



## Alexion Reports Fourth Quarter and Full Year 2011 Results

- Soliris® (eculizumab) Net Product Sales Increased 45 Percent to \$783 Million in 2011 -
- Continued Strong Uptake of Soliris by New PNH Patients; U.S. Launch in aHUS Begins —
- Pipeline Progresses with Five Compounds Targeting Severe and Ultra-Rare Disorders -

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

### Fourth Quarter 2011 Financial Highlights:

- Q4 2011 net product sales increased 46 percent to \$227.6 million, compared to \$156.0 million in Q4 2010.
- Q4 2011 GAAP net income increased 82 percent, to \$48.2 million, or \$0.25 per share, compared to Q4 2010 GAAP net income of \$26.5 million, or \$0.14 per share.
- Q4 2011 non-GAAP net income increased 65 percent to \$80.5 million, or \$0.41 per share, compared to Q4 2010 non-GAAP net income of \$48.6 million, or \$0.26 per share.

### Full-Year 2011 Financial Highlights:

- 2011 net product sales increased 45 percent to \$783.4 million, compared to \$541.0 million in 2010.
- 2011 GAAP net income increased 81 percent to \$175.3 million, or \$0.91 per share, compared to 2010 GAAP net income of \$97.0 million, or \$0.52 per share.
- 2011 non-GAAP net income increased 59 percent to \$266.1 million, or \$1.38 per share, compared to 2010 non-GAAP net income of \$167.3 million, or \$0.89 per share.

Alexion Pharmaceuticals, Inc. (NASDAQ: ALXN) today announced financial results for the quarter and year ended December 31, 2011. For the three months ended December 31, 2011, Alexion Pharmaceuticals, Inc. ("Alexion", or the "Company") reported net product sales of Soliris® (eculizumab) of \$227.6 million, compared to \$156.0 million for the same period in 2010. The year-on-year increase of 45 percent resulted primarily from strong additions of new patients with paroxysmal nocturnal hemoglobinuria (PNH) globally, with a small contribution from the US launch of Soliris in atypical Hemolytic Uremic Syndrome (aHUS) during the last months of 2011.

Soliris was approved for patients with PNH in the US (2007), European Union (2007), Japan (2010) and other territories as the first and only treatment indicated for this ultra-rare, debilitating and life-threatening blood disease. In addition, in 2011, Soliris was approved as the first and only treatment for patients with aHUS in the US (September 2011) and European Union (November 2011). aHUS is an ultra-rare, life-threatening, genetic disease.

Alexion's non-GAAP operating results are equal to GAAP operating results adjusted for the impact of share-based compensation, taxes that are not payable in cash (non-cash tax adjustment), amortization of acquired intangible assets, and costs associated with acquisitions. The non-cash tax adjustment represents the reduction in cash taxes attributable to the utilization of US net operating losses. The following summary table is provided for investors' convenience:

(in thousands, except per share amounts)  
(unaudited)

	Three months ended		Twelve months ended	
	December		December	
	2011	2010	2011	2010
Total revenues	\$ 227,559	\$ 155,975	\$ 783,431	\$ 540,957
GAAP net income	\$ 48,170	\$ 26,450	\$ 175,315	\$ 97,030

Share-based compensation	10,337	7,605	44,763	32,338
Acquisition-related costs	2,322	722	13,486	722
Amortization of purchased intangibles	104	-	382	-
Non-cash tax adjustment	19,547	13,860	32,155	37,229
Non-GAAP net income	<u>\$ 80,480</u>	<u>\$ 48,637</u>	<u>\$ 266,101</u>	<u>\$ 167,319</u>
Shares used in computing diluted earnings per share (GAAP)	193,370	188,586	191,806	186,074
Shares used in computing diluted earnings per share (non-GAAP)	194,732	190,416	193,539	188,494
GAAP earnings per share - diluted	<u>\$ 0.25</u>	<u>\$ 0.14</u>	<u>\$ 0.91</u>	<u>\$ 0.52</u>
Non-GAAP earnings per share - diluted	<u>\$ 0.41</u>	<u>\$ 0.26</u>	<u>\$ 1.38</u>	<u>\$ 0.89</u>

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

The Company reported non-GAAP net income of \$80.5 million, or \$0.41 per share, in the fourth quarter of 2011, compared to non-GAAP net income of \$48.6 million, or \$0.26 per share, in the fourth quarter of 2010.

Alexion's non-GAAP operating expenses for Q4 2011 were \$111.2 million, compared to \$82.8 million for Q4 2010. Non-GAAP research and development (R&D) expenses for Q4 2011 were \$32.1 million, compared to \$25.4 million for Q4 2010. The increase in R&D expenses primarily reflected the expansion of the Company's development programs. Non-GAAP selling, general and administrative (SG&A) expenses for Q4 2011 were \$79.1 million, compared to \$57.4 million for Q4 2010. The increase in SG&A expenses primarily reflected Alexion's growing global operations for PNH and aHUS.

#### Fourth Quarter GAAP Financial Results:

Alexion reported GAAP net income of \$48.2 million, or \$0.25 per share in the fourth quarter of 2011, compared to Q4 2010 GAAP net income of \$26.5 million, or \$0.14 per share.

On a GAAP basis, operating expenses for Q4 2011 were \$123.4 million, compared to \$90.7 million for Q4 2010. GAAP R&D expenses for Q4 2011 were \$34.4 million, compared to \$27.2 million for Q4 2010. GAAP SG&A expenses were \$86.6 million for Q4 2011, compared to \$62.8 million for Q4 2010.

#### Full Year 2011 Non-GAAP Financial Results:

The Company reported non-GAAP net income of \$266.1 million in 2011, or \$1.38 per share, compared to non-GAAP net income of \$167.3 million, or \$0.89 per share, in 2010.

Alexion's non-GAAP operating expenses for the full year 2011 were \$403.2 million, compared to \$294.1 million for 2010. Non-GAAP R&D expenses for 2011 were \$127.7 million, compared to \$90.4 million for the prior year. The increase in R&D expenses primarily reflected the expansion of the Company's development programs. Non-GAAP SG&A expenses for 2011 were \$275.5 million, compared to \$203.7 million in 2010. The increase in SG&A expenses primarily reflected Alexion's growing global operations.

#### Full Year 2011 GAAP Financial Results:

Alexion reported GAAP net income of \$175.3 million, or \$0.91 per share in 2011 compared to 2010 GAAP net income of \$97.0 million, or \$0.52 per share.

Alexion's GAAP operating expenses for the full year 2011 were \$459.5 million, compared to \$325.9 million for the prior year. GAAP R&D expenses for 2011 were \$137.4 million, compared to \$98.4 million in 2010. GAAP SG&A expenses were \$308.2 million in 2011, compared to \$226.8 million for the prior year.

#### Balance Sheet:

As of December 31, 2011, the Company had \$540.9 million in cash, cash equivalents and marketable securities compared to \$361.6 million at December 31, 2010. The year-end 2011 cash balance does not reflect the purchase price for the Company's Enobia acquisition, which closed February 7, 2012 and was paid for with a combination of cash on hand and proceeds from the Company's new debt facility, and will be reflected in Alexion's Q1 2012 results.

"Following strong performance in our major global initiatives in 2011, we enter 2012 with the broadest commercial platform and the most robust development pipeline in Alexion's history," said Leonard Bell, M.D., Chief Executive Officer of Alexion. "Throughout 2012, we will focus on reaching more patients with PNH and serving the first patients with aHUS in the US and Europe. At the same time, we will accelerate our investigation of Soliris and four additional highly innovative compounds across eight severe and ultra-rare indications."

### **Global Commercial Operations:**

#### PNH

During Q4 2011, a substantial number of new patients with PNH were started on Soliris therapy in Alexion's core territories of the US, Western Europe and Japan. Patients with PNH in Australia and Canada, as well as in various other nations of Europe, Asia-Pacific, and Latin America are also receiving Soliris.

#### aHUS

Soliris was approved by the US Food and Drug Administration in September and by the European Commission in November as the first treatment for patients with aHUS. Following the US approval, Alexion began serving patients in the US during Q4. The EU approval will enable Alexion to begin serving patients in initial European countries in 2012.

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

Alexion currently has development programs underway with its five highly innovative compounds: eculizumab (Soliris) and four additional novel drugs beyond eculizumab that have the potential to become first-in-class therapies for patients with other severe and ultra-rare disorders.

#### Eculizumab Programs

- **Nephrology: STEC-HUS and Acute Humoral Kidney Rejection (AHR)**  
Interim data from the Company's open-label study of eculizumab in patients with Shiga toxin *E. Coli* related Hemolytic Uremic Syndrome (STEC-HUS), a severe, ultra-rare, and life-threatening inflammatory disorder, were presented at the American Society of Nephrology Conference in Philadelphia in November 2011. Final data from the study is expected later in 2012.  
  
Enrollment has commenced in a Company-sponsored multi-national living-donor kidney transplant trial in patients at elevated risk of AHR.
- **Neurology: NMO and MG**  
Programs with eculizumab are ongoing in two severe and ultra-rare neurologic disorders, Neuromyelitis Optica (NMO) and Myasthenia Gravis (MG). Data from the investigator initiated Phase 2 clinical trial of eculizumab in severe refractory NMO are expected in 2012. As previously announced, data from the Company's Phase 2 study in MG were presented in the fall of 2011.

#### Ultra-Rare Disease Programs With Highly Innovative Compounds Beyond Eculizumab

- **Asfotase Alfa**  
Asfotase alfa is an innovative, first-in-class targeted enzyme replacement therapy in Phase 2 clinical trials for patients with hypophosphatasia (HPP), an ultra-rare, genetic, and life-threatening metabolic disease with no effective treatment options.
- **cPMP Replacement Therapy**  
Alexion is accelerating the development of a cPMP replacement therapy for the treatment of patients with Molybdenum Cofactor Deficiency Type A, an ultra-rare, genetic metabolic disorder that is fatal in newborns. The Company is currently conducting IND enabling studies.
- **TT30**  
Alexion is now enrolling patients in a Phase I study to characterize the mechanism of action of TT30, a unique inhibitor of the alternative complement pathway, and to develop initial safety data.
- **ALXN1007**  
A Phase I study of ALXN1007, an innovative anti-inflammatory antibody, is underway to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of this compound in healthy volunteers.

## 2012 Financial Guidance:

In 2012, worldwide net product sales are expected to be within a range of \$1.04 to \$1.07 billion. On a non-GAAP basis, R&D expenses are anticipated to be in the range of \$220 to \$230 million, and SG&A expenses in the range of \$345 to \$355 million, which excludes \$20 to \$25 million in Enobia acquisition-related costs. The Company's share-based compensation expense for the year is expected to be in a range of \$50 to \$52 million. Cost of sales is expected to be approximately 12 percent of net product sales. Excluding the tax impact of the integration and structuring of the Enobia acquisition that Alexion will undertake throughout 2012, the GAAP effective tax rate is expected to be in the range of 32 to 34 percent. The non-GAAP effective tax rate, reported on a cash tax liability basis, is expected to be in the range of 8 to 10 percent. Based on a forecast of approximately 197 million diluted shares outstanding, Alexion is providing guidance of \$1.60 to \$1.70 for non-GAAP 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 9, at 10:00 a.m., Eastern Time. To participate in this call, dial 866-730-5770 (USA) or 857-350-1594 (International), passcode 36208284, 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 12:00 p.m., Eastern Time. The replay number is 888-286-8010 (USA) or 617-801-6888 (International), passcode 69128488. The audio webcast can be accessed at [www.alexionpharma.com](http://www.alexionpharma.com).

## About Soliris:

Soliris is a first-in-class terminal complement inhibitor developed from the laboratory through regulatory approval and commercialization by Alexion. Soliris is approved in the US, European Union, Japan and other countries as the first and only treatment for patients with paroxysmal nocturnal hemoglobinuria (PNH), a debilitating, ultra-rare and life-threatening blood disorder, characterized by complement-mediated hemolysis (destruction of red blood cells). Soliris is also approved in the US and the European Union as the first and only treatment for patients with atypical Hemolytic Uremic Syndrome (aHUS), a debilitating, ultra-rare and life-threatening genetic disorder characterized by complement-mediated thrombotic microangiopathy, or TMA (blood clots in small vessels). Soliris is indicated to inhibit complement-mediated TMA. The effectiveness of Soliris in aHUS is based on the effects on TMA and renal function. Prospective clinical trials in additional patients are ongoing to confirm the benefit of Soliris in patients with aHUS. Soliris is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS). Alexion's breakthrough approach in complement inhibition has received the pharmaceutical industry's highest honors: the 2008 Prix Galien USA Award for Best Biotechnology Product with broad implications for future biomedical research and the 2009 Prix Galien France Award in the category of Drugs for Rare Diseases. More information including the full prescribing information on Soliris is available at [www.soliris.net](http://www.soliris.net).

## About Alexion:

Alexion Pharmaceuticals, Inc. is a biopharmaceutical company focused on serving patients with severe and ultra-rare disorders through the innovation, development and commercialization of life-transforming therapeutic products. Alexion is the global leader in complement inhibition, and has developed and markets Soliris® (eculizumab) as a treatment for patients with PNH and aHUS, two debilitating, ultra-rare and life-threatening disorders caused by chronic uncontrolled complement activation. Soliris is currently approved in more than 35 countries for the treatment of PNH, and in the United States and the European Union for the treatment of aHUS. Alexion is evaluating other potential indications for Soliris and is developing four other highly innovative biotechnology product candidates. This press release and further information about Alexion Pharmaceuticals, Inc. can be found at: [www.alexionpharma.com](http://www.alexionpharma.com).

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*This news release contains forward-looking statements, including statements related to guidance regarding anticipated financial results for 2012, assessment of the Company's financial position and commercialization efforts, medical benefits and commercial potential for Soliris for PNH and aHUS and other potential indications, plans to pursue reimbursement approvals in the European Union, expansion of clinical and commercial operations to additional countries, medical and commercial potential of Alexion's complement-inhibition technology and other technologies, plans for clinical programs for each of our product candidates, progress in developing commercial infrastructure, and interest and acceptance regarding 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 for PNH and aHUS and other potential indications, delays in arranging satisfactory manufacturing capabilities and establishing commercial infrastructure, the possibility that results of clinical trials are not predictive of safety and efficacy results of Soliris in broader patient populations in the disease studied or other diseases, the risk that recent acquisitions will not result in short-term or long-term benefits, the possibility that current results of commercialization are not predictive of future rates of adoption of Soliris in PNH, aHUS or other diseases, 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, aHUS 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 three and nine months ended September 30, 2011 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**  
(in thousands, except per share amounts)  
(unaudited)

	Three months ended December		Twelve months ended December	
	2011	2010	2011	2010
Net product sales	\$ 227,559	\$ 155,975	\$ 783,431	\$ 540,957
Cost of sales (1)	28,798	20,222	93,140	64,437
Operating expenses:				
Research and development (1)	34,398	27,177	137,421	98,394
Selling, general and administrative (1)	86,567	62,825	308,176	226,766
Acquisition-related costs (2)	2,322	722	13,486	722
Amortization of purchased intangibles	104	-	382	-
Total operating expenses	<u>123,391</u>	<u>90,724</u>	<u>459,465</u>	<u>325,882</u>
Operating income	75,370	45,029	230,826	150,638
Other expense	<u>(1,292)</u>	<u>(782)</u>	<u>(1,158)</u>	<u>(1,627)</u>
Income before income taxes	74,078	44,247	229,668	149,011
Income tax provision (3)	25,908	17,797	54,353	51,981
Net income	<u>\$ 48,170</u>	<u>\$ 26,450</u>	<u>\$ 175,315</u>	<u>\$ 97,030</u>
Earnings per common share				
Basic	<u>\$ 0.26</u>	<u>\$ 0.15</u>	<u>\$ 0.96</u>	<u>\$ 0.54</u>
Diluted	<u>\$ 0.25</u>	<u>\$ 0.14</u>	<u>\$ 0.91</u>	<u>\$ 0.52</u>
Shares used in computing earnings per common share				
Basic	<u>184,452</u>	<u>180,136</u>	<u>183,220</u>	<u>178,542</u>
Diluted	<u>193,370</u>	<u>188,586</u>	<u>191,806</u>	<u>186,074</u>

(1) The following table summarizes the share-based compensation expense included in the respective captions of the condensed consolidated statements of operations:

	Three months ended December		Twelve months ended December	
	2011	2010	2011	2010
Cost of sales	\$ 613	\$ 411	\$ 2,375	\$ 1,266
Research and development	2,270	1,739	9,759	7,878
Selling, general and administrative	7,454	5,455	32,629	23,194
	<u>\$ 10,337</u>	<u>\$ 7,605</u>	<u>\$ 44,763</u>	<u>\$ 32,338</u>

- (2) The following table summarizes the acquisition-related costs included in the condensed consolidated statements of operations:

	Three months ended December		Twelve months ended December	
	2011	2010	2011	2010
Transaction and separation costs	\$ 2,039	\$ 722	\$ 12,086	\$ 722
Adjustments to fair value of contingent consideration	283	-	1,400	-
	<u>\$ 2,322</u>	<u>\$ 722</u>	<u>\$ 13,486</u>	<u>\$ 722</u>

- (3) The following table summarizes the non-cash tax adjustment, which represents the reduction in cash taxes attributable to the utilization of US net operating losses (NOL's):

	Three months ended December		Twelve months ended December	
	2011	2010	2011	2010
Non-cash tax adjustment	\$ 19,547	\$ 13,860	\$ 32,155	\$ 37,229

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

	December 31, 2011	December 31, 2010
Cash, cash equivalents and marketable securities	\$ 540,865	\$ 361,605
Trade accounts receivable, net	244,288	168,732
Inventories	81,386	62,165
Deferred tax assets, current	19,132	19,643
Other current assets	55,599	34,411
Property, plant and equipment, net	165,852	162,240
Deferred tax assets, noncurrent	103,868	154,569
Intangibles assets, net	91,604	24,146
Goodwill	79,639	19,954
Other noncurrent assets	12,518	4,572
Total assets	<u>\$ 1,394,751</u>	<u>\$ 1,012,037</u>
Accounts payable and accrued expenses	\$ 202,093	\$ 123,056
Other current liabilities	28,132	15,459
Long-term debt	-	3,718
Contingent consideration	18,120	-
Other noncurrent liabilities	11,914	10,068
Total liabilities	<u>260,259</u>	<u>152,301</u>
Total stockholders' equity	1,134,492	859,736
Total liabilities and stockholders' equity	<u>\$ 1,394,751</u>	<u>\$ 1,012,037</u>

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