July 30, 2015

Alexion Reports Second Quarter 2015 Results

- Soliris® (eculizumab) Net Product Sales of $636 Million; Increased 24% Year-on-Year Despite Currency Headwinds; 31% Volume Increase Year-on-Year -

- 2015 Revenue Guidance Increased Reflecting Strong Growth of Soliris in PNH and aHUS -

- Positive CHMP Opinions Received for Strensiq™ (asfotase alfa) for Hypophosphatasia (HPP) and Kanuma™ (sebelipase alfa) for Lysosomal Acid Lipase Deficiency (LAL-D) in the European Union -

- Strensiq Approved in Japan; Kanuma NDA Filed in Japan -

- Exceeded Target Enrollment in Eculizumab Refractory Myasthenia Gravis Registration Trial -

- Completed Synageva Acquisition -

CHESHIRE, Conn.--(BUSINESS WIRE)-- Alexion Pharmaceuticals, Inc. (NASDAQ:ALXN) today announced financial results for the second quarter of 2015. Net product sales of Soliris® (eculizumab) grew to $636 million, a 24% increase, compared to $512.5 million for the same period in 2014, despite currency headwinds. Non-GAAP diluted earnings per share (EPS) for the second quarter of 2015 were $1.44, compared to $1.12 in the second quarter of 2014. On a GAAP basis, diluted EPS for the second quarter of 2015 was $0.83 per share, impacted by $40.1 million, or $0.20 per share, related to acquisition and restructuring costs resulting from the Synageva acquisition, compared to $0.83 in the second quarter of 2014.

"In the second quarter of 2015, we achieved many significant commercial, development and financial milestones while also closing the Synageva acquisition to strengthen our position as the global leader in serving patients with devastating and rare diseases," said David Hallal, Chief Executive Officer of Alexion. "In the second half of 2015, we will continue to serve more patients with PNH and aHUS, while simultaneously launching Strensiq and Kanuma globally, and advancing our broad pipeline of innovative therapies to support our future growth."

Second Quarter 2015 Financial Highlights

- Net product sales of Soliris® were $636 million compared to $512.5 million in the same quarter last year.
- Non-GAAP R&D expense was $116.6 million compared to $85.1 million in the same quarter last year. GAAP R&D expense was $131.7 million compared to $92.6 million in the same quarter last year.
- Non-GAAP SG&A expense was $169.1 million compared to $139.5 million in the same quarter last year. GAAP SG&A expense was $221.4 million compared to $159.5 million in the same quarter last year.
- Non-GAAP effective tax rate was a benefit of 0.6% compared to tax expense of 8.0% in the same quarter last year. In Q2 2015, the Company benefitted from the utilization of operating losses from Synageva in 2015.
- Non-GAAP diluted EPS was $1.44, compared to $1.12 in the same quarter last year. On a GAAP basis, diluted EPS was $0.83 compared to $0.83 in the same quarter last year. Q2 2015 GAAP EPS was impacted by $40.1 million, or $0.20 per share, related to acquisition and restructuring costs resulting from the Synageva acquisition.
- As of June 30, 2015, Alexion had cash, cash equivalents and marketable securities of $1.5 billion.

Product and Pipeline Updates

Complement Portfolio

- **Neurology- Myasthenia Gravis (MG):** Alexion exceeded the target enrollment in the REGAIN study, a single, multinational, placebo-controlled, registration trial of eculizumab in refractory MG.
- **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 2015.
- **Kidney Transplant- Antibody-Mediated Rejection (AMR):** Alexion reported preliminary 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 Transplant Congress.
- **ALXN 1210 and ALXN 5500:** The Company advanced Phase 1 studies with its first two next-generation Soliris molecules, and expects to initiate a Phase 2 trial with ALXN 1210 in patients with paroxysmal nocturnal hemoglobinuria (PNH) in 2015.
- **ALXN 1007:** Enrollment and dosing are ongoing in two Phase 2 proof-of-concept studies in patients with graft versus host disease involving the lower gastrointestinal tract (GI-GVHD) and antiphospholipid syndrome (APS), two severe, autoimmune diseases with potentially life-threatening complications. Alexion expects to have interim data from the GI-GVHD study later this year.

Metabolic Portfolio

- **Strensiq™ (asfotase alfa):** Strensiq received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommending marketing authorization for long-term enzyme replacement therapy in patients with pediatric-onset HPP. Strensiq was also approved by Japan's Ministry of Health, Labour and Welfare (MHLW) for the treatment of patients with HPP. The regulatory process for Strensiq in the U.S. is ongoing. The Food and Drug Administration (FDA) previously granted Breakthrough Therapy designation for Strensiq and accepted Alexion's Biologics License Application (BLA) for Priority Review.
- **Kanuma™ (sebelipase alfa):** Kanuma received a positive CHMP opinion from the EMA recommending marketing authorization for long-term enzyme replacement therapy in patients of all ages with lysosomal acid lipase deficiency (LAL-D). In Q2, a New Drug Application for Kanuma was also submitted to Japan's MHLW as a treatment for patients with LAL-D. The regulatory process for Kanuma in the U.S. is ongoing. The FDA granted Breakthrough Therapy designation for Kanuma for LAL-D presenting in infants and accepted the BLA for Priority Review.
- **SBC-103:** Enrollment was completed in a Phase 1/2 trial of SBC-103, an enzyme replacement therapy being investigated for patients with mucopolysaccharidosis IIIB, or MPS IIIB. Preliminary data are expected in the second half of 2015.
- **cPMP Replacement Therapy (ALXN 1101):** Alexion completed enrollment in the synthetic cPMP bridging study in patients with molybdenum cofactor deficiency (MoCD) Type A and enrollment in a natural history study is ongoing. The Company plans to initiate a pivotal study with ALXN 1101 by the end of 2015. Alexion received Breakthrough Therapy designation for its cPMP replacement therapy in 2013.

Preclinical Portfolio

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

2015 Financial Guidance

Alexion today announced that the Company is revising upward its revenue guidance for 2015 from the previous range of $2.55 to $2.6 billion, now to the higher and narrower range of $2.6 to $2.62 billion, which includes an approximately negative 6 percent, or $160 million, foreign exchange impact compared to 2014 exchange rates.

Alexion is reducing its 2015 non-GAAP tax rate guidance to the lower range of 3 percent to 4 percent, from the previous range of 7 percent to 9 percent. Alexion is also reducing its longer-term non-GAAP tax rate guidance to the lower range of 12 percent to 14 percent in 2019 and beyond, from the previous range of 14 percent to 16 percent, a reduction of 2 percent.

Alexion is also revising 2015 non-GAAP financial guidance as follows, which reflects the inclusion of Synageva financial results into Alexion's consolidated results beginning June 22, 2015, the acquisition closing date:

Cost of sales	8% to 9% of net product sales
Research and development expense	$520 to $540 million
Selling, general and administrative expense	$690 to $710 million
Interest expense	$55 million
Effective tax rate	3% to 4 %
Diluted shares outstanding	219 million

As a result of these changes, Alexion is revising 2015 non-GAAP EPS guidance to the range of $4.70 to $4.80 per share, from the previous range of $5.60 to $5.80 per share.

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 30, at 10:00 a.m., Eastern Time. To participate in this call, dial 1-888-500-6973 (USA) or + 719-457-2643 (International), passcode 3227303 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 3227303. The audio webcast and slide presentation 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 Strensiq™ (asfotase alfa)

Strensiq™ (asfotase alfa) is an investigational first-in-class bone-targeted enzyme replacement therapy designed to address the underlying cause of hypophosphatasia (HPP)—deficient alkaline phosphatase (ALP). By replacing deficient ALP, treatment with Strensiq aims to improve the elevated enzyme substrate levels and improve the body's ability to mineralize bone, thereby preventing serious skeletal and systemic patient morbidity and premature death.

The FDA granted Breakthrough Therapy designation for Strensiq and accepted Alexion's Biologics License Application (BLA) for Priority Review. Alexion has also submitted a Marketing Authorization Application (MAA) for Strensiq to the EMA. Strensiq is approved by Japan's Ministry of Health, Labour and Welfare (MHLW) for the treatment of patients with HPP.

About Kanuma™ (sebelipase alfa)

Kanuma™ (sebelipase alfa) is an investigational first-in-class enzyme replacement therapy designed to address the underlying cause of lysosomal acid lipase deficiency (LAL-D). By replacing deficient LAL, treatment with Kanuma aims to reduce substrate accumulation and improve lipid metabolism to prevent chronic lipid accumulation, vital organ damage and premature death.

The FDA granted Breakthrough Therapy designation for Kanuma for LAL Deficiency presenting in infants. The FDA accepted the Kanuma BLA for Priority Review, and the EMA validated the MAA for Kanuma and is reviewing it under accelerated assessment. In addition, a New Drug Application for Kanuma has been submitted to Japan's MHLW.

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. Alexion is also establishing a premier global metabolic rare disease franchise with the development of two late-stage therapies, Strensiq™ (asfotase alfa) for hypophosphatasia (HPP) and Kanuma™ (sebelipase alfa) for 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. As the global leader in complement inhibition, Alexion is strengthening and broadening its portfolio of complement inhibitors across diverse platforms, including evaluating potential indications for Soliris in additional severe and ultra-rare disorders. 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, Strensiq and Kanuma, medical and commercial potential of Alexion's complement-inhibition technology and other technologies, commercial potential associated with the expected launches of Strensiq and Kanuma 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 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 March 31, 2015 and in our other filings with the U.S. Securities and Exchange Commission, including the Registration Statement on Form S-4 filed on May 22, 2015. 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, upfront and milestone payments related to license and collaboration agreements, intangible asset impairments, restructuring expenses, 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 six month periods ended June 30, 2015 and 2014.

(Tables Follow)

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

	Three months ended June 30		Six months ended June 30	
	2015	**2014**	**2015**	**2014**
Net product sales	$ 635,983	$ 512,495	$1,236,316	$1,079,111
Other revenue	227	-	227	-
Total revenues	636,210	512,495	1,236,543	1,079,111
Cost of sales	52,007	39,626	121,406	72,565
Operating expenses:				
Research and development	131,693	92,554	352,773	284,011
Selling, general and administrative	221,383	159,477	408,499	288,768
Impairment of intangible asset	-	-	-	3,464
Acquisition-related costs	33,821	1,989	45,800	1,951
Restructuring expenses	16,224	-	23,276	-
Total operating expenses	403,121	254,020	830,348	578,194

Operating income	181,082	218,849	284,789	428,352
Other income (expense)	(3,790)	(203)	(552)	2,205
Income before income taxes	177,292	218,646	284,237	430,557
Income tax provision	7,077	52,151	22,699	104,708
Net income	$ 170,215	$ 166,495	$ 261,538	$ 325,849
Earnings per common share				
Basic	$ 0.84	$ 0.84	$ 1.30	$ 1.65
Diluted	$ 0.83	$ 0.83	$ 1.29	$ 1.62
Shares used in computing earnings per common share				
Basic	202,234	197,880	200,806	197,838
Diluted	204,546	201,524	203,302	201,715

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

	Three months ended June 30		Six months ended June 30	
	2015	**2014**	**2015**	**2014**
Net income reconciliation:				
GAAP net income	$ 170,215	$ 166,495	$ 261,538	$ 325,849
Share-based compensation expense	67,000	28,414	109,797	52,254
Acquisition-related costs (1)	33,821	1,989	48,778	1,951
Upfront and milestone payments related to license and collaboration agreements	1,750	-	114,250	101,925
Impairment of intangible assets	-	-	-	3,464
Restructuring expenses (2)	16,224	-	23,276	-
Non-cash taxes (3)	8,722	32,174	5,050	56,228
Non-GAAP net income	$ 297,732	$ 229,072	$ 562,689	$ 541,671
GAAP earnings per share - diluted	$ 0.83	$ 0.83	$ 1.29	$ 1.62
Non-GAAP earnings per share - diluted	$ 1.44	$ 1.12	$ 2.72	$ 2.65
Shares used in computing diluted earnings per share (GAAP)	204,546	201,524	203,302	201,715
Shares used in computing diluted earnings per share (non-GAAP)	206,934	204,435	205,488	204,631
Cost of sales reconciliation:				
GAAP cost of sales	$ 52,007	$ 39,626	$ 121,406	$ 72,565
Share-based compensation expense	(1,344)	(964)	(2,753)	(1,847)
Non-GAAP cost of sales	$ 50,663	$ 38,662	$ 118,653	$ 70,718
Research and development expense reconciliation:				
GAAP research and development expense	$ 131,693	$ 92,554	$ 352,773	$ 284,011
Share-based compensation expense	(13,329)	(7,453)	(24,413)	(15,437)

Upfront and milestone payments related to license and collaboration agreements	(1,750)	-	(114,250)	(101,925)
Non-GAAP research and development expense	$ 116,614	$ 85,101	$ 214,110	$ 166,649
Selling, general and administrative expense reconciliation:				
GAAP selling, general and administrative expense	$ 221,383	$ 159,477	$ 408,499	$ 288,768
Share-based compensation expense	(52,327)	(19,997)	(82,631)	(34,970)
Non-GAAP selling, general and administrative expense	$ 169,056	$ 139,480	$ 325,868	$ 253,798
Income tax provision reconciliation:				
GAAP income tax provision	$ 7,077	$ 52,151	$ 22,699	$ 104,708
Non-cash taxes (3)	(8,722)	(32,174)	(5,050)	(56,228)
Non-GAAP income tax provision (benefit)	$ (1,645)	$ 19,977	$ 17,649	$ 48,480

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

	Three months ended June 30		Six months ended June 30	
	2015	2014	2015	2014
Acquisition-related costs:				
Transaction costs	$ 26,799	$ -	$ 29,777	$ -
Integration costs	2,978	-	2,978	-
Changes in fair value of contingent consideration	4,044	1,989	16,023	1,951
	$ 33,821	$ 1,989	$ 48,778	$ 1,951

(2) Restructuring expenses of $16.2 million were related to $10.3 million resulting from the Synageva acquisition and an additional $5.9 million related to the European headquarters relocation.

(3) Non-cash taxes represents the adjustment from GAAP tax expense to the amount of taxes that are payable (receivable) in cash in the current period. In the second quarter 2015, the Company completed the acquisition of Synageva which resulted in a benefit to both GAAP and non-GAAP taxes from the utilization of Synageva's operating losses in 2015. The tax benefit recorded in the second quarter is resulting from the application of the lower full year tax rate to the first half of the year.

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

	June 30, 2015	December 31, 2014
Cash and cash equivalents	$ 1,322,123	$ 943,999
Marketable securities	172,229	1,017,567
Trade accounts receivable, net	535,824	432,888
Inventories	234,347	176,441
Prepaid expenses and other current assets	268,715	225,134
Property, plant and equipment, net	555,388	392,248
Intangible assets, net	4,824,520	587,046
Goodwill	5,007,142	254,073
Other assets	247,431	172,566
Total assets	$13,167,719	$ 4,201,962
Accounts payable and accrued expenses	$ 454,384	$ 439,248
Deferred revenue	88,366	58,837

Current portion of long-term debt	131,250	48,000
Deferred tax liabilities, current	42,018	12,476
Other current liabilities	53,151	48,179
Long-term debt, less current portion	3,368,750	9,500
Facility lease obligation	129,560	107,099
Contingent consideration	129,546	116,425
Other liabilities	217,823	60,180
Total liabilities	4,614,848	899,944
Total stockholders' equity	8,552,871	3,302,018
Total liabilities and stockholders' equity	$13,167,719	$ 4,201,962

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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.