



Alexion Reports Third Quarter 2009 Results

***Earnings Guidance Revised Upward on Stronger-Than-Expected Sales
New Patients Starting on Soliris(R) in U.S. and Europe Drive Strong Quarter
Soliris Now Being Studied in 12 Clinical Trials Across Eight Disorders***

Third Quarter 2009 Financial Highlights:

- **Soliris(R) (eculizumab) net product sales in Q3 increased 34 percent to \$102.6 million in Q3 2009 compared to \$76.5 million in Q3 2008. Soliris net product sales in Q3 increased 44 percent compared to the \$71.2 million of sales for in-quarter shipments of Soliris in Q3 2008, which excluded \$5.3 million from shipments that occurred in quarters prior to Q3 2008.**
- **Q3 GAAP net income was \$26.7 million, or \$0.29 per diluted share, compared to GAAP net income of \$19.7 million, or \$0.23 per diluted share, in Q3 2008.**
- **Q3 non-GAAP net income was \$33.7 million, or \$0.37 per diluted share, compared to non-GAAP net income of \$25.7 million, or \$0.29 per diluted share, in Q3 2008.**

CHESHIRE, Conn., Oct 22, 2009 (BUSINESS WIRE) -- Alexion Pharmaceuticals, Inc. ("Alexion" or the "Company," NASDAQ: ALXN) today announced financial results for the quarter ended September 30, 2009.

Third Quarter 2009 Financial Results:

For the three months ended September 30, 2009, Alexion reported total revenues of \$102.6 million from net product sales of Soliris(R) (eculizumab), compared to \$76.5 million for the year-ago quarter, Q3 2008. As previously reported, Q3 2008 sales included recognition of \$71.2 million from shipments of Soliris that occurred during that quarter and \$5.3 million associated with shipments of Soliris in previous quarters. Soliris sales in Q3 2009 increased 44 percent compared to the \$71.2 million of in-quarter shipments in Q3 2008.

Total revenues in Q3 2009 increased by 11 percent compared to total revenues of \$92.3 million in the prior quarter, Q2 2009. The increase in sales was primarily driven by the addition of significant numbers of new patients receiving Soliris in the U.S. and in European countries. There was no material impact on revenues from Euro-Dollar exchange rates between Q2 2009 and Q3 2009 as the impact from the stronger Euro in Q3 2009 was offset by Euro hedging rates previously 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 patients with paroxysmal nocturnal hemoglobinuria ("PNH"), a rare, debilitating and life-threatening blood disorder.

The Company reports both GAAP operating results and non-GAAP operating results. Non-GAAP operating results are equal to GAAP operating results less the impact of share-based compensation. The following summary table is provided for investors' convenience. A further reconciliation and explanation of the GAAP to non-GAAP figures appears at the end of this announcement.

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

	Quarter Ended September 30,	
	2009	2008
Total revenues	\$ 102,628	\$ 76,500
GAAP net income	\$ 26,731	\$ 19,689
Share-based compensation	6,979	5,990
Non-GAAP net income	\$ 33,710	\$ 25,679
GAAP net income per share - diluted	\$ 0.29	\$ 0.23
Non-GAAP net income per share - diluted	\$ 0.37	\$ 0.29

Third Quarter 2009 Non-GAAP Financial Results

The Company reported non-GAAP net income for Q3 2009 of \$33.7 million, or \$0.37 per diluted share, compared to non-GAAP net income of \$25.7 million, or \$0.29 per diluted share, in the year-ago quarter, Q3 2008.

Alexion's non-GAAP total operating expenses for Q3 2009 were \$55.9 million, compared to \$41.0 million for Q3 2008. Non-GAAP research and development ("R&D") expenses for Q3 2009 were \$19.2 million, compared to \$13.7 million for the year-ago quarter. The increase in R&D expenses from the year-ago quarter primarily reflects the expansion of the Company's clinical trial programs. Non-GAAP selling, general and administrative ("SG&A") expenses for Q3 2009 were \$36.7 million, compared to \$27.3 million for Q3 2008. The increase in non-GAAP SG&A expenses primarily reflected costs associated with the expansion of the Company's commercial operations in existing markets in the U.S. and Europe, as well as in additional countries in Europe, and in Canada, Latin America and Asia-Pacific.

Third Quarter 2009 GAAP Financial Results

Alexion reported GAAP net income for Q3 2009 of \$26.7 million, or \$0.29 per diluted share, compared to GAAP net income of \$19.7 million, or \$0.23 per diluted share, for Q3 2008.

On a GAAP basis, operating expenses for Q3 2009 were \$62.8 million, compared to \$46.9 million for Q3 2008. R&D expenses for Q3 2009 were \$21.3 million, compared to \$14.9 million for the year-ago quarter. The increase in R&D expenses from the year-ago quarter primarily reflects the expansion of the Company's clinical trial programs. SG&A expenses were \$41.5 million for Q3 2009, compared to \$32.1 million for Q3 2008. The increase in GAAP SG&A expenses primarily reflected costs associated with the expansion of the Company's commercial operations in existing markets in the U.S. and Europe, as well as in additional countries in Europe, and in Canada, Latin America and Asia-Pacific.

Balance Sheet:

As of September 30, 2009, the Company had \$166.9 million in cash, cash equivalents and restricted cash, compared to \$147.6 million at June 30, 2009. Alexion reduced the principal balance on its Rhode Island manufacturing facility mortgage by \$24 million during Q3 2009 and has subsequently paid the remaining \$20 million balance on this loan.

"In Q3, we continued to execute strongly on both our operational and research initiatives. We are serving a growing number of patients with PNH, while building our global presence to help more patients in countries around the world," said Leonard Bell, M.D., Chief Executive Officer. "Our research and development teams made important progress in Q3. We are deepening our focus in our lead development areas of nephrology and transplant, while also investigating Soliris as a potential treatment for patients with an increasing number of other rare, severe complement-mediated disorders."

Research and Development:

Since Soliris was first approved as a treatment for patients with PNH, researchers have been evaluating the potential of Soliris as a therapy for patients suffering with other rare and severe complement-mediated disorders. There are currently 12 clinical trials underway with Soliris in eight such conditions, with primary focus on nephrology and organ transplant.

Nephrology: Atypical Hemolytic Uremic Syndrome (aHUS)

Enrollment of adult and adolescent patients for our lead nephrology program, atypical Hemolytic Uremic Syndrome, or aHUS, was initiated in four open-label clinical studies with Soliris. Like PNH, aHUS is a severe, ultra-rare complement-inhibitor deficiency disorder. During Q3, two case reports were published in scientific journals regarding patients with aHUS who were treated with Soliris. Because aHUS frequently affects children, often with devastating results, Alexion is developing protocols to study Soliris as a treatment for pediatric patients with aHUS.

Later this month, at the American Society of Nephrology Conference in San Diego, independent investigators will present three case reports of pediatric patients with rare kidney diseases who were treated with Soliris. Investigators will present two case reports of patients with aHUS treated with Soliris and a separate case report regarding a patient with a second rare kidney disorder, dense deposit disease, treated with Soliris.

Transplant: Acute Humoral Kidney Rejection (AHR)

Soliris is also 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. The Company is also evaluating expansion of its kidney transplant program to include controlled clinical trials in multiple centers in North America, Europe and Australia. In addition, the Company is now funding further new investigator-initiated studies in patients at elevated risk of rejection following kidney transplant. Further, Alexion is also evaluating strategies to investigate the use of Soliris in patients undergoing transplantation of other organs.

Oncology Program

Alexion is on track with patient enrollment and dosing in a clinical study of its anti-CD200 antibody in patients with chronic lymphocytic leukemia. Early pharmacodynamic and biologic data suggest drug activity in this patient population. The Company is also moving forward with its anti-CD200 program to include patients with multiple myeloma.

2009 Financial Guidance:

Alexion is revising upward its previously announced guidance for worldwide Soliris net product sales, from a previous range of \$368 to \$378 million, now to a higher range of \$383 to \$385 million for the full-year 2009. The Company expects to achieve these results despite an anticipated negative impact of approximately \$3 million on Q4 2009 revenues compared to Q3 2009, resulting from lower Euro hedging rates previously set at lower levels.

Driven primarily by the stronger-than-expected sales forecast, full-year 2009 financial guidance for non-GAAP diluted earnings per share ("EPS") is being revised upward, from the previously announced range of \$1.01 to \$1.06, to a higher range of \$1.15 to \$1.18.

Guidance for total operating expenses remains within the previously announced range of \$220 to \$235 million, and is now narrowed to \$220 to \$226 million. Guidance for SG&A expenses remains within the previously announced range of \$140 to \$150 million, and is now narrowed to \$143 to \$146 million. Full-year guidance for R&D expenses is now being revised downward, from a previous range of \$80 to \$85 million, now to a lower range of \$77 to \$80 million as the Company prioritizes its R&D activities. Guidance for gross margin is being reiterated at 87 to 89 percent of net product sales. Taxes are expected to remain within the previously announced range of five percent to seven percent. The guidance for R&D and SG&A expenses excludes share-based compensation, which is being reiterated in a range of \$28 to \$30 million for the year.

Conference Call/Webcast Information

Alexion will host a conference call/webcast to discuss matters mentioned in this release. The call is scheduled for today, October 22, 2009, at 10:00 a.m., Eastern Time. To participate in this call, dial 719-457-2677, confirmation code 9630484, 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 today. The replay number is 719-457-0820, confirmation code 9630484. The audio webcast can be accessed at www.alexionpharma.com.

About Soliris

Soliris has been approved by the U.S. Food and Drug Administration (March 2007), the European Commission (June 2007), Health Canada (January 2009) and Australia's Therapeutic Goods Administration (February 2009) 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. All four jurisdictions 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, disabling fatigue, impaired quality of life, severe 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 and kidney diseases, transplant, cancer, and autoimmune disorders. Soliris is Alexion's first marketed product, approved in the U.S. and Europe in 2007, and Canada and Australia in 2009. Alexion is evaluating other potential indications for Soliris, and is pursuing development of other antibody product candidates in early stages of development. This press release and 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 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 financial information follows this press release. Throughout this release, 2009 financial information is unaudited.

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This news release contains forward-looking statements, including statements related to guidance regarding anticipated financial results for 2009; assessment of the Company's growth, 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 expansion of clinical programs for CD200 and Soliris in non-PNH indications and the timing of presentation of case reports of patients treated with Soliris. 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 capability 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 won't agree to license any necessary intellectual property to us 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 PNH patients are inaccurate, the possibility that Alexion will not be able to expand the use of Soliris into new markets and for new indications, the risk that Alexion will not be able to successfully complete clinical and preclinical programs for its new product candidates, including CD200 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 June 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.

Selected Financial Data

(Unaudited)

(Amounts in thousands, except per share amounts)

Consolidated Statements of Operations Data:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2009	2008	2009	2008
Revenues:				
Net product sales	\$ 102,628	\$ 76,500	\$ 276,151	\$ 181,605
Contract research revenues	-	-	-	95
Total revenues	102,628	76,500	276,151	181,700
Cost of sales	11,895	8,948	32,167	21,554
Operating expenses:				
Research and development	21,323	14,874	58,700	47,306
Selling, general and administrative	41,523	32,064	120,880	94,754
Total operating expenses	62,846	46,938	179,580	142,060
Operating income	27,887	20,614	64,404	18,086
Other income (expense):				
Investment income	125	690	612	2,071
Interest expense	(80)	(634)	(522)	(1,975)
Foreign currency loss	(250)	(566)	(379)	(200)
Debt exchange expense	-	-	(3,395)	-
	(205)	(510)	(3,684)	(104)
Income before income taxes	27,682	20,104	60,720	17,982
Income tax provision	951	415	2,681	169
Net income	\$ 26,731	\$ 19,689	\$ 58,039	\$ 17,813
Net income per share				
Basic	\$ 0.31	\$ 0.26	\$ 0.69	\$ 0.24
Diluted	\$ 0.29	\$ 0.23	\$ 0.65	\$ 0.22
Shares used in computing net income per share				
Basic	87,447	76,658	84,464	75,794
Diluted	90,946	89,843	90,246	88,797

Consolidated Balance Sheet Data:

	As of	
	September 30, 2009	December 31, 2008
Cash, cash equivalents and restricted cash (a) \$	166,869	\$ 139,711
Trade accounts receivable, net	109,455	74,476
Inventories	43,116	49,821
Other current assets	16,167	14,792
Property, plant and equipment	160,104	139,885
Other noncurrent assets	56,295	58,866
Total assets	<u>\$ 552,006</u>	<u>\$ 477,551</u>
Accounts payable and accrued expenses	\$ 83,517	\$ 54,855
License payable	-	25,000
Current debt obligations	20,000	2,500
Other current liabilities	4,900	2,063
Long term debt	9,918	141,222
Other noncurrent liabilities	6,433	4,910
Total liabilities	<u>124,768</u>	<u>230,550</u>
Total stockholders' equity	<u>427,238</u>	<u>247,001</u>
Total liabilities and stockholders' equity	<u>\$ 552,006</u>	<u>\$ 477,551</u>

(a) Amount includes restricted cash of \$1,574 and \$1,699 at September 30, 2009 and December 31, 2008, respectively.

Reconciliation of GAAP to Non-GAAP Financial Information:

Non-GAAP operating results are equal to GAAP operating results less the impact of share-based compensation expense. The following table represents a reconciliation of GAAP to non-GAAP financial information for the three and nine months ended September 30, 2009 and 2008:

	Reported GAAP Amounts	Share-Based Compensation Adjustment	Non-GAAP Excluding Share-Based Compensation
Three Months Ended September 30, 2009			
Research and development	\$ 21,323	\$ (2,108)	\$ 19,215
Selling, general and administrative	41,523	(4,871)	36,652
Operating expenses	62,846	(6,979)	55,867
Net income	26,731	6,979	33,710
Net income per share			
Basic	\$ 0.31	\$ 0.08	\$ 0.39
Diluted	\$ 0.29	\$ 0.08	\$ 0.37
Shares used in computing earnings per share			
Basic	87,447		87,447
Diluted	90,946		92,143
Three Months Ended September 30, 2008			
Research and development	\$ 14,874	\$ (1,200)	\$ 13,674
Selling, general and administrative	32,064	(4,790)	27,274
Operating expenses	46,938	(5,990)	40,948
Net income	19,689	5,990	25,679
Net income per share			
Basic	\$ 0.26	\$ 0.08	\$ 0.33
Diluted	\$ 0.23	\$ 0.07	\$ 0.29
Shares used in computing earnings per share			
Basic	76,658		76,658
Diluted	89,843		91,108
Nine Months Ended September 30, 2009			
Research and development	\$ 58,700	\$ (6,163)	\$ 52,537
Selling, general and administrative	120,880	(15,690)	105,190
Operating expenses	179,580	(21,853)	157,727
Net income	58,039	21,853	79,892
Net income per share			

Basic	\$	0.69	\$	0.26	\$	0.95
Diluted	\$	0.65	\$	0.24	\$	0.88
Shares used in computing earnings per share						
Basic		84,464				84,464
Diluted		90,246				91,488
Nine Months Ended September 30, 2008						
Research and development	\$	47,306	\$	(4,352)	\$	42,954
Selling, general and administrative		94,754		(13,529)		81,225
Operating expenses		142,060		(17,881)		124,179
Net income		17,813		17,881		35,694
Net income per share						
Basic	\$	0.24	\$	0.24	\$	0.47
Diluted	\$	0.22	\$	0.20	\$	0.41
Shares used in computing earnings per share						
Basic		75,794				75,794
Diluted		88,797				90,262

SOURCE: Alexion Pharmaceuticals, Inc.

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