



## Alexion Reports Fourth Quarter and Full Year 2008 Results

CHESHIRE, Conn., Feb 12, 2009 (BUSINESS WIRE) -- Alexion Pharmaceuticals, Inc. (NASDAQ: ALXN):

**-- \$259 Million in Soliris(R) Sales in First Full Commercial Year --**

**-- Continued Strong Uptake of Soliris in U.S. and Europe in Q4 --**

**-- Soliris Research Programs Progress: Clinical Data in PNH and Other Rare Diseases Presented at ASH and ASN --**

### 2008 and Fourth Quarter Financial Highlights:

- Total 2008 Soliris(R) (eculizumab) net product sales were \$259.0 million, compared to \$66.4 million in 2007.
- Soliris net product sales were \$77.4 million in Q4 2008, reflecting a strong addition of new patients during the quarter, compared to \$33.9 million in Q4 2007.
- Soliris net product sales in Q4 2008 increased nine percent compared to Q3 2008 net product sales of \$71.2 million for shipments that occurred in Q3, despite a negative impact from foreign exchange. Q3 2008 net product sales additionally included recognition of a further \$5.3 million for Soliris shipments that occurred in previous quarters.
- 2008 GAAP net income was \$33.1 million, or \$0.39 per diluted share, compared to a GAAP net loss of \$92.3 million, or \$1.27 per share, in 2007.
- 2008 non-GAAP net income was \$56.8 million, or \$0.64 per diluted share, compared to a non-GAAP net loss of \$72.1 million, or a net loss of \$0.99 per share, in 2007.
- Q4 GAAP net income was \$15.3 million, or \$0.17 per diluted share, compared to a GAAP net loss of \$12.3 million, or \$0.17 per share, in Q4 2007.
- Q4 non-GAAP net income was \$21.1 million, or \$0.23 per diluted share, compared to a non-GAAP net loss of \$8.5 million, or \$0.11 per share, in Q4 2007.

Alexion Pharmaceuticals, Inc. (NASDAQ: ALXN) today announced financial results for the quarter and year ended December 31, 2008.

### Fourth Quarter 2008 Financial Results:

For the three months ended December 31, 2008, Alexion Pharmaceuticals, Inc. ("Alexion" or, the "Company") reported net product sales of Soliris(R) (eculizumab) of \$77.4 million, reflecting a strong addition of new patients, compared to \$33.9 million for the same period in 2007. Net product sales in Q4 2008 increased nine percent over Q3 2008 net product sales of \$71.2 million for shipments that occurred in Q3, despite a negative impact from foreign exchange in Q4 2008. Q3 2008 net product sales additionally included recognition of a further \$5.3 million for Soliris shipments that occurred in previous quarters.

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 results and non-GAAP results. Non-GAAP results are equal to GAAP results less the impact of share-based compensation. The following summary table is provided for investors' convenience. A complete reconciliation and explanation of the GAAP to non-GAAP figures appear below.

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

	Quarter Ended December 31,		Year Ended December 31,	
	2008	2007	2008	2007
Total Revenues	\$ 77.4	\$ 33.9	\$ 259.1	\$ 72.0
GAAP Net Income (Loss)	15.3	(12.3 )	33.1	(92.3 )
Share-Based Compensation	5.8	3.8	23.7	20.2
Non-GAAP Net Income (Loss)	\$ 21.1	\$ (8.5 )	\$ 56.8	\$ (72.1 )
GAAP Net Income (Loss) Per Share	\$ 0.17	\$ (0.17 )	\$ 0.39	\$ (1.27 )

Non-GAAP Net Income (Loss) Per Share \$ 0.23      \$ (0.11      )      \$ 0.64      \$ (0.99      )

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

#### **Fourth Quarter Non-GAAP Financial Results:**

The Company reported non-GAAP net income for the fourth quarter of \$21.1 million, or \$0.23 per share, compared to a non-GAAP net loss of \$8.5 million, or \$0.11 per share, in the fourth quarter of 2007.

Alexion's non-GAAP operating expenses for the fourth quarter of 2008 were \$48.3 million, compared to \$40.4 million for the fourth quarter of 2007. Non-GAAP R&D expenses for Q4 2008 were \$13.6 million, compared to \$14.7 million for the year-ago quarter. Non-GAAP selling, general and administrative (SG&A) expenses for the fourth quarter were \$34.7 million, compared to \$25.8 million for the fourth quarter of 2007. The increase in non-GAAP SG&A expenses primarily reflected costs associated with the continuing development of the Company's commercial operations in the U.S. and Europe, as well as costs associated with an expanded presence at medical conferences.

#### **Fourth Quarter GAAP Financial Results:**

Alexion reported GAAP net income of \$15.3 million for the fourth quarter of 2008, or \$0.17 per diluted share, compared to a GAAP net loss of \$12.3 million, or \$0.17 per share, in the fourth quarter of 2007.

On a GAAP basis, operating expenses for the fourth quarter of 2008 were \$54.1 million, compared to \$44.2 million for the same period last year. GAAP R&D expenses for the fourth quarter were \$15.3 million, compared to \$15.6 million for the same period last year. GAAP SG&A expenses were \$38.8 million, compared to \$28.6 million for the fourth quarter of 2007. The increase in GAAP SG&A expenses primarily reflected costs associated with the continuing development of the Company's commercial operations in the U.S. and Europe, as well as costs associated with an expanded presence at medical conferences.

#### **Full Year 2008 Financial Results:**

For the year ended December 31, 2008, the first full fiscal year of Soliris commercialization, the Company reported net product sales of Soliris of \$259.0 million, an increase of 290 percent compared to \$66.4 million in 2007, the year in which Soliris launched in the U.S. and Europe.

Alexion's non-GAAP operating expenses for the full year 2008 were \$172.4 million, compared to \$144.9 million for 2007. Non-GAAP R&D expenses for 2008 were \$56.5 million, compared to \$60.4 million for the prior year. The decrease in non-GAAP R&D expenses primarily reflected a decrease in clinical development expense in 2008 related to the completion of certain studies. Non-GAAP SG&A expenses for 2008 were \$115.9 million, compared to \$84.5 million in 2007. The increase in non-GAAP SG&A expenses primarily reflected costs associated with the continuing development of the Company's commercial operations in the U.S. and Europe.

The Company reported non-GAAP net income of \$56.8 million in 2008, or \$0.64 per diluted share, compared to a non-GAAP net loss of \$72.1 million, or a net loss of \$0.99 per share, in 2007.

On a GAAP basis, operating expenses for 2008 were \$196.1 million, compared to \$165.1 million for the prior year. GAAP R&D expenses for 2008 were \$62.6 million, compared to \$69.0 million in 2007. The decrease in GAAP R&D expenses primarily reflected a decrease in clinical development expense in 2008 related to the completion of certain studies. GAAP SG&A expenses were \$133.5 million in 2008, compared to \$96.1 million for the prior year. The increase in GAAP SG&A expenses primarily reflected costs associated with the continuing development of the Company's commercial operations in the U.S. and Europe.

Alexion reported GAAP net income of \$33.1 million, or \$0.39 per share in 2008, compared to a GAAP net loss of \$92.3 million, or a net loss of \$1.27 per share, for 2007.

"In 2008, the first full year of Soliris commercialization, Alexion achieved outstanding execution of its business initiatives and brought the clinical benefits of Soliris to patients in more than 18 countries," said Leonard Bell, M.D., Chief Executive Officer of Alexion. "Our strong financial position enables our continued expansion of the Soliris franchise for patients with PNH and other severe and rare disorders, and our broadening clinical pipeline reflects the potential opportunities for Soliris and our oncology platform. We remain committed to our objective that every patient who can benefit from Soliris will have access to Soliris."

#### **Balance Sheet:**

As of December 31, 2008, the Company had \$139.7 million in cash, cash equivalents, restricted cash and marketable

securities, compared to \$106.7 million at December 31, 2007. The outstanding balance on the Company's \$25 million revolving credit facility remained at zero throughout the fourth quarter.

#### **Soliris Commercial Update:**

The number of patients on Soliris therapy increased significantly during the fourth quarter, driven by continued growth in the U.S. and in Europe. The Company has now completed pricing and reimbursement processes for launch in the five largest European markets of France, Germany, Italy, Spain and the United Kingdom.

In Canada, Soliris received marketing approval in late January for all patients with PNH. Alexion is working with public and private healthcare organizations to make Soliris commercially available to the first patients in that country by late 2009.

In January, Alexion reported that Soliris had received orphan drug designation in Japan. As a result of the designation, a New Drug Application (NDA) for Soliris would receive priority review from the Japanese regulatory authorities once it is submitted, and the drug would have 10 years of market exclusivity as a treatment for patients with PNH. The Company expects to submit its Japanese NDA in 2009, and has started to establish its commercial organization in Japan in anticipation of a commercial launch of Soliris in that country in 2010.

In Australia, the Company is currently working with the regulatory agency and expects a decision on its marketing application for Soliris in 2009. Alexion is building its commercial organization in Australia and expects a commercial launch in that country by the end of 2009.

#### **Q4 Research and Development Progress:**

##### **Soliris as a Treatment for Patients with PNH**

At the American Society of Hematology (ASH) Annual Meeting in December, Japanese researchers presented positive results from AEGIS, an open-label registration study examining Soliris as a treatment for Japanese patients with PNH. In AEGIS, the pre-specified primary efficacy endpoint of change in hemolysis was achieved; key secondary endpoints were also achieved.

In separate studies presented at ASH, researchers reported a high prevalence of pulmonary arterial hypertension (PAH) in patients with PNH and also the presence of a hypercoagulable state in patients without a history of transfusion or blood clots. Investigators reported that Soliris significantly reduced measures of PAH and measures of inflammation and thrombotic activity in these patients.

##### **Soliris as an Investigational Treatment for Patients with Other Rare and Severe Diseases**

With the FDA approval in 2007 of Soliris as a treatment for PNH, a complement-inhibitor deficiency disease, Alexion became the first company to discover and then 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-inhibitor deficiency diseases, as well as those with other severe, complement-mediated conditions.

Clinical studies are being initiated in patients with two other rare, severe complement-inhibitor deficiency diseases: atypical hemolytic uremic syndrome (aHUS) and dense deposit disease, two diseases in which the lack of naturally occurring complement inhibitors can cause life-threatening kidney damage. Case studies of aHUS patients treated with Soliris were presented in the fourth quarter at both ASH and the American Society of Nephrology (ASN) meeting and were published in January 2009 in the *New England Journal of Medicine*. Patient enrollment is continuing in a study of kidney transplant patients who are known to have a higher risk of organ rejection. Data on the first of these patients were presented in the fourth quarter at ASN.

In neurology, patients are being enrolled 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. In addition, patient screening has commenced in an investigator-sponsored clinical trial evaluating the use of Soliris in a second neurologic disease, multifocal motor neuropathy.

##### **Oncology Program**

Patient enrollment and dosing is continuing in a Phase I/II study of Alexion's novel, first-in-class humanized anti-CD200 monoclonal antibody, in patients with chronic lymphocytic leukemia (CLL).

#### **2009 Financial Guidance:**

In 2009, worldwide net product sales are expected to be within a range of \$360 to \$375 million. Gross margin is expected to be

in the range of 87 to 89 percent. Excluding share-based compensation, R&D expenses in 2009 are anticipated to be in the range of \$80 to \$85 million, and selling, general and administrative expenses in the range of \$140 to \$150 million. The Company's share-based compensation expenses for the year are expected to be in a range of approximately \$28 to \$30 million. Taxes on non-GAAP income are expected to be in a range of five percent to seven percent. Alexion is providing guidance of \$1.00 to \$1.05 for non-GAAP diluted earnings per share 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, February 12, 2009, at 10:00 a.m., Eastern Time. To participate in this call, dial 719-325-4745, confirmation code 8549129, 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 8549129. The audio webcast can be accessed at [www.alexionpharm.com](http://www.alexionpharm.com).

#### About Soliris

Soliris is the first product approved for the treatment of PNH in the U.S., European Union and other countries. 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, and the Company began commercial sale of Soliris in the U.S. during April 2007. 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, 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: <http://www.alexionpharm.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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*This news release contains forward-looking statements, including statements related to guidance regarding anticipated financial results for 2009, assessment of the Company's financial position and commercialization efforts, potential benefits and commercial potential for Soliris, timing for launch of commercial sales of Soliris in Canada, Japan and Australia, timing for submission of NDA in Japan and expectations for receipt of regulatory approval in Japan and Australia; potential of Alexion's complement-inhibition technology for treatment of diseases other than PNH; plans for clinical programs for CD200 and Soliris in non-PNH indications; progress in developing commercial infrastructure 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 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, 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, 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.

**ALEXION PHARMACEUTICALS, INC.**

**Selected Financial Data**

(Unaudited)

(Amounts in thousands, except per share data)

<b>Consolidated Statements of Operations Data:</b>	<b>Three Months Ended December 31</b>		<b>Twelve Months Ended December 31</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
Revenues:				
Net product sales	\$ 77,399	\$ 33,858	\$ 259,004	\$ 66,381
Contract research revenues	-	-	95	5,660
Total revenues	77,399	33,858	259,099	72,041
Cost of sales	6,812	3,391	28,366	6,696
Operating expenses:				
Research and development	15,275	15,643	62,581	68,961
Selling, general and administrative	38,789	28,570	133,543	96,142
Total operating expenses	54,064	44,213	196,124	165,103
Operating income (loss)	16,523	(13,746 )	34,609	(99,758 )
Other income (expense):				
Investment income	739	1,356	2,810	8,080
Interest expense	(432 )	(635 )	(2,407 )	(2,489 )
Foreign currency gain (loss)	(82 )	208 )	(282 )	1,132 )
	225	929	121	6,723
Income tax provision (benefit)	1,412	(487 )	1,581	(745 )
Net income (loss)	\$ 15,336	\$ (12,330 )	\$ 33,149	\$ (92,290 )
Net income (loss) per share				
basic	\$ 0.19	\$ (0.17 )	\$ 0.43	\$ (1.27 )
diluted	\$ 0.17	\$ (0.17 )	\$ 0.39	\$ (1.27 )
Shares used in computing net income (loss) per share				
basic	80,260	74,330	77,680	72,622
diluted	90,479	74,330	89,967	72,622

**Consolidated Balance Sheet Data:**

**As of  
December 31, 2008 December 31, 2007**

Cash, cash equivalents and marketable securities (a)	\$ 139,711	\$ 106,712
Total assets	477,551	334,357
Total stockholders' equity	247,001	101,556

(a) Amount includes restricted cash of \$1,699 and \$958 at December 31, 2008 and December 31, 2007, respectively.

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 months and full years ended December 31, 2008 and 2007:

<b>Reported GAAP Amounts</b>	<b>Share-Based Compensation Adjustment</b>	<b>Non-GAAP Excluding Share-Based Compensation</b>
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**Year 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	\$ 0.30		\$ 0.73
Diluted	\$ 0.39	\$ 0.26		\$ 0.64
Shares used in computing net income				
Basic	77,680			77,680
Diluted	89,967			91,359
<b>Year Ended December 31, 2007</b>				
Research and development	\$ 68,961	\$ (8,544	)	\$ 60,417
Selling, general and administrative	96,142	(11,630	)	84,512
Operating expenses	165,103	(20,174	)	144,929
Net loss	(92,290	)	20,174	(72,116
				)
Basic and diluted net loss per share	\$ (1.27	)	\$ 0.28	\$ (0.99
				)
<b>Three Months Ended December 31, 2008</b>				
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	\$ 0.07		\$ 0.26
Diluted	\$ 0.17	\$ 0.06		\$ 0.23
Shares used in computing net income				
Basic	80,260			80,260
Diluted	90,479			91,588
<b>Three Months Ended December 31, 2007</b>				
Research and development	\$ 15,643	\$ (989	)	\$ 14,654
Selling, general and administrative	28,570	\$ (2,799	)	25,771
Operating expenses	44,213	(3,788	)	40,425
Net loss	(12,330	)	3,788	(8,542
				)
Basic and diluted net loss per share	\$ (0.17	)	\$ 0.05	\$ (0.11
				)

SOURCE: Alexion Pharmaceuticals, Inc.

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