



## Alexion Reports Second Quarter 2011 Results

**-- Soliris<sup>®</sup> (eculizumab) Net Product Sales Increased 48% to \$185.7 Million --**

**-- Guidance Revised Upward for Revenues and Non-GAAP EPS --**

**-- Soliris for aHUS Granted Priority Review in the US —**

**-- STEC-HUS Program Added to Development Pipeline --**

### Second Quarter 2011 Financial Highlights:

- Q2 2011 revenues increased 48 percent to \$185.7 million, compared to \$125.8 million in Q2 2010
- Q2 2011 GAAP net income increased 60 percent to \$34.7 million, or \$0.18 per share, compared to GAAP net income of \$21.8 million, or \$0.12 per share, in Q2 2010
- Q2 2011 non-GAAP net income increased 54 percent to \$56.8 million, or \$0.29 per share, compared to non-GAAP net income of \$36.9 million, or \$0.20 per share, in Q2 2010

CHESHIRE, Conn.--(BUSINESS WIRE)-- Alexion Pharmaceuticals, Inc. (NASDAQ: ALXN) today announced financial results for the three and six months ended June 30, 2011. Alexion Pharmaceuticals, Inc. ("Alexion" or, the "Company") reported net product sales of Soliris<sup>®</sup> (eculizumab) of \$185.7 million in Q2, reflecting steady addition of new patients, compared to \$125.8 million for the same period in 2010.

Soliris, approved in the US (2007), European Union (2007), Japan (2010) and in other territories, is the only drug specifically indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH), an ultra-rare, debilitating and life-threatening blood disease.

Alexion's non-GAAP operating results are equal to GAAP operating results less the impact of share-based compensation, taxes that are not payable in cash (non-cash taxes), amortization of acquired intangible assets, and costs associated with acquisitions. A reconciliation of GAAP and non-GAAP results is summarized below:

(in thousands of US dollars, except per-share data)

	Three months ended		Six months ended	
	June 30		June 30	
	2011	2010	2011	2010
Total revenues	\$ 185,699	\$ 125,834	\$351,825	\$243,412
GAAP net income	\$ 34,745	\$ 21,773	\$ 61,575	\$ 42,707
Share-based compensation	11,834	8,250	23,165	16,354
Acquisition-related costs	1,000	-	10,928	-
Amortization of purchased intangibles	104	-	174	-
Non-cash tax expense	9,095	6,923	17,205	12,439
Non-GAAP net income	<u>\$ 56,778</u>	<u>\$ 36,946</u>	<u>\$113,047</u>	<u>\$ 71,500</u>
Shares used in computing diluted earnings per share (GAAP)	191,187	185,150	190,790	184,680
Shares used in computing diluted earnings per share (non-GAAP)	193,048	187,704	192,605	187,222
GAAP earnings per share - diluted	<u>\$ 0.18</u>	<u>\$ 0.12</u>	<u>\$ 0.32</u>	<u>\$ 0.23</u>

Non-GAAP earnings per share - diluted

\$ 0.29 \$ 0.20 \$ 0.59 \$ 0.38

The Company effected a 2-for-1 stock split in the form of a 100 percent stock dividend on May 20, 2011. All share and per-share amounts in this press release have been adjusted to reflect this split.

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

The Company reported non-GAAP net income of \$56.8 million, or \$0.29 per share, for the second quarter of 2011, compared to non-GAAP net income of \$36.9 million, or \$0.20 per share, in the second quarter of 2010.

Alexion's non-GAAP operating expenses for Q2 2011 were \$102.6 million, compared to \$71.8 million for Q2 2010. Non-GAAP research and development (R&D) expenses for Q2 2011 were \$33.4 million, compared to \$21.7 million for Q2 2010. The increase in R&D expenses primarily reflected the expansion of the Company's clinical trial programs, including costs associated with product supply and services for the STEC-HUS trial initiated in the quarter. Non-GAAP selling, general and administrative (SG&A) expenses for Q2 2011 were \$69.2 million, compared to \$50.1 million for Q2 2010. The increase in non-GAAP SG&A expenses primarily reflected costs associated with the expansion of the Company's commercial operations related to new geographies and with the preparation for potential launch of Soliris in aHUS.

### **Second Quarter GAAP Financial Results:**

Alexion reported GAAP net income of \$34.7 million, or \$0.18 per share, compared to Q2 2010 GAAP net income of \$21.8 million, or \$0.12 per share.

On a GAAP basis, operating expenses for Q2 2011 were \$114.9 million, compared to \$79.8 million for Q2 2010. GAAP R&D expenses for Q2 2011 were \$35.6 million, compared to \$23.7 million for Q2 2010. GAAP SG&A expenses were \$78.2 million for Q2 2011, compared to \$56.1 million for Q2 2010.

### **Balance Sheet:**

As of June 30, 2011, the Company had \$368.0 million in cash, cash equivalents and marketable securities, compared to \$348.8 million at the end of Q1 2011. During Q2, the Company repaid \$60 million of short-term debt that was incurred related to the two acquisitions which closed during Q1 2011.

"In the second quarter, we continued to serve a growing number of new patients with PNH in our core territories of the US, Western Europe and Japan," said Leonard Bell, M.D., Chief Executive Officer of Alexion. "During Q2, we also focused on responding to the urgent public health crisis related to the STEC-HUS outbreak in Germany. Towards the end of this year, we expect to complete the aHUS regulatory process in the US and are likewise focused on further accelerating the development of our pipeline portfolio, which now comprises the widest group of compounds and ultra-rare disorders in our history."

### **Research and Development Programs:**

#### aHUS Regulatory Submissions

In April, the Company announced that it had submitted marketing applications to the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for Soliris as a treatment for patients with atypical Hemolytic Uremic Syndrome (aHUS). During Q2, the FDA granted Priority Review status for the application in the US. If approval is granted, the Company anticipates a US launch for eculizumab in aHUS in the fourth quarter of 2011.

#### Transplant: Acute Humoral Kidney Rejection (AHR)

Eculizumab is being investigated as a treatment for patients undergoing kidney transplant who are at elevated risk of antibody mediated rejection, also known as acute humoral rejection (AHR). The FDA and EMA have approved clinical protocols for a global, company-sponsored controlled clinical trial evaluating eculizumab to prevent AHR in patients undergoing kidney transplant. The Company is preparing to initiate a living-donor study in the fall of 2011 and a deceased-donor study near year-end.

#### STEC-HUS

Following authorization by the Paul-Ehrlich-Institut (PEI), Germany's healthcare regulatory body for biologics, and an access program for patients initiated in May, Alexion initiated an open-label clinical trial to investigate eculizumab as a treatment for patients with Shiga-toxin producing E. coli hemolytic uremic syndrome (STEC-HUS) in Germany.

## 2011 Financial Guidance:

Alexion's 2011 revenue guidance has been revised upward, from the previously announced range of \$720 to \$740 million, now to the higher range of \$745 to \$755 million. The upward revision in revenue guidance takes into account continued global growth of Soliris for PNH, and the potential for the launch of Soliris for aHUS in the US in Q4, which could occur if a positive decision on the Company's application is received from the FDA. Guidance for non-GAAP EPS has been revised upward from the previous range of \$1.05 to \$1.12 (adjusted for the 2-for-1 stock split effected in May 2011) now to the higher range of \$1.10 to \$1.15, based on a forecast of approximately 194 million diluted shares outstanding for the year.

On a non-GAAP basis, guidance for 2011 R&D expenses has been increased from the previous range of \$128 to \$138 million to the higher range of \$138 to \$143 million. Guidance for 2011 non-GAAP SG&A expenses has been narrowed within the previous range, to \$275 to \$280 million. Guidance for share-based compensation expense for the year has been increased from the previous range of approximately \$39 to \$41 million to the higher range of approximately \$42 to \$44 million. Cost of sales has been reiterated at approximately 13 percent of sales. Guidance for 2011 GAAP tax rate has been reiterated in the range of 30 to 32 percent; the non-GAAP effective tax rate, reported on a cash tax liability basis, has been reiterated in the range of 10 to 12 percent.

## 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 21, 2011, at 10:00 a.m., Eastern Time. To participate in this call, dial 888-437-9357 (USA) or 719-325-2407 (International), confirmation code 9969620 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 888-203-1112 (USA) or 719-457-0820 (International), confirmation code 9969620. 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 has been approved in the US, European Union, Japan and other territories as the first treatment for patients with PNH, an ultra-rare, debilitating and life-threatening blood disorder defined by chronic uncontrolled complement activation, which causes chronic red blood cell destruction (hemolysis), leading to blood clots, organ failure, and shortened survival. Prior to these approvals, there were no therapies specifically available for the treatment of patients with PNH. Soliris (eculizumab) is not approved for the treatment of aHUS or other indications other than PNH. Alexion's breakthrough approach to complement inhibition has received some of 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 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, a debilitating, ultra-rare and life-threatening blood disorder. Soliris is approved in more than 35 countries. Alexion is evaluating other potential indications for Soliris and is pursuing development of other innovative biotechnology 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 amounts. Alexion believes that these non-GAAP financial measures, when considered together with the GAAP amounts, 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 for measuring the Company's performance. These non-GAAP financial measures are not intended to be considered in isolation or as a substitute for GAAP amounts. A reconciliation of the GAAP to non-GAAP amounts is included in this press release.*

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*This news release contains forward-looking statements, including statements related to guidance regarding anticipated financial results for 2011, 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, 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, risks related to the integration of the operations of Taligen Therapeutics into Alexion, the possibility that initial 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 Annual Report on Form 10-Q for the three months ended March 31, 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 June 30		Six months ended June 30	
	2011	2010	2011	2010
Net product sales	\$ 185,699	\$ 125,834	\$ 351,825	\$ 243,412
Cost of sales (1)	21,745	13,721	40,973	27,720
Operating expenses:				
Research and development (1)	35,646	23,690	66,456	46,064
Selling, general and administrative (1)	78,180	56,098	144,037	106,733
Acquisition-related costs (2)	1,000	-	10,928	-
Amortization of purchased intangibles	104	-	174	-
Total operating expenses	<u>114,930</u>	<u>79,788</u>	<u>221,595</u>	<u>152,797</u>
Operating income	49,024	32,325	89,257	62,895
Other income (expense)	<u>63</u>	<u>(242)</u>	<u>656</u>	<u>(739)</u>
Income before income taxes	49,087	32,083	89,913	62,156
Income tax provision (3)	14,342	10,310	28,338	19,449
Net income	<u>\$ 34,745</u>	<u>\$ 21,773</u>	<u>\$ 61,575</u>	<u>\$ 42,707</u>
Earnings per common share				
Basic	<u>\$ 0.19</u>	<u>\$ 0.12</u>	<u>\$ 0.34</u>	<u>\$ 0.24</u>
Diluted	<u>\$ 0.18</u>	<u>\$ 0.12</u>	<u>\$ 0.32</u>	<u>\$ 0.23</u>
Shares used in computing earnings per common share				
Basic	<u>182,962</u>	<u>178,004</u>	<u>182,347</u>	<u>177,510</u>
Diluted	<u>191,187</u>	<u>185,150</u>	<u>190,790</u>	<u>184,680</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		Six months ended	
	June 30		June 30	
	2011	2010	2011	2010
<b>Share-based compensation expense:</b>				
Cost of sales	\$ 572	\$ 250	\$ 1,117	\$ 565
Research and development	2,245	2,025	4,978	4,110
Selling, general and administrative	9,017	5,975	17,070	11,679
	<u>\$ 11,834</u>	<u>\$ 8,250</u>	<u>\$ 23,165</u>	<u>\$ 16,354</u>

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

	Three months ended		Six months ended	
	June 30		June 30	
	2011	2010	2011	2010
Transaction and separation costs	\$ 255	\$ -	\$ 10,047	\$ -
Adjustments to fair value of contingent consideration	745	-	881	-
	<u>\$ 1,000</u>	<u>\$ -</u>	<u>\$ 10,928</u>	<u>\$ -</u>

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

	Three months ended		Six months ended	
	June 30		June 30	
	2011	2010	2011	2010
Non-cash taxes	\$ 9,095	\$ 6,923	\$ 17,205	\$ 12,439

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

	June 30, 2011	December 31, 2010
Cash, cash equivalents and marketable securities	\$ 368,009	\$ 361,605
Trade accounts receivable, net	212,720	168,732
Inventories, net	75,222	62,165
Deferred tax assets, current	20,863	19,643
Other current assets	23,581	34,411
Property, plant and equipment, net	163,763	162,240
Deferred tax assets, noncurrent	135,518	154,569
Intangibles assets, net	94,019	24,146
Goodwill	80,033	19,954
Other noncurrent assets	5,847	4,572
Total assets	<u>\$1,179,575</u>	<u>\$ 1,012,037</u>
Accounts payable and accrued expenses	\$ 154,683	\$ 123,056
Other current liabilities	33,086	15,459
Long term debt	-	3,718
Contingent consideration	17,601	-
Other noncurrent liabilities	20,703	10,068
Total liabilities	<u>226,073</u>	<u>152,301</u>
Total stockholders' equity	<u>953,502</u>	<u>859,736</u>

Total liabilities and stockholders' equity \$1,179,575 \$ 1,012,037

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