Alexion Reports Fourth Quarter and Full Year 2009 Results

Soliris(R) Net Product Sales Increased 49% to $386.8 Million in 2009
Continued Strong Uptake of Soliris By New Patients in U.S. and Europe in Q4
Soliris Development Programs Advance in aHUS and Transplant
Fourth Quarter 2009 Financial Highlights:

- **Q4 2009 revenues increased 43% to $110.6 million, compared to $77.4 million in Q4 2008.**
- **Q4 2009 GAAP net income was $237.1 million, or $2.59 per share, which includes $215.5 million from a non-recurring tax benefit. Excluding this one-time tax benefit, net income was $21.6 million, or $0.24 per share.**
- **Q4 2009 non-GAAP net income increased to $28.5 million, compared to non-GAAP net income of $21.1 million in Q4 2008. Q4 non-GAAP earnings per share increased 35% to $0.31 per share, compared to $0.23 per share, in Q4 2008.**

2009 Financial Highlights:

- **2009 revenues increased 49% to $386.8 million, compared to $259.1 million in 2008.**
- **2009 GAAP net income was $295.2 million, or $3.26 per share, which includes $215.5 million from a non-recurring tax benefit. Excluding this one-time tax benefit, 2009 net income was $79.7 million, or $0.88 per share.**
- **2009 non-GAAP net income increased to $108.4 million, compared to non-GAAP net income of $56.8 million in 2008. 2009 non-GAAP earnings per share increased 84% to $1.18 per share, compared to $0.64 per share, in 2008.**

CHESHIRE, Conn., Feb 11, 2010 (BUSINESS WIRE) -- Alexion Pharmaceuticals, Inc. (NASDAQ: ALXN) today announced financial results for the quarter and year ended December 31, 2009. For the three months ended December 31, 2009, Alexion Pharmaceuticals, Inc. ("Alexion" or, the "Company") reported net product sales of Soliris(R) (eculizumab) of $110.6 million, reflecting strong additions of new patients, compared to $77.4 million for the same period in 2008. Net product sales in Q4 2009 increased 8 percent, compared to $102.6 million in Q3 2009, despite a previously anticipated negative impact of approximately $3 million from Euro hedging rates set at lower levels.

Soliris, approved by the U.S. Food and Drug Administration (FDA) in March 2007 and the European Commission (EC) in June 2007, is the only drug specifically indicated for the treatment of all patients with paroxysmal nocturnal hemoglobinuria (PNH), a rare, debilitating and life-threatening blood disease.

Recognition of Tax Benefit and Reversal of Valuation Allowance

At December 31, 2009, Alexion had U.S. net operating losses (NOLs) of $665 million and research tax credits of $33 million. During Q4 2009, as a result of its sustained profitability and forecasts for future taxable earnings, and in accordance with GAAP, Alexion released the valuation allowance on a substantial portion of its deferred tax assets. The valuation release resulted in the recognition of a non-recurring tax benefit of $215.5 million, which is reflected in the Company's GAAP results for the fourth quarter. In order to provide comparable information about its earnings, Alexion reported taxes on a cash tax liability basis in Q4 2009 for non-GAAP purposes and will continue to do so during 2010.

Historically, Alexion's non-GAAP operating results have been equal to GAAP operating results less only the impact of share-based compensation. Additionally, taxes that are not payable in cash (non-cash taxes) are now excluded from non-GAAP results. The following summary table is provided for investors' convenience. A complete reconciliation of the GAAP to non-GAAP figures appears below.

(Thousands of U.S. dollars, except per-share data)

	Quarter Ended December 31,		Year Ended December 31,	
	2009	2008	2009	2008
Total revenues	$ 110,649	$ 77,399	$ 386,800	$ 259,099
GAAP net income	$ 237,127	$ 15,336	$ 295,166	$ 33,149
Share-based compensation	6,881	5,801	28,734	23,682
Tax provision (benefit)	(214,533)	1,412	(211,852)	1,581
Pre-tax non-GAAP income	$ 29,475	$ 22,549	$ 112,048	$ 58,412
Cash taxes	$ (983)	$ (1,412)	$ (3,664)	$ (1,581)
Non-GAAP net income	$ 28,492	$ 21,137	$ 108,384	$ 56,831
GAAP net income per share - diluted	$ 2.59	$ 0.17	$ 3.26	$ 0.39
Non-GAAP net income per share - diluted	$ 0.31	$ 0.23	$ 1.18	$ 0.64

Fourth Quarter Non-GAAP Financial Results:

The Company reported non-GAAP net income of $28.5 million, or $0.31 per share, for the fourth quarter of 2009, compared to non-GAAP net income of $21.1 million, or $0.23 per share, in the fourth quarter of 2008.

Alexion's non-GAAP operating expenses for Q4 2009 were $68.2 million, compared to $48.3 million for Q4 2008. Non-GAAP R&D expenses for Q4 2009 were $20.3 million, compared to $13.6 million for Q4 2008. The increase in R&D expenses primarily reflected the expansion of the Company's clinical trial programs. Non-GAAP selling, general and administrative (SG&A) expenses for Q4 2009 were $47.9 million, compared to $34.7 million for Q4 2008. The increase in non-GAAP SG&A expenses primarily reflected costs associated with the expansion of the Company's commercial operations in new geographies, particularly Japan, as well as costs associated with an expanded presence at medical conferences.

Fourth Quarter GAAP Financial Results:

Alexion reported GAAP net income of $237.1 million, or $2.59 per share, for the fourth quarter of 2009, including $215.5 million from recognizing the release of the valuation allowance on its deferred tax assets. Excluding the tax benefit, Q4 2009 net income was $21.6 million, or $0.24 per share.

On a GAAP basis, operating expenses for Q4 2009 were $75.1 million, compared to $54.1 million for Q4 2008. GAAP R&D expenses for Q4 2009 were $23.2 million, compared to $15.3 million for Q4 2008. GAAP SG&A expenses were $51.9 million for Q4 2009, compared to $38.8 million for Q4 2008.

Full Year 2009 Non-GAAP Financial Results:

For the year ended December 31, 2009, the Company reported net product sales of Soliris of $386.8 million, an increase of 49% compared to $259.0 million in 2008.

Alexion's non-GAAP operating expenses for the full year 2009 were $225.9 million, compared to $172.4 million for 2008. Non-GAAP R&D expenses for 2009 were $72.9 million, compared to $56.5 million for the prior year. The increase in R&D expenses primarily reflected the expansion of the Company's clinical trial programs. Non-GAAP SG&A expenses for 2009 were $153.1 million, compared to $115.9 million in 2008. The increase in non-GAAP SG&A expenses primarily reflected costs associated with the expansion of the Company's commercial operations in the U.S., Europe, Japan, Canada, Latin America and Asia-Pacific.

The Company reported non-GAAP net income of $108.4 million in 2009, or $1.18 per share, compared to non-GAAP net income of $56.8 million, or $0.64 per share, in 2008.

Full Year 2009 GAAP Financial Results:

Alexion reported GAAP net income of $295.2 million, or $3.26 per share in 2009, including $215.5 million from the release of the valuation allowance on deferred tax assets. Excluding the tax benefit, 2009 net income was $79.7 million, or $0.88 per share.

On a GAAP basis, operating expenses for 2009 were $254.7 million, compared to $196.1 million for the prior year. GAAP R&D expenses for 2009 were $81.9 million, compared to $62.6 million in 2008. GAAP SG&A expenses were $172.8 million in 2009, compared to $133.5 million for the prior year.

"Our global team executed consistently as it focused on patients' needs, enabling us to exceed our operational, clinical and financial objectives for 2009," said Leonard Bell, M.D., Chief Executive Officer of Alexion. "We ended the year with strong momentum to continue achieving our three central growth initiatives: serving more patients in existing countries, expanding into new territories, and advancing our development programs for Soliris."

Balance Sheet:

As of December 31, 2009, the Company had $176.2 million in cash, cash equivalents and marketable securities compared to $138.0 million at December 31, 2008.

Q4 Research and Development Progress:

During 2009, Alexion made significant progress on advancing the development of Soliris as a treatment for patients suffering from additional rare and severe complement-mediated disorders. There are currently 12 clinical trials underway with Soliris in eight such conditions, with increasing focus in the two lead areas of nephrology and transplant.

Nephrology: Atypical Hemolytic Uremic Syndrome (aHUS)

The Company expects to complete enrollment in its four clinical studies of Soliris as a treatment for patients with aHUS by mid-year 2010. The trials are divided between aHUS patients who are plasma-therapy-sensitive, and those who are resistant to plasma-therapy. Once enrolled, patients are treated with Soliris for 26 weeks. Like PNH, aHUS is a severe, ultra-rare complement-inhibitor deficiency disorder. Because aHUS frequently affects children, often with devastating results, Alexion is developing protocols to study Soliris as a treatment for pediatric patients with aHUS.

Transplant: Acute Humoral Kidney Rejection (AHR)

Soliris is being investigated for the prevention of antibody-mediated rejection, also known as acute humoral rejection, in patients at increased risk. As previously reported, an investigator at the Mayo Clinic is conducting a study of 20 patients undergoing kidney transplantation who are known to be at elevated risk for AHR. Alexion is planning to initiate controlled clinical trials in elevated-risk kidney transplant patients in multiple centers in North America, Europe and Australia. In addition, the Company is now supporting further new investigator-initiated studies in patients at elevated risk of rejection following kidney transplant. Alexion is also developing strategies to investigate the use of Soliris in patients undergoing transplantation of other organs.

Oncology Program

In addition to its research initiatives with Soliris, Alexion is developing its anti-CD200 antibody, which was recently assigned the name samalizumab. In this oncology program, the Company remains on track with patient enrollment and dosing in a clinical study of samalizumab in patients with chronic lymphocytic leukemia. The Company is also initiating screening of patients with multiple myeloma as it expands its samalizumab program and is considering trials in rare, solid tumors as well.

Manufacturing:

The Company's Rhode Island manufacturing facility has now received final approval from the European Commission to serve as an additional source of supply for commercial Soliris in European countries, which make up more than half of Alexion's market. Earlier this month, Alexion received clarification from the FDA regarding the agency's requirements for granting final approval to the Rhode Island facility. Based on this communication, Alexion continues to expect to receive FDA approval of this facility by the end of 2010.

2010 Financial Guidance:

In 2010, worldwide net product sales are expected to be within a range of $505 to $520 million. Gross margin is expected to be in the range of 87 to 88 percent. Excluding share-based compensation, R&D expenses are anticipated to be in the range of $95 to $100 million, and selling, general and administrative expenses in the range of $185 to $195 million. The Company's share-based compensation expenses for the year are expected to be in a range of approximately $32 to $34 million. GAAP taxes are expected to be in a range of 30 percent to 32 percent. Non-GAAP taxes, reported on a cash tax liability basis, are expected to be in the range of 11 percent to 12 percent, compared to 3.3 percent in 2009. Based on this expected non-GAAP tax rate and a forecast of 94 million diluted shares outstanding, Alexion is providing guidance of $1.60 to $1.65 for non-GAAP earnings per share for the year. This guidance represents earnings growth of approximately 40 percent from 2009 to 2010, despite a year-on-year increase in the cash tax rate of approximately 8 percent.

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, February 11, 2010, at 10:00 a.m., Eastern Time. To participate in this call, dial 785-830-7991, confirmation code 2369934, 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 719-457-0820, confirmation code 2369934. The audio webcast can be accessed at www.alexionpharma.com.

About Soliris

Soliris has been approved by the U.S. Food and Drug Administration (FDA), the European Commission (EC) and healthcare authorities in other countries as the first treatment for all patients with PNH, an ultra-rare, debilitating and life-threatening blood disorder defined by hemolysis, or the destruction of red blood cells. The FDA and EC reviewed and approved their respective marketing applications for Soliris under their priority review or accelerated assessment procedures. In patients with PNH, hemolysis can cause life-threatening thromboses, recurrent pain, kidney disease, fatigue, impaired quality of life, anemia, pulmonary hypertension, shortness of breath and intermittent episodes of dark-colored urine (hemoglobinuria). Soliris is the only treatment that blocks this hemolysis. Prior to these approvals, there were no therapies specifically available for the treatment of patients with PNH. PNH treatment was limited to symptom management through periodic blood transfusions, non-specific immunosuppressive therapy and, infrequently, bone marrow transplantations -- a procedure that carries its own substantial risks of mortality and morbidity. Alexion is committed to the objective that every patient with PNH who can benefit from Soliris will have access to Soliris.

About Alexion

Alexion Pharmaceuticals, Inc. is a biopharmaceutical company working to develop and commercialize life-changing drug therapies for patients with serious and life-threatening medical conditions. Alexion is engaged in the discovery, development and commercialization of therapeutic products aimed at treating patients with a wide array of severe disease states, including hematologic, kidney and neurologic diseases, transplant rejection, cancer and autoimmune disorders. Soliris is Alexion's first marketed product, approved in the U.S., European Union and other countries as a treatment for all patients with PNH. Alexion is evaluating other potential indications for Soliris, and is pursuing development of other antibody product candidates in early stages of development. Further information about Alexion Pharmaceuticals, Inc. can be found at www.alexionpharma.com.

This press release includes certain non-GAAP financial measures that involve adjustments to GAAP figures. Alexion believes that these non-GAAP financial measures, when considered together with the GAAP figures, can enhance an overall understanding of Alexion's past financial performance and its prospects for the future. The non-GAAP financial measures are included with the intent of providing both management and investors with a more complete understanding of underlying operational results and trends. In addition, these non-GAAP financial measures are among the primary indicators Alexion management uses for planning and forecasting purposes and measuring the company's performance. These non-GAAP financial measures are not intended to be considered in isolation or as a substitute for GAAP figures. A reconciliation of the GAAP to non-GAAP figures follows this press release.

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This news release contains forward-looking statements, including statements related to guidance regarding anticipated financial results for 2010, projected tax rates, assessment of the Company's financial position and commercialization efforts, potential benefits and commercial potential for Soliris, potential of Alexion's complement-inhibition technology for treatment of diseases other than PNH; plans for clinical programs for Soliris in non-PNH indications and for samalizumab; progress in developing commercial infrastructure, obtaining FDA approval of the Company's manufacturing facility and interest about 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, delays in arranging satisfactory manufacturing capabilities and establishing commercial infrastructure, delays in developing or adverse changes in commercial relationships, the possibility that results of clinical trials are not predictive of safety and efficacy results of Soliris in broader patient populations, the possibility that initial results of commercialization are not predictive of future rates of adoption of Soliris, 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 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 Quarterly Report on Form 10-Q for the period ended September 30, 2009 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
(unaudited)

(in thousands, except per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2009	**2008**	**2009**	**2008**
Revenues:				
Net product sales	$ 110,649	$ 77,399	$ 386,800	$ 259,004
Contract research revenues	-	-	-	95
Total revenues	110,649	77,399	386,800	259,099
Cost of sales	12,892	6,812	45,059	28,366
Operating expenses:				
Research and development	23,215	15,275	81,915	62,581
Selling, general and administrative	51,887	38,789	172,767	133,543
Total operating expenses	75,102	54,064	254,682	196,124
Operating income	22,655	16,523	87,059	34,609
Other income (expense):				
Investment income	174	739	786	2,810
Interest expense	(84)	(432)	(606)	(2,407)
Foreign currency loss	(151)	(82)	(530)	(282)
Debt exchange expense	-	-	(3,395)	-
	(61)	225	(3,745)	121
Income before income taxes	22,594	16,748	83,314	34,730
Income tax (benefit) provision	(214,533)	1,412	(211,852)	1,581
Net income	$ 237,127	$ 15,336	$ 295,166	$ 33,149
Net income per share				
Basic	$ 2.70	$ 0.19	$ 3.46	$ 0.43
Diluted	$ 2.59	$ 0.17	$ 3.26	$ 0.39
Shares used in computing net income per share				
Basic	87,885	80,260	85,326	77,680
Diluted	91,449	90,479	90,582	89,967

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

	As of	
	December 31, 2009	**December 31, 2008**
Cash, cash equivalents, marketable securities	$ 176,220	$ 138,012
Trade accounts receivable, net	113,731	74,476
Inventories	40,885	49,821
Deferred tax assets	16,726	972
Other current assets	27,955	13,820
Property, plant and equipment	164,691	139,885
Deferred tax assets, noncurrent	194,308	3,397
Other noncurrent assets	51,885	57,168
Total assets	$ 786,401	$ 477,551
Accounts payable and accrued expenses	$ 83,160	$ 54,855
License payable	-	25,000
Current debt obligations	-	2,500
Other current liabilities	2,155	2,063
Long term debt	9,918	141,222
Other noncurrent liabilities	2,812	4,910
Total liabilities	98,045	230,550

Total stockholders' equity	688,356	247,001
Total liabilities and stockholders' equity	$ 786,401	$ 477,551

Non-GAAP operating results are equal to GAAP operating results less the impact of share-based compensation expense and non-cash taxes. The following table represents a reconciliation of GAAP to non-GAAP financial information for the three months and full years ended December 31, 2009 and 2008:

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

	Reported GAAP Amounts	Share-Based Compensation	Non-Cash Taxes	Non-GAAP Amounts
Three Months Ended December 31, 2009				
Research and development	$ 23,215	$ (2,889)	$ -	$ 20,326
Selling, general and administrative	51,887	(3,992)	-	47,895
Operating expenses	75,102	(6,881)	-	68,221
Net income	237,127	6,881	(215,516) **(a)**	28,492
Net income per share				
Basic	$ 2.70			$ 0.32
Diluted	$ 2.59			$ 0.31
Shares used in computing earnings per share				
Basic	87,885			87,885
Diluted	91,449			92,532
Three Months Ended December 31, 2008				
Research and development	$ 15,275	$ (1,714)	$ -	$ 13,561
Selling, general and administrative	38,789	(4,087)	-	34,702
Operating expenses	54,064	(5,801)	-	48,263
Net income	15,336	5,801	-	21,137
Net income per share				
Basic	$ 0.19			$ 0.26
Diluted	$ 0.17			$ 0.23
Shares used in computing earnings per share				
Basic	80,260			80,260
Diluted	90,479			91,588
Twelve Months Ended December 31, 2009				
Research and development	$ 81,915	$ (9,052)	$ -	$ 72,863
Selling, general and administrative	172,767	(19,682)	-	153,085
Operating expenses	254,682	(28,734)	-	225,948
Net income	295,166	28,734	(215,516) **(a)**	108,384
Net income per share				
Basic	$ 3.46			$ 1.27
Diluted	$ 3.26			$ 1.18
Shares used in computing earnings per share				
Basic	85,326			85,326
Diluted	90,582			91,780
Twelve Months Ended December 31, 2008				
Research and development	$ 62,581	$ (6,066)	$ -	$ 56,515
Selling, general and administrative	133,543	(17,616)	-	115,927
Operating expenses	196,124	(23,682)	-	172,442
Net income	33,149	23,682	-	56,831
Net income per share				
Basic	$ 0.43			$ 0.73
Diluted	$ 0.39			$ 0.64
Shares used in computing earnings per share				
Basic	77,680			77,680

Diluted	89,967	91,359

(a) For the three and twelve months ended December 31, 2009, the non-cash tax adjustment includes the impact of the reversal of the valuation allowance on our deferred tax assets, primarily related to U.S. net operating losses (NOLs) and research tax credits.

SOURCE: Alexion Pharmaceuticals, Inc.

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