operating income	154,568	236,659	439,357	665,011
Other income and expense:				
Investment income	1,967	2,250	7,077	6,177
Interest expense	(19,971)	(655)	(24,593)	(2,433)
Foreign currency gain (loss)	2,795	(2,045)	1,755	(1,989)
Income before income taxes	139,359	236,209	423,596	666,766
Income tax provision	323,116	58,478	345,815	163,186
Net income (loss)	$(183,757)	$177,731	$ 77,781	$ 503,580
Earnings (loss) per common share				
Basic	$ (0.81)	$ 0.90	$ 0.37	$ 2.54
Diluted	$ (0.81)	$ 0.88	$ 0.37	$ 2.50
Shares used in computing earnings (loss) per common share				
Basic	226,228	198,052	209,373	197,910
Diluted	226,228	201,313	211,808	201,528

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	
	2015	2014	2015	2014
Net income (loss) reconciliation:				

GAAP net income (loss)	$ (183,757)	$ 177,731	$ 77,781	$ 503,580
Share-based compensation expense	51,056	28,366	160,853	80,621
Amortization of purchased intangible assets (1)	36,608	-	36,608	-
Acquisition-related costs (2)	35,759	8,303	81,559	10,254
Restructuring expenses (3)	7,461	-	30,737	-
Impairment of intangible asset	-	-	-	3,464
Upfront and milestone payments related to license and collaboration agreements	-	-	114,250	101,925
Non-cash taxes (4)	321,792	43,866	326,842	100,094
Non-GAAP net income	$ 268,919	$ 258,266	$ 828,630	$ 799,938
GAAP earnings (loss) per share - diluted	$ (0.81)	$ 0.88	$ 0.37	$ 2.50
Non-GAAP earnings per share - diluted	$ 1.16	$ 1.27	$ 3.87	$ 3.91
Shares used in computing diluted earnings (loss) per share (GAAP)	226,228	201,313	211,808	201,528
Shares used in computing diluted earnings per share (non-GAAP)	230,875	203,992	214,146	204,417
Cost of sales reconciliation:				
GAAP cost of sales	$ 54,057	$ 51,858	$ 175,463	$ 124,423
Share-based compensation expense	(1,470)	(1,059)	(4,223)	(2,906)
Non-GAAP cost of sales	$ 52,587	$ 50,799	$ 171,240	$ 121,517
Research and development expense reconciliation:				
GAAP research and development expense	$ 165,664	$ 100,661	$ 518,437	$ 384,672
Share-based compensation expense	(19,087)	(7,936)	(43,500)	(23,374)
Upfront and milestone payments related to license and collaboration agreements	-	-	(114,250)	(101,925)
Non-GAAP research and development expense	$ 146,577	$ 92,725	$ 360,687	$ 259,373
Selling, general and administrative expense reconciliation:				
GAAP selling, general and administrative expense	$ 212,520	$ 157,665	$ 621,019	$ 446,433
Share-based compensation expense	(30,499)	(19,371)	(113,130)	(54,341)
Non-GAAP selling, general and administrative expense	$ 182,021	$ 138,294	$ 507,889	$ 392,092
Income tax provision reconciliation:				
GAAP income tax provision	$ 323,116	$ 58,478	$ 345,815	$ 163,186
Non-cash taxes (4)	(321,792)	(43,866)	(326,842)	(100,094)
Non-GAAP income tax provision	$ 1,324	$ 14,612	$ 18,973	$ 63,092

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

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

	Three months ended September 30		Nine months ended September 30	
	2015	2014	2015	2014
Acquisition-related costs:				
Transaction costs	$ -	$ -	$ 26,799	$ -
Integration costs	6,075	-	9,053	-
Changes in fair value of contingent consideration	29,684	8,303	45,707	10,254
	$ 35,759	$ 8,303	$ 81,559	$ 10,254

(3)Restructuring expenses of $7.5 million includes $3.2 million resulting from the Synageva acquisition and $4.3 million related to the European headquarters relocation.

(4)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 results from a change in the deferred tax liability associated with an outside basis difference in our captive partnership.

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

	Three months ended September 30		Nine months ended September 30	
	2015	2014	2015	2014
Soliris	$ 665,404	$ 555,146	$1,901,720	$1,634,257
Strensiq	357	-	357	-
Kanuma	30	-	30	-
Total net product sales	665,791	555,146	1,902,107	1,634,257
Royalty revenue	846	-	1,073	-
Total other revenue	846	-	1,073	-
Total revenues	$ 666,637	$ 555,146	$1,903,180	$1,634,257

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

	September 30, 2015	December 31, 2014
Cash and cash equivalents	$ 1,163,281	$ 943,999
Marketable securities	295,211	1,017,567
Trade accounts receivable, net	512,253	432,888
Inventories	236,542	176,441
Prepaid expenses and other current assets	272,932	225,134
Property, plant and equipment, net	618,733	392,248
Intangible assets, net	4,787,901	587,046
Goodwill	5,015,519	254,073
Other assets	250,643	172,566
Total assets	$ 13,153,015	$ 4,201,962
Accounts payable and accrued expenses	$ 404,961	$ 439,248
Deferred revenue	49,944	58,837
Deferred tax liabilties, current	132,619	12,476
Current portion of long-term debt	175,000	48,000

Other current liabilities	4,336	48,179
Long-term debt, less current portion	3,325,000	9,500
Deferred tax liabilties	417,319	7,046
Facility lease obligation	149,604	107,099
Contingent consideration	158,678	116,425
Other liabilities	82,685	53,134
Total liabilities	4,900,146	899,944
Total stockholders' equity	8,252,869	3,302,018
Total liabilities and stockholders' equity	$ 13,153,015	$ 4,201,962

View source version on businesswire.com: http://www.businesswire.com/news/home/20151029005421/en/

Alexion:
Media
Stephanie Fagan, 203-271-8223
Senior Vice President, Corporate Communications
or
Kim Diamond, 203-439-9600
Executive Director, Corporate Communications
or
Investors
Elena Ridloff, CFA, 203-699-7722
Executive Director, Investor Relations

Source: Alexion Pharmaceuticals, Inc.