

# Alexion Reports Fourth Quarter and Full Year 2010 Results

February 10, 2011

- Soliris® Net Product Sales Increased 40 Percent to \$541 Million in 2010 —
- Continued Strong Uptake of Soliris by New Patients in Core Territories: U.S., Western Europe and Japan
  - aHUS and Transplant Programs Advance —
  - Taligen and Orphatec Acquisitions Expand Rare Disease Pipeline -

# Fourth Quarter 2010 Financial Highlights:

- Q4 2010 net product sales increased 41 percent to \$156.0 million, compared to \$110.6 million in Q4 2009.
- Q4 2010 GAAP net income was \$26.5 million, or \$0.28 per share, compared to Q4 2009 GAAP net income of \$237.1 million, or \$2.59 per share, which included a non-recurring tax benefit of \$215.5 million, or \$2.36 per share.
- Q4 2010 non-GAAP net income increased 71 percent to \$48.6 million, or \$0.51 per share, compared to Q4 2009 non-GAAP net income of \$28.5 million, or \$0.31 per share.

#### Full-Year 2010 Financial Highlights:

- 2010 net product sales increased 40 percent to \$541.0 million, compared to \$386.8 million in 2009.
- 2010 GAAP net income was \$97.0 million, or \$1.04 per share, compared to 2009 GAAP net income of \$295.2 million, or \$3.26 per share, which included a non-recurring tax benefit of \$215.5 million, or \$2.38 per share.
- 2010 non-GAAP net income increased 54 percent to \$167.3 million, or \$1.78 per share, compared to 2009 non-GAAP net income of \$108.4 million, or \$1.18 per share.

CHESHIRE, Conn.--(BUSINESS WIRE)-- Alexion Pharmaceuticals, Inc. (NASDAQ: ALXN) today announced financial results for the quarter and year ended December 31, 2010. For the three months ended December 31, 2010, Alexion Pharmaceuticals, Inc. ("Alexion", or the "Company") reported net product sales of Soliris® (eculizumab) of \$156.0 million, reflecting strong additions of new patients, compared to \$110.6 million for the same period in 2009.

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

Historically, Alexion's non-GAAP operating results have been equal to GAAP operating results less the impact of share-based compensation and taxes that are not payable in cash (non-cash taxes). Additionally, acquisition-related expenses are excluded from non-GAAP results. The following summary table is provided for investors' convenience.

(in thousands, except per-share data)

	Th	Three Months Ended December 31,			Twelve Months Ended  December 31,		
		2010	2009	_	2010	_	2009
Net product sales	<u>\$ 1</u>	55,975	\$ 110,649	\$	540,957	<u>\$</u> _	386,800
GAAP net income	\$	26,450	\$ 237,127	\$	97,030	\$	295,166
Share-based compensation Acquisition expense		7,605 722	6,878		32,338 722		28,731
Non-cash taxes		13,860	(215,516)		37,229		(215,516)
Non-GAAP net income	\$	48,637	\$ 28,489	\$	167,319	\$	108,381
Shares used in computing diluted earnings per share (GAAP) Shares used in computing diluted earnings per share (non-GAAP)		94,293 95,208	91,449 92,532		93,037 94,247		90,582 91,780

\$ 0.28 \$	2.59	\$ 1.04 \$	3.26
\$ 0.51 \$	0.31	\$ 1.78 \$	1.18

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

The Company reported non-GAAP net income of \$48.6 million, or \$0.51 per share, in the fourth quarter of 2010, compared to non-GAAP net income of \$28.5 million, or \$0.31 per share, in the fourth quarter of 2009.

Alexion's non-GAAP operating expenses for Q4 2010 were \$82.8 million, compared to \$68.2 million for Q4 2009. Non-GAAP research and development (R&D) expenses for Q4 2010 were \$25.4 million, compared to \$20.3 million for Q4 2009. The increase in R&D expenses primarily reflected the expansion of the Company's clinical trial programs. Non-GAAP selling, general and administrative (SG&A) expenses for Q4 2010 were \$57.4 million, compared to \$47.9 million for Q4 2009. The increase in SG&A expenses primarily reflected Alexion's growing global operations and the Company's expanded participation at medical conferences.

# **Fourth Quarter GAAP Financial Results:**

Alexion reported GAAP net income of \$26.5 million, or \$0.28 per share in the fourth quarter of 2010, compared to Q4 2009 GAAP net income of \$237.1 million, or \$2.59 per share, which included a non-recurring tax benefit of \$215.5 million, or \$2.36 per share.

On a GAAP basis, operating expenses for Q4 2010 were \$90.7 million, compared to \$75.1 million for Q4 2009. GAAP R&D expenses for Q4 2010 were \$27.2 million, compared to \$23.2 million for Q4 2009. GAAP SG&A expenses were \$63.5 million for Q4 2010, compared to \$51.9 million for Q4 2009.

#### Full Year 2010 Non-GAAP Financial Results:

The Company reported non-GAAP net income of \$167.3 million in 2010, or \$1.78 per share, compared to non-GAAP net income of \$108.4 million, or \$1.18 per share, in 2009.

Alexion's non-GAAP operating expenses for the full year 2010 were \$294.1 million, compared to \$225.9 million for 2009. Non-GAAP R&D expenses for 2010 were \$90.4 million, compared to \$72.9 million for the prior year. The increase in R&D expenses primarily reflected the expansion of the Company's clinical trial programs. Non-GAAP SG&A expenses for 2010 were \$203.7 million, compared to \$153.1 million in 2009. The increase in SG&A expenses primarily reflected Alexion's growing global operations and expanded participation at medical conferences.

#### Full Year 2010 GAAP Financial Results:

Alexion reported GAAP net income of \$97.0 million, or \$1.04 per share in 2010 compared to 2009 GAAP net income of \$295.2 million, or \$3.26 per share, which included a non-recurring tax benefit of \$215.5 million, or \$2.38 per share.

Alexion's GAAP operating expenses for the full year 2010 were \$325.9 million, compared to \$254.7 million for the prior year. GAAP R&D expenses for 2010 were \$98.4 million, compared to \$81.9 million in 2009. GAAP SG&A expenses were \$227.5 million in 2010, compared to \$172.8 million for the prior year.

# **Balance Sheet:**

As of December 31, 2010, the Company had \$361.6 million in cash, cash equivalents and marketable securities compared to \$176.2 million at December 31, 2009. In January and February 2011, the Company used \$114 million of available cash for the Taligen and Orphatec acquisitions described below.

# **Q4 Research and Development Progress:**

During the fourth quarter of 2010, Alexion made significant progress on advancing the development of eculizumab as a treatment for patients suffering from additional rare and severe complement-mediated disorders beyond PNH, with a focus on its two lead nephrology programs in aHUS and transplant.

#### atypical Hemolytic Uremic Syndrome (aHUS)

In November 2010, researchers at the American Society of Nephrology (ASN) annual meeting in Denver presented positive data from the Company's two Phase 2 26-week studies of eculizumab as a treatment for adult and adolescent patients with aHUS. aHUS is an ultra-rare, chronic and life-threatening disease in which uncontrolled complement activation causes blood clots in small blood vessels throughout the body (thrombotic microangiopathy, or TMA) leading to kidney failure, stroke, heart attack and death.

The Company has completed dosing in these two Phase 2 clinical studies of eculizumab as an investigational treatment for patients with aHUS. A separate clinical study in pediatric patients with aHUS, as well as an additional study in adult patients, is ongoing.

# 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, or AHR. The Company is supporting investigator-initiated studies in elevated-risk kidney transplantation in the U.S. and Australia. Separately, an investigator-initiated study in patients with ABO blood-type incompatibility is enrolling. Alexion is now planning two global, company-sponsored controlled clinical trials evaluating eculizumab to prevent AHR in patients undergoing kidney transplant. The global studies are expected to commence in multiple centers this year following protocol finalization.

#### **Acquisition of Orphatec Assets:**

This morning, Alexion announced that it has purchased patents and assets from Germany-based Orphatec Pharmaceuticals GmbH related to an investigational therapy for patients with molybdenum cofactor deficiency (MoCD) Type A. MoCD Type A is an ultra-rare metabolic disease in newborns in which a genetic deficiency of cPMP causes a deficiency of molybdenum cofactor, which in turn leads to catastrophic brain damage, with survival generally measured in weeks or months.

Deficiency of the cofactor leads to accumulation of neurotoxic sulfite, resulting in uncontrollable seizures, severe and rapid neurological damage and death. There are currently no treatment options for patients with MoCD Type A.

The investigational therapy is designed to replace the deficient cPMP, which enables MoCD production so that the infant's body can eliminate the toxic sulfite. Scientific discoveries underlying this highly innovative therapy were pioneered in Germany, and have led to encouraging early clinical experience with cPMP replacement therapy in several newborns. Investigators in Germany and Australia have reported clinically meaningful results in the first patient treated.

The Orphatec assets were purchased with an upfront cash payment of approximately \$3 million plus contingent payments which would be earned upon reaching various development, regulatory and commercial milestones.

#### **Taligen Acquisition:**

On January 31, 2011, Alexion announced that it acquired Taligen Therapeutics, Inc., a privately held development-stage biotechnology company based in Cambridge, Massachusetts. The acquisition was completed with an upfront cash payment of \$111 million for 100 percent of Taligen's equity interests. Additional contingent payments would be earned upon reaching various clinical efficacy and product approval milestones in both the U.S. and European Union for up to six product candidates. The acquisition broadens Alexion's portfolio of product candidates and accelerates the Company's capabilities in translational medicine by bringing additional accomplished researchers to the Company to form the nucleus of a Translational Medicine Group in Cambridge, Massachusetts. Alexion aims to accelerate the development of promising pre-clinical compounds from the acquisition, including potential treatments for patients with ophthalmic diseases such as age-related macular degeneration (AMD), as well as other novel regulators of the complement inflammatory pathways targeting the treatment of patients with rare disorders.

"In 2010, we exceeded our clinical and commercial objectives. We served significantly greater numbers of patients with PNH in our core territories of the U.S., Western Europe and Japan, and made important progress in our lead pipeline programs," said Leonard Bell, M.D., Chief Executive Officer of Alexion. "In 2011, we are accelerating our initiatives to serve more patients with PNH in our core territories and new countries, as well as increasing our commitment to the more rapid innovation of first-in-class therapies for patients with debilitating and life-threatening rare diseases."

#### 2011 Financial Guidance:

In 2011, worldwide net product sales are expected to be within a range of \$715 to \$735 million. On a non-GAAP basis, R&D expenses are anticipated to be in the range of \$128 to \$138 million, and selling, general and administrative expenses in the range of \$270 to \$280 million. The Company's share-based compensation expense for the year is expected to be in a range of approximately \$39 to \$41 million. Cost of sales is expected to be approximately 13 percent of net product sales. The GAAP effective tax rate is expected to be in the range of 30 to 32 percent. The non-GAAP effective tax rate, reported on a cash tax liability basis, is expected to be in the range of 10 to 12 percent. Based on a forecast of approximately 97 million diluted shares outstanding, Alexion is providing guidance of \$2.10 to \$2.25 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 10, 2011, at 10:00 a.m., Eastern Time. To participate in this call, dial 719-457-2735, confirmation code 6342085, 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 6342085. The audio webcast can be accessed at <a href="https://www.alexionpharma.com">www.alexionpharma.com</a>.

# **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 U.S., 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 hemolysis. Prior to these approvals, there were no therapies specifically available for the treatment of patients with PNH. Eculizumab (Soliris) is not approved for the treatment of aHUS, transplant or other indications other than PNH. Alexion's innovative 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 <a href="https://www.soliris.net">www.soliris.net</a>.

# **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. Alexion 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 and kidney diseases, neurologic disorders, ophthalmic, transplant, other inflammatory disorders, and cancer. Soliris® (eculizumab), Alexion's first marketed product, is approved in more than 35 countries as a therapy for patients with PNH, a debilitating and ultra-rare life-threatening blood disorder. 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: <a href="https://www.alexionpharma.com">www.alexionpharma.com</a>.

# [ALXN-E]

This news release contains forward-looking statements, including statements related to guidance regarding anticipated financial results for 2011, projected tax rates, assessment of the Company's financial position and commercialization efforts, potential benefits and commercial potential for Soliris, potential of Alexion's complement-inhibition technology for treatment of diseases other than PNH; plans for clinical programs for Soliris in non-PNH indications and for samalizumab; plans for recently acquired companies and programs; 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 capabilities 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 risk that recent acquisitions will not result in short-term or long-term benefits, risks related to the integration of the operations of Taligen into Alexion, the possibility that initial results of commercialization are not predictive of future rates of adoption of Soliris, 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 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 period ended September 30, 2010 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)

		nths Ended nber 31, 2009	Twelve Months Ended  December 31,  2010 2009			
Net product sales	\$155,975	\$ 110,649	\$ 540,957	\$ 386,800		
Cost of sales (1)	20,222	12,892	64,437	45,059		
Operating expenses: Research and development (1) Selling, general and administrative (1)	27,177 63,547	23,215 51,887	98,394 227,488	81,915 172,767		
Total operating expenses	90,724	75,102	325,882	254,682		
Operating income	45,029	22,655	150,638	87,059		
Other expense	(782)	(61)	(1,627)	(350)		
Debt exchange expense		-		(3,395)		
Income before income taxes	44,247	22,594	149,011	83,314		
Income tax provision (benefit)	17,797	(214,533)	51,981	(211,852)		
Net income	\$ 26,450	\$ 237,127	\$ 97,030	\$ 295,166		
Earnings per common share Basic	\$ 0.29	\$ 2.70	\$ 1.09	\$ 3.46		
Diluted	\$ 0.28	\$ 2.59	\$ 1.04	\$ 3.26		
Shares used in computing earnings per common share Basic Diluted	90,068	87,885 91,449	89,271 93,037	85,326 90,582		

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

	Three Months Ended December 31,			Twelve Months Ended December 31,				
		2010	2009		2010			2009
Share-based compensation expense:								
Cost of sales	\$	411	\$	-	\$	1,266	\$	-
Research and development		1,739		2,886		7,878		9,049
Selling, general and administrative		5,455		3,992		23,194		19,682
	\$	7,605	\$	6,878	\$	32,338	\$	28,731

# ALEXION PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands) (unaudited)

	De	cember 31,	December 31,		
		2010		2009	
Cash, cash equivalents and marketable securities	\$	361,605	\$	176,220	
Trade accounts receivable, net		168,732		113,731	
Inventories, net		62,165		40,885	
Deferred tax assets, current		19,643		16,726	
Other current assets		34,411		25,894	
Property, plant and equipment, net		162,240		164,691	
Deferred tax assets, noncurrent		154,569		194,308	
Other noncurrent assets		48,672		53,946	
Total assets	\$	1,012,037	\$	786,401	
Accounts nevable and accrued expenses	\$	123,056	æ	78,445	
Accounts payable and accrued expenses Other current liabilities	Φ	•	Φ	,	
		15,459		6,817	
Long term debt		3,718		9,918	
Other noncurrent liabilities		10,068		2,865	
Total liabilities		152,301		98,045	
Total stockholders' equity		859,736		688,356	
Total liabilities and stockholders' equity	\$	1,012,037	\$	786,401	

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