Alexion Reports Third Quarter 2008 Results

CHESHIRE, Conn., Oct 23, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Continued Strong Uptake of Soliris(R) in U.S. and Europe

Reported Net Sales of $76.5 Million Include Recognition of $5.3 Million for Prior Quarter Shipments

Company Revises Revenue Guidance Upward and Expense Guidance Downward, and Forecasts GAAP Profit in Full Year 2008

Pipeline Progress in Hematology, Oncology, Transplant, Neurology

Third Quarter 2008 Financial Highlights:

-- Soliris(R) (eculizumab) net product sales of $76.5 million in Q3 2008 consisted of $71.2 million in net product sales for shipments that occurred in Q3 plus recognition of $5.3 million from net product sales associated with the decision of certain government payors during Q3 to reimburse for Soliris shipments that occurred in previous quarters.

-- Q3 GAAP net income was $19.7 million, or $0.23 per diluted share, compared to a GAAP net loss of $20.1 million, or $0.27 net loss per share, in Q3 2007.

-- Q3 non-GAAP net income was $25.7 million, or $0.29 per diluted share, compared to a non-GAAP net loss of $14.0 million, or $0.19 net loss per share, in Q3 2007. Q3 2008 non-GAAP net income, excluding the recognition of $5.3 million from prior-quarter shipments would be $20.8 million, or $0.23 per diluted share.

Alexion Pharmaceuticals, Inc. ("Alexion" or the "Company," Nasdaq: ALXN) today announced financial results for the quarter ended September 30, 2008.

Third Quarter 2008 Financial Results:

For the three months ended September 30, 2008, Alexion reported total revenues of $76.5 million from net product sales of Soliris(R) (eculizumab), compared to total revenues of $21.8 million for the same period in 2007. The Q3 2008 revenues consisted of $71.2 million of net product sales from Soliris shipments during Q3, plus recognition of $5.3 million from net product sales associated with the Q3 2008 decision of certain government payors to reimburse for past Soliris shipments. The $71.2 million in sales from shipments during Q3 represents a 19 percent increase from Soliris net product sales of $59.6 million in the prior quarter, Q2 2008.

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 disease.

The Company reports both GAAP operating results and non-GAAP operating results. Non-GAAP operating results are equal to GAAP operating results excluding 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.

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

	Quarter Ended Sept. 30, 2008	2007
Net Product Sales	$76.5	$21.8
Total Revenues	$76.5	$22.1
GAAP Net Income (Loss)	$19.7	$(20.1)
Share-Based Compensation	$6.0	$6.1
Non-GAAP Net Income (Loss)	$25.7	$(14.0)
GAAP Net Income (Loss) Per Share - Diluted	$0.23	($0.27)
Non-GAAP Net Income (Loss) Per Share - Diluted	$0.29	($0.19)

The Company effected a 2-for-1 stock split in the form of a 100 percent stock dividend for shareholders of record on August 12, 2008, with payment on August 22, 2008. All share and per-share amounts have been adjusted to reflect this split.

Third Quarter 2008 (Q3 2008) Non-GAAP Financial Results

The Company reported non-GAAP net income for Q3 2008 of $25.7 million, or $0.29 per diluted share, compared to a non-GAAP net loss of $14.0 million, or $0.19 per share, in the year-ago quarter, Q3 2007. Alexion reported non-GAAP net income of $8.4 million, or $0.10 per diluted share, in the prior quarter, Q2 2008.

Q3 2008 non-GAAP net income, excluding the recognition of $5.3 million in prior quarter shipments, would be $20.8 million, or $0.23 per diluted share.

Alexion's non-GAAP operating expenses for Q3 2008 were $41.0 million, compared to $35.8 million for Q3 2007. Non-GAAP research and development ("R&D") expenses for Q3 2008 were $13.7 million, compared to $14.0 million for the year-ago quarter. Non-GAAP selling, general and administrative ("SG&A") expenses for Q3 2008 were $27.3 million, compared to $21.7 million for Q3 2007. 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. and Europe to support the ongoing commercial launch of Soliris.

Third Quarter 2008 GAAP Financial Results

Alexion reported GAAP net income for the third quarter of 2008 of $19.7 million, or $0.23 per diluted share, compared to a GAAP net loss of $20.1 million, or $0.27 net loss per share, for Q3 2007 and GAAP net income of $2.4 million, or $0.03 per share, in the prior quarter, Q2 2008.

On a GAAP basis, operating expenses for Q3 2008 were $46.9 million, compared to $41.9 million for Q3 2007. R&D expenses for Q3 2008 were $14.9 million, compared to $16.9 million for the year-ago quarter. The decrease in R&D expenses in Q3 2008 compared with the year ago quarter primarily reflects the capitalization of a portion of stock-based compensation in 2008. SG&A expenses were $32.0 million for Q3 2008, compared to $24.9 million for Q3 2007. The increase in GAAP SG&A expenses primarily reflected costs associated with the expansion of the Company's commercial operations in the U.S. and Europe to support the ongoing commercial launch of Soliris.

Balance Sheet:

As of September 30, 2008, the Company had $126.4 million in cash, cash equivalents, restricted cash and marketable securities, compared to $106.7 million at December 31, 2007. During the quarter, the Company repaid the outstanding balance on its revolving credit facility, and the facility remains available for borrowing.

Prix Galien Award:

On September 24, 2008, Soliris received the Prix Galien USA 2008 Award for Best Biotechnology Product with broad implications for future biomedical research. The Award recognizes the scientific innovation represented by the first-in-class complement-inhibition technology of Soliris, and the impact the drug is having on the lives of patients with PNH. The 11-member Prix Galien USA Award Committee includes seven Nobel Laureates, and the Award is considered the pharmaceutical and biotechnology industry's highest accolade.

"The Prix Galien was a gratifying acknowledgement of our breakthrough scientific discovery and development underlying Soliris, which spanned more than 15 years, and has resulted in life-changing benefits for patients suffering with PNH," said Leonard Bell, M.D., Chief Executive Officer of Alexion. "The Award reflects our ongoing commitment to the PNH community, and also points to the potential of our complement-inhibition technology to provide treatments to patients with other rare, severe and life-threatening diseases."

Research and Development:

Soliris as a Treatment for Patients with PNH

In the third quarter, Alexion began analysis of the data collected during its AEGIS study, a single registration study to evaluate the safety, efficacy and pharmacology of Soliris as a treatment for Japanese patients with PNH. The Company expects top-line data to be presented at an upcoming international scientific meeting and to file its application for marketing authorization with the Japanese regulatory authorities in 2009.

Soliris as a Treatment for Patients with Other Rare and Severe Diseases

With the FDA approval of Soliris as a treatment for PNH in 2007, Alexion became the first company to discover and develop a terminal complement inhibitor into a commercial product. The Company is currently developing clinical programs to investigate the use of Soliris as a treatment for patients with other complement-mediated disorders, including three severe, life-threatening and rare hematologic disorders: atypical hemolytic uremic syndrome ("aHUS"), a disease in which the lack of naturally occurring complement inhibitors can cause life-threatening kidney damage; catastrophic anti-phospholipid syndrome ("CAPS"), a disorder in which uncontrollable blood clotting often leads to multiple organ failure; and cold hemagglutinin disease ("CAD"), an auto-immune hemolytic anemia.

In neurology, the first patients are now being screened for inclusion in a clinical study of Soliris as a treatment for patients with myasthenia gravis ("MG"), a rare, disabling and sometimes life-threatening complement-mediated neurologic disorder. The Company previously announced that it had received FDA authorization of an Investigational New Drug application ("IND") for the study. In addition, patient enrollment is continuing in an investigator-sponsored clinical trial evaluating the use of Soliris in a population of kidney transplant patients who are known to have a higher risk of organ rejection.

Oncology Program

Alexion is developing its novel, first-in-class humanized anti-CD200 monoclonal antibody, which is designed to enhance the immune response to several types of malignant tumors. The antibody targets the CD200 molecule, which is upregulated in several cancers, including chronic lymphocytic leukemia ("CLL"), multiple myeloma, melanoma, ovarian cancer and neuroblastoma. During the third quarter, the U.S. Patent and Trademark Office issued a composition-of-matter patent covering Alexion's anti-CD200 antibody. Antibody dosing in a Phase I/II study in patients with CLL continued in the third quarter.

Q3 2008 Soliris Commercial Update:

In the third quarter, the Company continued to add significant numbers of newly identified patients in the U.S. and in European countries, and to transition other treated patients to full commercial status. Patients are on commercial Soliris in more than 15 countries.

"Our disease awareness efforts, diagnostic initiatives and patient access programs are helping to reach our objective that every patient with PNH who can benefit from Soliris will have access to Soliris," said David Keiser, President and Chief Operating Officer of Alexion. "In the U.S., we are seeing a continued increase in diagnostic testing of patients with a higher likelihood of having PNH, resulting in more effective identification of PNH patients. In Europe, more patients in more countries are obtaining the drug through their national healthcare systems. We are especially pleased that the English government will fund treatment for patients with PNH starting in the second quarter of 2009."

2008 Financial Guidance:

Alexion is revising upward its previously announced guidance for worldwide Soliris net product sales, from a previous range of $235 to $245 million to a higher range of $256 to $258 million for full-year 2008. In addition, the Company now forecasts that it will report a GAAP profit for both the fourth quarter and the full year 2008.

This revenue guidance anticipates that incremental growth in Q4 2008 patient numbers and unit sales will be similar to or higher than that experienced in Q3, and takes into account expectations for a weaker Euro in Q4 2008 compared with Q3 2008.

The Company is revising downward its expense guidance. Guidance for the cost of sales, including royalties, remains unchanged at 12 percent to 14 percent of net product sales. Full-year 2008 guidance is reiterated for R&D expenses in a range of $65 to $70 million. Full-year 2008 guidance for SG&A expenses is revised downward from a previous range of $115 to $125 million to a reduced range of $113 to $118 million. The reduction in SG&A guidance is partially driven by the Company's expectations for a weaker Euro in Q4 2008 compared with Q3 2008. Full year guidance for 2008 total operating expenses is revised downward from a previous range of $180 to $195 million to a reduced range of $178 to $188 million. The guidance for R&D and SG&A expenses excludes share-based compensation expense, which is expected to be in a range of $24 to $26 million for the year.

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 23, 2008, at 10:00 a.m., Eastern Time. To participate in this call, dial 719-325-4764, confirmation code 4334407, 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 4334407. The audio webcast can be accessed at www.alexionpharma.com.

About Soliris

Soliris is the first product approved for the treatment of patients with PNH in the U.S. and Europe. PNH is a rare, debilitating and life-threatening blood disorder defined by the destruction of red blood cells, or hemolysis. 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, or eculizumab, is the only treatment that blocks this hemolysis.

About Alexion

Alexion Pharmaceuticals, Inc. is a biopharmaceutical company working to develop and deliver life-changing drug therapies for patients with serious and life-threatening medical conditions. The Company 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 diseases, cancer and autoimmune disorders. In March 2007, the FDA granted marketing approval for the Company's first product, Soliris for all patients with PNH. In June 2007, the European Commission granted marketing approval for Soliris in the European Union for all patients with PNH. The Company is evaluating other potential indications for Soliris, as well as other formulations of eculizumab for additional clinical indications. In addition, Alexion is pursuing development of an anti-CD200 monoclonal antibody as a treatment for patients with cancer, and evaluating 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 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 non-GAAP to GAAP figures follows this press release.

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ALEXION PHARMACEUTICALS, INC.
Selected Financial Data
(Unaudited)
(Amounts in thousands, except per share amounts)

Consolidated Statements of Operations Data:	Three Months Ended September 30		Nine Months Ended September 30	
	2008	2007	2008	2007
Revenues:				
Net product sales	$ 76,500	$ 21,793	$181,605	$ 32,524
Contract research revenues	-	317	95	5,660
Total revenues	76,500	22,110	181,700	38,184
Cost of sales	8,948	2,154	21,554	3,305
Operating expenses:				
Research and development	14,874	16,906	47,306	53,318
Selling, general and administrative	32,064	24,944	94,754	67,571
Total operating expenses	46,938	41,850	142,060	120,889

Operating income (loss)	20,614	(21,894)	18,086	(86,010)
Other income (expense):				
Investment income	690	1,796	2,071	6,724
Interest expense	(634)	(643)	(1,975)	(1,854)
Foreign currency gain (loss)	(566)	578	(200)	924
	(510)	1,731	(104)	5,794
Income tax provision (benefit)	415	(78)	169	(258)
Net income (loss)	$ 19,689	$(20,085)	$ 17,813	$(79,958)
Net income (loss) per share				
Basic	$ 0.26	$ (0.27)	$ 0.24	$ (1.11)
Diluted	$ 0.23	$ (0.27)	$ 0.22	$ (1.11)
Shares used in computing net income (loss) per common share				
Basic	76,658	73,328	75,794	72,046
Diluted	89,843	73,328	88,797	72,046

Consolidated Balance Sheet Data:

	As of	
	September 30, 2008	December 31, 2007
Cash, cash equivalents and marketable securities (a)	$126,402	$106,712
Total assets	430,343	334,357
Total stockholders' equity	173,760	101,556

(a) Amount includes restricted cash of $552 and $958 at September 30, 2008 and December 31, 2007, respectively.

ALEXION PHARMACEUTICALS, INC.
Selected Financial Data
(Unaudited) (Amounts in thousands, except per share amounts)

Non-GAAP financial information is adjusted to exclude the impact of share-based compensation. The following table represents a reconciliation of GAAP to non-GAAP financial information for the three and nine months ended September 30, 2008 and 2007, as well as the three months ended June 30, 2008:

	Reported GAAP Amounts	Share-Based Compensation Adjustment	Non-GAAP Excluding Share-Based Compensation
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 (loss)	17,813	17,881	35,694
Net income (loss) per share			
Basic	$ 0.24	$ 0.24	$ 0.47
Diluted	$ 0.22	$ 0.20	$ 0.41 (a)
Shares used in computing net income (loss)			
Basic	75,794		75,794
Diluted	88,797		90,262
Nine Months Ended September 30, 2007			
Research and development	$ 53,318	$ (7,555)	$ 45,763
Selling, general and administrative	67,571	(8,831)	58,740
Operating expenses	120,889	(16,386)	104,503
Net loss	(79,958)	16,386	(63,572)
Basic and diluted net loss per share	$ (1.11)	$ 0.23	$ (0.88)
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 (a)
Shares used in computing net income			
Basic	76,658		76,658
Diluted	89,843		91,108
Three Months Ended September 30, 2007			
Research and development	$ 16,906	$ (2,867)	$ 14,039
Selling, general and administrative	24,944	(3,198)	$ 21,746
Operating expenses	41,850	(6,065)	$ 35,785
Net loss	(20,085)	6,065	$ (14,020)
Basic and diluted net loss per share	$ (0.27)	$ 0.09	$ (0.19)
Three Months Ended June 30, 2008			
Research and development	$ 16,825	$ (1,525)	$ 15,300
Selling, general and administrative	32,907	(4,479)	$ 28,428
Operating expenses	49,732	(6,004)	$ 43,728
Net income	2,374	6,004	$ 8,378
Net income per share			
Basic	$ 0.03	$ 0.08	$ 0.11
Diluted	$ 0.03	$ 0.08	$ 0.10
Shares used in computing net income			
Basic	75,684		75,684
Diluted	78,990		89,968

(a) In accordance with FAS 128, diluted earnings per share for the three and nine months ended September 30, 2008 includes the dilutive impact of 9,538 if-converted shares from the Company's convertible notes. Earnings per share for these periods is calculated by adding back to net income the interest expense associated with the convertible notes and by adding the if-converted shares to the shares used to compute net income per share. The interest expense was $528 and $1,694, respectively, for the three and nine months ended September 30, 2008.

SOURCE Alexion Pharmaceuticals, Inc.

http://www.alexionpharma.com