# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 8-K

# **CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) January 19, 2005

# ENZON PHARMACEUTICALS, INC. (Exact name of registrant as specified in its charter)

(Sta	Delaware ate or other jurisdiction of incorporation	0-12957 (Commission file Number)	22-2372868 (IRS Identification No.)
	685 Route 202/206, Bridgewater, New Jersey (Address of principal executive offices)		08807 (Zip Code)
Registrant's telephone number, including area code (908) 541-8600			
(Former name or former address, if changed since last report)			
Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:			
	Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)		
	Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)		
	Pre-commencement communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)		
	Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))		

#### **Item 8.01 Other Events**

Enzon Pharmaceuticals Inc. ("ENZON"; NASDAQ: ENZN) reported today that the United States Food and Drug Administration (FDA) provided an action letter to INEX Pharmaceuticals Corporation (TSX: IEX) detailing that the anticancer drug Marqibo(TM) (vincristine sulfate liposomes injection) is "not approvable" under the FDA's accelerated approval regulations based on the Phase 2b clinical trial data submitted.

The FDA's "not approvable" decision was expected after the FDA's Oncologic Drugs Advisory Committee voted December 1, 2004 against recommending accelerated approval for Marqibo as a treatment for patients with relapsed aggressive non-Hodgkin's lymphoma (NHL) based on the Phase 2b clinical trial data and comparison to available therapy.

The action letter from the FDA provides a list of deficiencies that need to be addressed prior to reapplying for approval, including the necessity to conduct additional studies. The FDA recommended such additional studies be randomized controlled studies comparing MARQIBO to other chemotherapy regimens. INEX and ENZON are currently evaluating the next steps for MARQIBO.

#### **Item 9.01 Exhibits**

Exhibit 99.1

Press Release dated January 19, 2005

# **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: January 19, 2005

By: <u>/s/ Kenneth J. Zuerblis</u>
Kenneth J. Zuerblis
Vice President, Finance and
Chief Financial Officer



### For Immediate Release

#### PRESS RELEASE

Contact: Susan M. Mesco

Director, Investor Relations

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#### FDA ISSUES NOT APPROVABLE LETTER FOR MARQIBO

Bridgewater, NJ – January 19, 2005 – Enzon Pharmaceuticals Inc. ("ENZON"; NASDAQ: ENZN) reported today that the United States Food and Drug Administration (FDA) provided an action letter to INEX Pharmaceuticals Corporation (TSX: IEX) detailing that the anticancer drug Marqibo(TM) (vincristine sulfate liposomes injection) is "not approvable" under the FDA's accelerated approval regulations based on the Phase 2b clinical trial data submitted.

ENZON said the FDA's "not approvable" decision was expected after the FDA's Oncologic Drugs Advisory Committee voted December 1, 2004 against recommending accelerated approval for Marqibo as a treatment for patients with relapsed aggressive non-Hodgkin's lymphoma (NHL) based on the Phase 2b clinical trial data and comparison to available therapy.

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## Margibo (vincristine sulfate liposomes injection)

Marqibo is a proprietary drug comprised of the widely used off-patent anticancer drug vincristine encapsulated in INEX's sphingosomal drug delivery technology. INEX's technology is designed to provide prolonged blood circulation, tumor accumulation and extended drug release at the cancer site. These characteristics are intended to increase the effectiveness and reduce the side effects of the encapsulated drug.

In addition to relapsed aggressive NHL, Marqibo is currently being evaluated in several phase 2 clinical trials as a treatment for first-line NHL (combination therapy), relapsed Hodgkin's disease, relapsed acute lymphoblastic leukemia, relapsed NHL in combination with the approved cancer drug Rituxan(R) (rituximab), and relapsed NHL in combination with the approved cancer drug etoposide.

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## **About Enzon**

Enzon Pharmaceuticals is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics to treat life-threatening diseases. The Company has developed or acquired a number of marketed products, including PEG-INTRON(R), marketed by Schering-Plough, and ABELCET(R), ONCASPAR(R), ADAGEN(R), and DEPOCYT(R), marketed in North America by Enzon's specialized sales force. Enzon's science-driven strategy includes an extensive drug development program that leverages the Company's macromolecular engineering technology platforms, including PEG modification and single-chain antibody (SCA(R) technologies. Internal research and development efforts are complemented by strategic transactions that provide access to additional marketed products and promising clinical compounds. Enzon has several drug candidates in various stages of development, independently and with partners. 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>.

All information in this press release is as of January 19, 2005 and the Company undertakes no duty to update this information.

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