Alexion Reports Third Quarter 2011 Results

-- Soliris® (eculizumab) Net Product Sales Increased 44% to $204 Million --

-- FDA Approved Soliris for Patients with aHUS --

-- Guidance Revised Upward Today for Revenues and Non-GAAP EPS --

Third Quarter 2011 Financial Highlights:

- Q3 2011 revenues increased 44 percent to $204.0 million, compared to $141.6 million in Q3 2010.
- Q3 2011 GAAP net income increased 135 percent to $65.6 million, or $0.34 per share, compared to $27.9 million, or $0.15 per share, in Q3 2010. Q3 2011 GAAP net income benefitted from the impact of tax credits of $16.3 million, or $0.09 per share, recognized this quarter.
- Q3 non-GAAP net income increased 54 percent to $72.6 million, or $0.37 per share, compared to $47.2 million, or $0.25 per share, in Q3 2010.

CHESHIRE, Conn.--(BUSINESS WIRE)-- Alexion Pharmaceuticals, Inc. (Nasdaq: ALXN) today announced financial results for the three and nine months ended September 30, 2011.

Third Quarter 2011 Financial Results:

For the three months ended September 30, 2011, Alexion Pharmaceuticals, Inc. ("Alexion" or the "Company") reported total revenues of $204.0 million from net product sales of Soliris® (eculizumab), compared to $141.6 million in Q3 2010, reflecting steady addition of new patients with paroxysmal nocturnal hemoglobinuria (PNH) during the quarter.

Soliris has been approved in the US (2007), European Union (2007), Japan (2010) and other territories as the first and only treatment indicated for patients with PNH, an ultra-rare, debilitating and life-threatening blood disease. In addition, Soliris was approved by the US Food and Drug Administration (FDA) on September 23, 2011 as the first and only treatment indicated for patients with atypical Hemolytic Uremic Syndrome (aHUS), an ultra-rare, life-threatening, genetic disease that progressively damages vital organs, leading to stroke, heart attack, kidney failure and death.

Alexion's non-GAAP operating results are equal to GAAP operating results adjusted for the impact of share-based compensation, taxes that are not payable in cash (non-cash tax adjustment), amortization of acquired intangible assets, and costs associated with acquisitions. The non-cash tax adjustment represents the change in cash taxes attributable to the utilization of US net operating losses. The following summary table is provided for investors' convenience:

(in thousands, except per share amounts)
(unaudited)

	Three months ended September 30		Nine months ended September 30	
	2011	**2010**	**2011**	**2010**
Total revenues	$ 204,047	$ 141,569	$ 555,872	$ 384,982
GAAP net income	$ 65,570	$ 27,873	$ 127,145	$ 70,580
Share-based compensation	11,261	8,379	34,426	24,733
Acquisition-related costs	236	-	11,164	-
Amortization of purchased intangibles	104	-	278	-
Non-cash tax adjustment	(4,597)	10,931	12,608	23,369
Non-GAAP net income	$ 72,574	$ 47,183	$ 185,621	$ 118,682

Shares used in computing diluted earnings per share (GAAP)	192,161	186,042	191,267	185,160
Shares used in computing diluted earnings per share (non-GAAP)	193,889	188,434	193,041	187,646
GAAP earnings per share - diluted	$ 0.34	$ 0.15	$ 0.66	$ 0.38
Non-GAAP earnings per share - diluted	$ 0.37	$ 0.25	$ 0.96	$ 0.64

Third Quarter 2011 Non-GAAP Financial Results:

The Company reported non-GAAP net income for Q3 2011 of $72.6 million, or $0.37 per share, an increase of 54 percent compared to $47.2 million, or $0.25 per share, in Q3 2010.

Alexion's non-GAAP operating expenses for Q3 2011 were $103.5 million, compared to $74.3 million for Q3 2010. Non-GAAP research and development (R&D) expenses for Q3 2011 were $34.1 million, compared to $23.1 million for Q3 2010. The increase in R&D expenses primarily reflected the Company's expanded clinical development programs. Non-GAAP selling, general and administrative (SG&A) expenses for Q3 2011 were $69.5 million, compared to $51.1 million for Q3 2010. The increase in SG&A expenses primarily reflected costs associated with the expansion of the Company's worldwide operations, including costs associated with the aHUS launch.

Third Quarter 2011 GAAP Financial Results:

The Company reported GAAP net income for Q3 2011 of $65.6 million, or $0.34 per share, compared to $27.9 million, or $0.15 per share, in Q3 2010.

Alexion's GAAP operating expenses for Q3 2011 were $114.5 million, compared to $82.4 million for Q3 2010. GAAP R&D expenses for Q3 2011 were $36.6 million, compared to $25.2 million for Q3 2010. GAAP SG&A expenses were $77.6 million for Q3 2011, compared to $57.2 million for Q3 2010. During Q3 2011, the Company recorded a GAAP tax benefit from the impact of tax credits of $16.3 million, or $0.09 per share.

As of September 30, 2011, the Company had $445.2 million in cash, cash equivalents and marketable securities, compared to $368.0 million at June 30, 2011.

"In the third quarter, we continued to serve a growing number of new patients with PNH in our core territories of the US, Western Europe and Japan," said Leonard Bell, M.D., Chief Executive Officer of Alexion. "The US approval for Soliris to treat children and adults with aHUS is a particularly important milestone for patients with this ultra-rare and life-threatening disorder. As we serve patients with PNH and aHUS, we are also continuing to advance our robust pipeline programs in other ultra-rare and severe disorders."

aHUS:

On September 23, 2011, Alexion announced that the US FDA approved Soliris for the treatment of pediatric and adult patients with aHUS, enabling the Company to commence the US introduction of Soliris in this second indication.

Also on September 23rd, the Company announced that the European Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending that the therapeutic indication for Soliris be extended to include the treatment of pediatric and adult patients with aHUS in the European Union. A final decision from the European Commission is expected in approximately two months from the CHMP's positive recommendation. If approval is granted at that time, the Company will then begin the process of obtaining reimbursement approval on a country-by-country basis in the European Union.

Research and Development Progress:

During the third quarter of 2011, Alexion made continued progress on advancing the development of Soliris (eculizumab) as a treatment for patients suffering from ultra-rare and severe complement-mediated disorders beyond PNH and aHUS.

Myasthenia Gravis

In September, Alexion announced that the Company's study of eculizumab in patients with severe and refractory myasthenia gravis, an ultra-rare and debilitating form of myasthenia gravis, showed a strong disease improvement signal. Data from the Phase 2 study were presented at the annual Myasthenia Gravis Foundation of America meeting. Alexion is now planning further investigation of eculizumab as a treatment for patients with severe and refractory myasthenia gravis.

STEC-HUS

The company-sponsored open-label clinical trial to investigate eculizumab as a treatment for patients with Shiga-toxin producing E. coli hemolytic uremic syndrome (STEC-HUS) is continuing in Germany.

Transplant: Acute Humoral Kidney Rejection (AHR)

Data from the investigator-initiated study in patients undergoing kidney transplant who are at elevated risk of antibody mediated rejection (also known as acute humoral rejection, or AHR) were published last month in the *American Journal of Transplantation*. Alexion expects to begin enrollment in a company-sponsored multi-national living-donor kidney transplant trial in patients at elevated risk of AHR by the end of the year.

Revised 2011 Financial Guidance:

Alexion's 2011 revenue guidance is being revised upward today, from the previously announced range of $760 to $768 million, now to the higher range of $770 to $775 million. The upward revision in revenue guidance reflects continued global growth of Soliris for PNH; no additional contribution is expected from aHUS operations beyond what had been included in earlier forecasts. Guidance for non-GAAP EPS is also being revised upward today from the previous range of $1.15 to $1.20 now to the higher range of $1.25 to $1.28, based on a forecast of approximately 194 million diluted shares outstanding for the year.

On a non-GAAP basis, guidance for 2011 R&D expenses is being reduced today from the previous range of $138 to $143 million to the lower range of $133 to $138 million. Guidance for 2011 cost of sales is being reduced from approximately 13 percent of sales to approximately 12 percent of sales.

The expected GAAP tax rate for the fiscal year 2011 is being reduced from the previous expected range of 30 to 32 percent to the lower range of 20 to 22 percent, due to the $16.3 million benefit from the impact of tax credits recognized in Q3 2011. The Q4 2011 GAAP tax rate is expected to be in the range of 28 to 30 percent. The expected full year non-GAAP tax rate is being reduced from the previous range of 10 to 12 percent, now to the lower range of 8 to 9 percent. Other items of 2011 guidance are being reiterated: non-GAAP SG&A expenses are expected to be in the range of $275 to $280 million, and share-based compensation expense is expected to be in the range of $42 to $44 million.

Conference Call/Web Cast Information:

Alexion will host a conference call/webcast to discuss matters mentioned in this release. The call is scheduled for today, October 20, at 10:00 a.m., Eastern Time. To participate in this call, dial 888-297-0339 (USA) or 719-785-9448 (International), confirmation code 7858784, 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), confirmation code 7858784. The audio webcast can be accessed at www.alexionpharma.com.

About Soliris:

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 US, European Union, Japan and other countries as the first and only treatment for patients with paroxysmal nocturnal hemoglobinuria (PNH), 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 US as the first and only treatment for patients with atypical Hemolytic Uremic Syndrome (aHUS), a debilitating, ultra-rare and life-threatening genetic disorder characterized by complement-mediated thrombotic microangiopathy (blood clots in small vessels). Alexion's breakthrough approach in complement inhibition has received the pharmaceutical industry's highest honors: the 2008 Prix Galien USA Award for Best Biotechnology Product with broad implications for future biomedical research and the 2009 Prix Galien France Award in the category of Drugs for Rare Diseases. More information on Soliris is available at www.soliris.net.

About Alexion:

Alexion Pharmaceuticals, Inc. is a biopharmaceutical company focused on serving patients with severe and ultra-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 more than 35 countries for the treatment of PNH, and in the United States for the treatment of aHUS. Alexion is evaluating other potential indications for Soliris and is pursuing development of other innovative biotechnology product candidates in early stages of development. This press release and further information about Alexion Pharmaceuticals, Inc. can be found at: www.alexionpharma.com.

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This news release contains forward-looking statements, including statements related to guidance regarding anticipated financial results for 2011, 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, plans to pursue reimbursement approvals in the European Union, expansion of clinical and commercial operations to additional countries, medical and commercial potential of Alexion's complement-inhibition technology and other technologies; plans for clinical programs for each of our product candidates; progress in developing commercial infrastructure, and interest and acceptance regarding Soliris in the patient, physician and payor communities. 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, delays in arranging satisfactory manufacturing capabilities and establishing commercial infrastructure, 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 recent acquisitions 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 risk that third parties will not agree to license any necessary intellectual property to Alexion on reasonable terms or at all, the risk that third party payors (including governmental agencies) will not 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 disorders is inaccurate, and a variety of other risks set forth from time to time in Alexion's filings with the Securities and Exchange Commission, including but not limited to the risks discussed in Alexion's Annual Report on Form 10-Q for the three and six months ended June 30, 2011 and in our other filings with the 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.

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	
	2011	**2010**	**2011**	**2010**
Net product sales	$ 204,047	$ 141,569	$ 555,872	$ 384,982
Cost of sales (1)	23,369	16,495	64,342	44,215
Operating expenses:				
Research and development (1)	36,567	25,153	103,023	71,217
Selling, general and administrative (1)	77,572	57,208	221,609	163,941
Acquisition-related costs (2)	236	-	11,164	-
Amortization of purchased intangibles	104	-	278	-
Total operating expenses	114,479	82,361	336,074	235,158
Operating income	66,199	42,713	155,456	105,609
Other income (expense)	(522)	(106)	134	(845)
Income before income taxes	65,677	42,607	155,590	104,764
Income tax provision (3)	107	14,734	28,445	34,184
Net income	$ 65,570	$ 27,873	$ 127,145	$ 70,580
Earnings per common share				
Basic	$ 0.36	$ 0.16	$ 0.70	$ 0.40
Diluted	$ 0.34	$ 0.15	$ 0.66	$ 0.38
Shares used in computing earnings per common share				
Basic	183,706	178,980	182,805	178,006
Diluted	192,161	186,042	191,267	185,160

(1)The following table summarizes the share-based compensation expense included in the respective captions of the condensed consolidated statements of operations:

	Three months ended September 30		Nine months ended September 30	
	2011	2010	2011	2010
Cost of sales	$ 645	$ 290	$ 1,762	$ 855
Research and development	2,511	2,029	7,489	6,139
Selling, general and administrative	8,105	6,060	25,175	17,739
	$ 11,261	$ 8,379	$ 34,426	$ 24,733

(2)The following table summarizes the acquisition-related costs included in the condensed consolidated statements of operations:

	Three months ended September 30		Nine months ended September 30	
	2011	2010	2011	2010
Transaction and separation costs	$ -	$ -	$ 10,047	$ -
Adjustments to fair value of contingent consideration	236	-	1,117	-
	$ 236	$ -	$ 11,164	$ -

(3)The following table summarizes the non-cash tax adjustment, which represents the change in cash taxes attributable to the utilization of US net operating losses (NOL's):

	Three months ended September 30		Nine months ended September 30	
	2011	2010	2011	2010
Non-cash tax adjustment	$ (4,597)	$ 10,931	$ 12,608	$ 23,369

During the three months ended September 30, 2011, the Company elected to claim both the foreign tax credit and orphan drug credit for the 2010 and 2011 tax years and the orphan drug credit for the 2009 tax year. The net federal income tax benefit recorded related to these elections was approximately $16.3 million. The non-cash tax adjustment during this period includes tax benefits recognized in the GAAP tax provision that were not received in cash.

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

	September 30, 2011	December 31, 2010
Cash, cash equivalents and marketable securities	$ 445,188	$ 361,605
Trade accounts receivable, net	221,293	168,732
Inventories	78,302	62,165
Deferred tax assets, current	19,995	19,643
Other current assets	52,578	34,411
Property, plant and equipment, net	164,153	162,240
Deferred tax assets, noncurrent	139,459	154,569
Intangibles assets, net	92,811	24,146
Goodwill	80,033	19,954
Other noncurrent assets	11,230	4,572
Total assets	$ 1,305,042	$ 1,012,037

Accounts payable and accrued expenses	$ 187,111	$ 123,056
Other current liabilities	24,133	15,459
Long-term debt	-	3,718
Contingent consideration	17,837	-
Other noncurrent liabilities	20,233	10,068
Total liabilities	249,314	152,301
Total stockholders' equity	1,055,728	859,736
Total liabilities and stockholders' equity	$ 1,305,042	$ 1,012,037

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Source: Alexion Pharmaceuticals, Inc.