

# **Enzon Reports Third Quarter 2009 Results**

BRIDGEWATER, N.J., Nov 03, 2009 (BUSINESS WIRE) -- Enzon Pharmaceuticals, Inc. (Nasdaq: ENZN) today announced its third quarter 2009 financial results. For the three months ended September 30, 2009, Enzon reported a net income of \$0.1 million or break-even on a diluted per-share basis, as compared to a net loss of \$2.0 million or \$0.05 on a diluted per-share basis for the third quarter of 2008. In the third quarter of 2009, the Products segment profitability grew 55% as compared to the third quarter of 2008. This was offset by a decline in revenues and profitability in the contract manufacturing segment. The Company also experienced a reduction of general and administrative costs from the third quarter of 2008. In 2008, the Company incurred expenses in connection with considered strategic initiatives.

"Net sales from our marketed products, in total, remain stable with unit growth in Oncaspar<sup>(R)</sup>, and Adagen<sup>(R)</sup>," said Jeffrey H. Buchalter, president and chief executive officer of Enzon. "The Company continues to identify and implement cost efficiencies across the organization."

# **Highlights**

- In October 2009, PEGINTRON<sup>(R)</sup> received a recommendation for approval as a treatment in addition to surgery in
  patients with metastatic melanoma from the FDA Advisory Committee. Enzon receives royalties on worldwide sales of
  PEGINTRON.
- Also in October 2009, CIMZIA<sup>(R)</sup> received European approval for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA). Enzon receives royalties on worldwide sales of CIMZIA.
- The Company will present data on its clinical and preclinical pipeline programs at the upcoming European Organization for Research and Treatment of Cancer (EORTC) meeting in November.
- The Company filed the Investigational New Drug (IND) Application with the FDA for the next-generation Adagen program early November.

#### **Revenues**

The following table reflects the revenues generated by product and segment for the three month periods ended September 30, 2009 and 2008.

	Three Months Ended (in thousands)						
	September 30, 2009 September 30, 2008 % Change						
Products							
Oncaspar	\$	12,495	\$	12,492	-		
DepoCyt		2,111		2,201	(4)		
Abelcet		5,654		6,636	(15)		
Adagen		8,358		7,583	10		
Total Products		28,618		28,912	(1)		
Royalties		13,665		14,611	(6)		
<b>Contract Manufacturing</b>	I	2,318		5,267	(56)		
Total Revenues	\$	44,601	\$	48,790	(9)		

#### **Products Segment**

Net product sales for the three months ended September 30, 2009 were essentially the same as compared to the same period of 2008. Oncaspar and Adagen experienced unit growth. However, this quarter's net sales were adversely impacted by an accrual made regarding claims for certain prior period chargebacks currently being disputed by the Company. Oncaspar unit growth is mainly attributable to the continued use and adoption in new pediatric and adult hospital and cooperative group protocols. DepoCyt and Adagen tend to fluctuate from quarter to quarter due to the dynamics of dosing, scheduling and diagnoses of the products' patient populations. Abelcet continues to be under competitive pressure. This quarter, net sales

were primarily impacted by price and to a lesser extent volume.

## **Royalties Segment**

PEGINTRON royalties account for the majority of the Company's total royalty revenues. During the three months ended September 30, 2009, PEGINTRON royalty revenue declined due to the impact from foreign exchange. Recently, the Company had two positive events related to its royalty segment as previously noted. First, PEGINTRON received a recommendation for approval from the FDA Advisory Committee for melanoma. Second, the European Commission approved Cimzia, for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA).

## **Contract Manufacturing Segment**

Contract manufacturing revenue for the three months ended September 30, 2009 was \$2.3 million compared to \$5.3 million for the comparable period of 2008. Revenues and earnings were affected primarily due to cancelled shipments and early discontinuation of processing for a CMO customer scheduled for termination in early 2010. The Company continues to evaluate new contract manufacturing opportunities.

# Cost of Product Sales and Contract Manufacturing

The Company's cost of goods sold was \$13.6 million for the three months ended September 30, 2009, compared to \$14.5 million for the three months ended September 30, 2008. This quarter the Company experienced a write-down of inventories of finished goods and raw materials associated with the contract manufacturing agreement noted above. Excluding this adjustment, the Company's gross margin continues to be favorably impacted as a result of the consolidation of the manufacturing facilities.

# **Research and Development**

For the three months ended September 30, 2009, research and development expenses were \$15.8 million, relatively unchanged compared to the three months ended September 30, 2008. We continue our ongoing efforts in our research and development pipeline, PEG-SN38, the HIF-1 alpha antagonist, Survivin antagonist and other LNA- and PEGylation- based programs, as well as our next-generation lifecycle programs for Oncaspar and Adagen. We continue to enroll patients in our Phase II trial evaluating our PEG-SN38 compound in metastatic colorectal cancer patients. We also continue to enroll patients in our LNA antagonist Phase I programs for HIF-1 alpha and Survivin. We will present data on the LNA compounds, as well as PEG-SN38 at the upcoming EORTC meeting in November. This quarter 28% of the total research and development costs were associated with lifecycle programs and the efforts to improve the manufacturing processes and pharmaceutical properties of Oncaspar and Adagen. As previously stated, the Company recently filed the IND for the next-generation Adagen program.

#### Selling, General and Administrative

Selling and marketing expenses consist primarily of sales and marketing programs to support our sales force as well as medical affairs activities. Selling and marketing expenses for the three months ended September 30, 2009 declined 21 percent from the third quarter of 2008. The decrease reflects the continued selective spending in the selling and marketing programs. General and administrative expenses also decreased 28 percent to \$7.7 million primarily due to expenses related to the Company's proposed strategic initiatives in 2008 and the initiatives the Company made in the beginning of 2009 to continue to improve efficiencies.

#### **Restructuring Charge**

Given the events in the CMO activities, the Company implemented cost reductions to minimize the financial impact going forward. This resulted in a reduction of employees at the Indianapolis facility. For the three months ended September 30, 2009 the Company incurred a total cost of \$0.6 million which was a result of the employee severance and related benefits for affected employees. For the three months ended September 30, 2008, severance costs associated with the consolidation of the South Plainfield facility were \$0.2 million.

#### Other Income (Expense)

Other income (expense) for the three months ended September 30, 2009 was a net expense of \$1.4 million, as compared to net expense of \$1.9 million for the three months ended September 30, 2008. Other income (expense) includes: net investment income, interest expense and other income or expense. Interest expense was \$2.8 million for the three-month period ended September 30, 2009 compared to \$3.0 million for the three-month period ended September 30, 2008. The reduction in interest expense is a result of the elimination of a portion of the outstanding 4 percent notes.

#### Income tax (benefit) provision

During the three months ended September 30, 2009 the Company recorded a net tax benefit of \$0.8 million which includes a reimbursement related to certain unused research and alternative minimum tax credit carryforwards and a reduction of foreign taxes due to a transfer price adjustment.

# **Cash and Investments**

Total cash reserves, which include cash and investments, were \$201.3 million as of September 30, 2009, as compared to \$206.9 million as of December 31, 2008. The decrease is primarily due the \$15.6 million used to the repurchase \$20.4 million of our 4 percent notes in 2009 offset by the cash provided by operating activities.

## **Adjusted Financial Results**

For the three months ended September 30, 2009, there were no adjustments to the reported net income of \$0.1 million or breakeven per diluted share, as compared to an adjusted net income of \$0.7 million or \$0.01 per diluted share for the three months ended September 30, 2008.

The following table reconciles the Company's net (loss) income and net (loss) income per diluted share as determined in accordance with U.S. generally accepted accounting principles (GAAP) to its adjusted net income and net income per diluted share for the three months ended September 30, 2009 and 2008 respectively:

	Three Months Ended (in thousands, except per-share amounts)								
	September 30, 2009				Septen	September 30, 2008			
		let ome		Net income er diluted share		Net s) income		Net (loss) income er diluted share <sup>(2)</sup>	
GAAP net income (loss) Adjustment to GAAP net loss:	\$	133	\$	0.00	\$	(2,020)	\$	(0.05)	
Add: Costs related to the proposed strategic initiatives $(1)$ Adjusted net income $(3)$	\$	- 133	\$	- 0.00	\$	2,694 674	\$	- 0.01	

<sup>(1)</sup> Adjusted financial results for the third quarter of 2008 exclude the costs related to the Company's proposed strategic initiatives (spin-off of the Company's biotechnology business or sale of the specialty pharmaceutical business).

<sup>(2)</sup> Computation of adjusted diluted earnings per share includes certain contingently issuable shares whereas GAAP loss per share does not. Per-share computation of individual reconciling items is not meaningful.

<sup>(3)</sup> Adjusted net income and adjusted net income per share, as Enzon defines them, may differ from similarly named measures used by other entities, and consequently, could be misleading unless all entities calculated and defined such items in the same manner. The Company believes that investors' understanding of its performance is enhanced by disclosing adjusted net income and adjusted net income per share reflecting adjustments for certain items that the Company deems to be non-recurring.

#### **Conference Call and Webcast**

Enzon will be hosting a live conference call today, November 3, 2009 at 10:00 am Eastern Time (ET). All interested parties may access the call by using the following information:

Domestic Dial-In Number:(877) 397-0272International Dial-In Number:(719) 325-4861Access Code:Enzon

The call will also be available via live audio webcast at the following site: <u>http://investor.enzon.com/eventdetail.cfm?</u> <u>eventid=74303</u>. Listeners should go to the website at least fifteen minutes before this event to download and install any necessary audio software. For those unable to attend the live audio webcast, a replay will be available beginning approximately one hour after the event. Additionally, a telephonic rebroadcast will also be available following the call. The rebroadcast will begin on Tuesday, November 3, 2009 at approximately 12:00 pm Eastern Time (ET) and end on Tuesday, November 10, 2009 at approximately 12:00 am Eastern Time (ET). It may be accessed using the following information:

Domestic Dial-In Number:(888) 203-1112International Dial-In Number:(719) 457-0820Replay Passcode:6129874

# About Enzon

Enzon Pharmaceuticals, Inc. is a biopharmaceutical company dedicated to developing, manufacturing and commercializing important medicines for patients with cancer and other life-threatening conditions. The Company has a portfolio of four marketed products, Oncaspar(R), DepoCyt(R), Abelcet(R) and Adagen(R). Enzon's drug development programs utilize several cutting-edge approaches, including its industry-leading PEGylation technology platform and the Locked Nucleic Acid (LNA) technology. Enzon's PEGylation technology was used to develop two of its products, Oncaspar and Adagen, and has created a royalty revenue stream from licensing partnerships for other products developed using the technology. Enzon also engages in contract manufacturing for several pharmaceutical companies to broaden its revenue base. Further information about Enzon and this press release can be found on the Company's web site at <a href="https://www.enzon.com">www.enzon.com</a>.

#### Forward Looking Statements

There are forward-looking statements contained herein, which can be identified by the use of forward-looking terminology such as the words "believes," "expects," "may," "will," "should," "potential," "anticipates," "plans," or "intends" and similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results, events or developments to be materially different from the future results, events or developments indicated in such forward-looking statements. Such factors include, but are not limited to the timing, success and cost of clinical studies; the ability to obtain regulatory approval of products, market acceptance of, and continuing demand for, Enzon's products and the impact of competitive products and pricing.A more detailed discussion of these and other factors that could affect results is contained in our filings with the U.S. Securities and Exchange Commission, including our annual report on Form 10-K for the period ended December 31, 2008. These factors should be considered carefully and readers are cautioned not to place undue reliance on such forward-looking statements. No assurance can be given that the future results covered by the forward-looking statements will be achieved. All information in this press release is as of the date of this press release and Enzon does not intend to update this information.

#### Enzon Pharmaceuticals, Inc. and Subsidiaries Consolidated Statements of Operations **Three Months** ended September 30, 2009 and 2008 (In thousands, except per-share amounts) (Unaudited)

	Se	ptember 30, 2009	September 30, 2008		
Revenues:					
Product sales, net	\$	28,618	\$	28,912	
Royalties		13,665		14,611	
Contract manufacturing		2,318		5,267	
Total revenues	-	44,601		48,790	
Costs and expenses:	-				
Cost of product sales and contract manufacturing	g	13,557		14,473	
Research and development		15,805		15,654	
Selling, general and administrative		13,669		18,253	
Amortization of acquired intangible assets		167		167	
Restructuring charges		634		249	
Total costs and expenses	-	43,832	_	48,796	
Operating income (loss)		769		(6)	
Other income (expense):	-				
Investment income, net		1,148		1,268	
Interest expense		(2,750)		(3,025)	
Other, net		175		(94)	
	-	(1,427)		(1,851)	
Loss before income tax	-	(658)		(1,857)	
Income tax (benefit) provision		(791)		163	

Net income (loss)	\$ 133	\$	(2,020)
Earnings (loss) per common share - basic	\$ 0.00	\$	(0.05)
Earnings (loss) per common share - diluted	\$ 0.00	\$	(0.05)
Weighted average shares - basic	 45,276		44,464
Weighted average shares - diluted	 45,765	_	44,464

#### Enzon Pharmaceuticals, Inc. and Subsidiaries Condensed Consolidated Balance Sheets September 30, 2009 and December 31, 2008 (In thousands) (Unaudited)

(Unauditeu)				
	September 30, 2009		December 31, 2008	
Assets				
Current assets:				
Cash and short-term investments	\$	110,513	\$	144,184
Accounts receivable, net		15,199		11,692
Inventories		17,061		16,268
Other current assets		7,626		5,281
Total current assets	_	150,399	-	177,425
Property and equipment, net		40,623	-	44,585
Other assets:			-	
Marketable securities		90,791		62,678
Amortizable intangible assets, net		52,514		60,654
Other assets		3,348		3,911
		146,653	-	127,243
Total assets	\$	337,675	\$	349,253
Liabilities and Stockholders' Equity Current liabilities:				
Accounts payable and accrued expenses	\$	29,740	\$	33,144
Notes payable		-		2,950
Total current liabilities		29,740	-	36,094
Notes payable		250,050		267,550
Other liabilities		4,482		3,948
Total liabilities		284,272	-	307,592
Stockholders' equity		53,403	-	41,661
Total liabilities and stockholders' equity	\$	337,675	\$	349,253
Common shares outstanding	_	45,404		45,032

# SOURCE: Enzon Pharmaceuticals, Inc.

Enzon Pharmaceuticals, Inc. Craig Tooman, 908-541-8777 EVP, Finance and Chief Financial Officer

# Copyright Business Wire 2009