



## Alexion Reports Second Quarter 2008 Results

CHESHIRE, Conn., July 29, 2008 /PRNewswire-FirstCall via COMTEX News Network/ --

Continued Strong Uptake of Soliris(R) in U.S. and Europe

First GAAP Profit; Sales Guidance Revised Upward

Two-For-One Stock Split Announced

Oncology and Kidney Transplantation Clinical Studies Progress

### Second Quarter 2008 Financial Highlights:

- Soliris(R) (eculizumab) net product sales were \$59.6 million in Q2 2008, an increase of 31 percent compared to \$45.5 million in Q1 2008. Net product sales of Soliris were \$9.8 million in the Q2 2007 initial launch quarter.
- Q2 GAAP net income was \$2.4 million, or \$0.06 per diluted share, compared to a GAAP net loss of \$27.2 million, or \$0.75 per share, in Q2 2007.
- Q2 non-GAAP net income was \$8.4 million, or \$0.20 per diluted share, compared to a non-GAAP net loss of \$21.8 million, or \$0.61 per share, in Q2 2007.

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

### Second Quarter 2008 Financial Results:

For the three months ended June 30, 2008, Alexion Pharmaceuticals, Inc. ("Alexion" or the "Company") reported total revenues of \$59.6 million compared to total revenues of \$9.8 million for the same period in 2007. Net product sales of Soliris accounted for all revenues in both periods. 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. Total revenues in Q2 2008 increased by 31 percent compared to total revenues of \$45.6 million in the prior quarter, Q1 2008.

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 June 30,	
	2008	2007
Net Product Sales	\$ 59.6	\$ 9.8
Total Revenues	\$ 59.6	\$ 9.8
GAAP Net Income (Loss)	\$ 2.4	\$(27.2)

Share-Based Compensation	\$ 6.0	\$ 5.3
	-----	-----
Non-GAAP Net Income (Loss)	\$ 8.4	\$ (21.8)
GAAP Net Income (Loss) Per Share - Diluted	\$ 0.06	\$ (0.75)
Non-GAAP Net Income (Loss) Per Share - Diluted	\$ 0.20	\$ (0.61)

## Second Quarter 2008 (Q2 2008) Non-GAAP Financial Results

The Company reported non-GAAP net income for Q2 2008 of \$8.4 million, or \$0.20 per diluted share, compared to a non-GAAP net loss of \$21.8 million, or \$0.61 per share, in the year-ago quarter, Q2 2007. Alexion reported non-GAAP net income of \$1.6 million, or \$0.04 per diluted share, in the prior quarter, Q1 2008.

Alexion's non-GAAP operating expenses for Q2 2008 were \$43.7 million, compared to \$32.6 million for Q2 2007. Non-GAAP research and development ("R&D") expenses for Q2 2008 were \$15.3 million, compared to \$12.9 million for the year-ago quarter. The increase in R&D costs in Q2 2008 was primarily the result of the Company's investments in drug development programs associated with the AEGIS study in Japan, additional indications for Soliris, and its anti-CD200 monoclonal antibody, as well as expenses for its EXPLORE trial. Non-GAAP selling, general, and administrative ("SG&A") expenses for Q2 2008 were \$28.4 million, compared to \$19.8 million for Q2 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.

## Second Quarter 2008 GAAP Financial Results

Alexion reported GAAP net income for the second quarter of 2008 of \$2.4 million, or \$0.06 per diluted share, compared to a GAAP net loss of \$27.2 million, or \$0.75 per share, for Q2 2007 and a GAAP net loss of \$4.2 million, or \$0.11 per share, in the prior quarter, Q1 2008.

On a GAAP basis, operating expenses for Q2 2008 were \$49.7 million, compared to \$38.0 million for Q2 2007. R&D expenses for Q2 2008 were \$16.8 million, compared to \$15.2 million for the year-ago quarter. The increase in R&D costs in Q2 2008 was primarily the result of the Company's investments in drug development programs associated with the AEGIS study in Japan, additional indications for Soliris, and its anti-CD200 monoclonal antibody, as well as expenses for its EXPLORE trial. SG&A expenses were \$32.9 million for Q2 2008, compared to \$22.8 million for Q2 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. Operating expenses for Q2 2008 included \$6.0 million of share-based compensation expense, compared to \$5.3 million in Q2 2007.

## Balance Sheet:

As of June 30, 2008, the Company had \$108.3 million in cash, cash equivalents, restricted cash, and marketable securities, compared to \$106.7 million at December 31, 2007. At the end of the quarter, the outstanding balance on the Company's revolving credit facility was \$5 million, compared to \$18 million at the end of Q1.

"In the second quarter, significant numbers of new patients with PNH in the U.S. and European countries joined those who were already receiving the benefits of Soliris therapy," said Leonard Bell, M.D., Chief Executive Officer of Alexion. "Our commitment is unwavering as we drive to make Soliris available to more patients with PNH, and as we begin additional development programs to help individuals suffering with other severe and life-threatening rare diseases."

## Stock Split:

Alexion's Board of Directors has approved a two-for-one stock split to be effected in the form of a 100 percent stock dividend. Shareholders of record as of the close of trading on August 12, 2008 will receive one additional share of Alexion common stock for each share they hold on that date. The payment date will be at the close of trading on August 22, 2008.

## Research and Development:

Soliris as a Treatment for Patients with PNH

During the second quarter, Alexion completed the 12-week patient dosing in its AEGIS study, a single registration study to evaluate the safety, efficacy and pharmacology of Soliris as a treatment for Japanese patients with PNH.

## 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 hematologic disorders: catastrophic anti-phospholipid syndrome ("CAPS"), atypical hemolytic uremic syndrome ("aHUS") and cold hemagglutinin disease ("CHAD").

Further, with FDA authorization during the quarter of an Investigational New Drug application ("IND") for Soliris in myasthenia gravis ("MG"), a rare, disabling and sometimes life-threatening complement-mediated neurologic disorder, Alexion is now preparing to initiate clinical studies of Soliris as a treatment for patients with severe MG. In addition, the Company is aware that dosing with Soliris has commenced 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 anti-CD200 monoclonal antibody, which is designed to enhance the immune response to several types of malignant tumors. In the second quarter, initial patient dosing commenced in a study of this antibody in patients with chronic lymphocytic leukemia ("CLL").

## Q2 2008 Soliris Commercial Update:

In the second quarter, the Company continued to add significant numbers of newly identified patients in the U.S. and in European countries and to transition clinical trial patients to full commercial status.

"Our focus on educating physicians on the natural history and clinical consequences of PNH and the benefits of Soliris therapy resulted in continued strong additions of new patients in the U.S. and Europe," said David Keiser, President and Chief Operating Officer of Alexion. "Additionally, we also observed an increase in the number of patients tested for PNH, as more physicians adopted standardized diagnostic pathways. These measures are helping more patients with PNH to avoid the years of suffering that have been typical with this disease. We remain focused on our objective that every patient who can benefit from Soliris will have access to it."

## 2008 Financial Guidance:

Alexion is revising upward its previously announced guidance for worldwide Soliris net product sales, from a range of \$215 to \$225 million to a range of \$235 to \$245 million for full-year 2008. Guidance for the cost of sales, including royalties, remains unchanged at 12 percent to 14 percent of net product sales.

Full-year 2008 financial guidance for R&D has been narrowed from the previously announced range of \$65 to \$75 million to a range of \$65 to \$70 million. Guidance with respect to SG&A expenses is being maintained in a range of \$115 to \$125 million. Thus, total operating expenses for 2008 are now expected to be within a range of \$180 to \$195 million, which is within the previously issued guidance of \$180 to \$200 million. This guidance for R&D and SG&A expenses excludes share-based compensation expenses, which have been revised downward from a range of \$26 to \$28 million to \$24 to \$26 million for the year.

The Company maintains its forecast of a non-GAAP profit for the full year 2008, and additionally, now expects to report a GAAP profit for the third and fourth quarters of 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, July 29, 2008, at 10:00 a.m., Eastern Time. To participate in this call, dial 719-325-4774, confirmation code 6410566, 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 6410566. The audio webcast can be accessed at [www.alexionpharma.com](http://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](http://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.

[ALXN-E]

This news release contains forward-looking statements, including statements related to guidance regarding anticipated financial results for 2008, potential benefits and commercial potential for Soliris, timing and effect of sales of Soliris in the United States and various European markets, status of reimbursement, price approval and funding processes in Europe, progress in developing commercial infrastructure, interest regarding Soliris in the patient, physician and payor communities and expectations about commencement of clinical trials and studies for Soliris in PNH and non-PNH indications, and other products. 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 of Soliris are not predictive of safety and efficacy and Soliris is found to be less safe or effective when utilized in broader patient populations, within the studied disease or other diseases, 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 risk that ongoing litigation may be resolved adversely, 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 March 31, 2008 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.

(Financial Tables Follow)

ALEXION PHARMACEUTICALS, INC.

Selected Financial Data

(Unaudited)

(Amounts in thousands, except per share amounts)

Consolidated Statements of

Operations Data:

Three Months Ended		Six Months Ended	
June 30		June 30	
2008	2007	2008	2007
-----	-----	-----	-----

Revenues:				
Net product sales	\$ 59,559	\$ 9,756	\$105,105	\$ 10,731
Contract research revenues	-	-	95	5,343
	-----	-----	-----	-----
Total revenues	59,559	9,756	105,200	16,074
Cost of sales	7,142	1,067	12,606	1,152
Operating expenses:				
Research and development	16,825	15,195	32,434	36,415
Selling, general and administrative	32,907	22,788	62,688	42,627
	-----	-----	-----	-----
Total operating expenses	49,732	37,983	95,122	79,042
	-----	-----	-----	-----
Operating income (loss)	2,685	(29,294)	(2,528)	(64,120)
	-----	-----	-----	-----
Other income (expense):				
Investment income	604	2,158	1,371	4,928
Interest expense	(736)	(511)	(1,332)	(1,211)
Foreign currency gain (loss)	(335)	373	368	346
	-----	-----	-----	-----
	(467)	2,020	407	4,063
	-----	-----	-----	-----
Income tax benefit	156	90	246	180
	-----	-----	-----	-----
Net income (loss)	\$ 2,374	\$(27,184)	\$(1,875)	\$(59,877)
	=====	=====	=====	=====
Net income (loss) per share				
Basic	\$ 0.06	\$ (0.75)	\$ (0.05)	\$ (1.68)
Diluted	\$ 0.06	\$ (0.75)	\$ (0.05)	\$ (1.68)
Shares used in computing net income				
(loss) per common share				
Basic	37,842	36,031	37,679	35,698
Diluted	39,495	36,031	37,679	35,698

Consolidated Balance Sheet Data:

As of

	-----	-----
	June 30, 2008	December 31, 2007
	-----	-----
Cash, cash equivalents		
and marketable securities (a)	\$ 108,281	\$ 106,712
Total assets	379,189	334,357
Total stockholders' equity	126,798	101,556

(a) Amount includes restricted cash of \$484 and \$958 at June 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 six months ended June 30, 2008 and 2007, as well as the three months ended March 31,

2008:

	Reported GAAP Amounts	Share-Based Compensation Adjustment	Non-GAAP Excluding Share-Based Compensation
	-----	-----	-----
Six Months Ended June 30, 2008			
Research and development	\$ 32,434	\$ (3,152)	\$ 29,282
Selling, general and administrative	62,688	(8,739)	53,949
Operating expenses	95,122	(11,891)	83,231
Net income (loss)	(1,875)	11,891	10,016
Net income (loss) per share			
Basic	\$ (0.05)	\$0.32	\$ 0.27
Diluted	\$ (0.05)	\$0.26	\$ 0.25 (a)
Shares used in computing net income (loss)			
Basic	37,679		37,679
Diluted	37,679		44,875
Six Months Ended June 30, 2007			
Research and development	\$ 36,415	\$ (4,687)	\$ 31,728
Selling, general and administrative	42,627	(5,633)	36,994
Operating expenses	79,042	(10,320)	68,722
Net loss	(59,877)	10,320	(49,557)
Basic and diluted net loss per share	\$ (1.68)	\$0.29	\$ (1.39)
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	\$ 0.06	\$ 0.16	\$0.22
Diluted	\$ 0.06	\$ 0.13	\$0.20 (a)
Shares used in computing net income			
Basic	37,842		37,842
Diluted	39,495		44,984
Three Months Ended June 30, 2007			
Research and development	\$ 15,195	\$ (2,302)	\$ 12,893
Selling, general and administrative	22,788	(3,037)	19,751
Operating expenses	37,983	(5,339)	32,644
Net loss	(27,184)	5,339	(21,845)
Basic and diluted net loss per share	\$ (0.75)	\$0.15	\$ (0.61)
Three Months Ended March 31, 2008			
Research and development	\$ 15,609	\$ (1,625)	\$ 13,984
Selling, general and administrative	29,781	(4,260)	25,521
Operating expenses	45,390	(5,885)	39,505
Net income (loss)	(4,249)	5,885	1,636
Basic and diluted net income (loss) per share			
	\$ (0.11)	\$ 0.16	\$ 0.04

(a) In accordance with FAS 128, non-GAAP diluted earnings per share for

the three and six months ended June 30, 2008 includes the dilutive impact of 4,679 if-converted shares from the Company's convertible notes. Non-GAAP 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 \$650 and \$1,165, respectively, for the three and six months ended June 30, 2008.

SOURCE Alexion Pharmaceuticals, Inc.

<http://www.alexionpharma.com>

Copyright (C) 2008 PR Newswire. All rights reserved

News Provided by COMTEX