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ENZON PHARMACEUTICALS INC

Form 8-K

November 05, 2004

UNITED STATES  
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): November 5, 2004

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

Delaware	0-12957	22-2372868
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification)

685 Route 202/206, Bridgewater, New Jersey 08807  
(Address of principal executive offices) (Zip Code)

(Registrant's telephone number, including area code: (908) 541-8600

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(Former name or former address, if changed since last report)

Item 8.01 Other Events

Inex Pharmaceuticals Corporation ("INEX"; TSX: IEX) and Enzon Pharmaceuticals Inc. ("Enzon"; NASDAQ: ENZN) announced today that they have filed a New Drug Submission (NDS) with the Therapeutics Products Directorate (TPD) of Health Canada for Marqibo(TM) (formerly referred to as Onco TCS).

The NDS is seeking marketing approval in Canada for Marqibo(TM) as a single-agent treatment for patients with relapsed aggressive non-Hodgkin's lymphoma (NHL) previously treated with at least two combination chemotherapy regimens.

INEX and Enzon will hear from the TPD within 45 days of filing as to whether or not the submission has been accepted for review. Subject to acceptance of the NDS for review, a response is anticipated from Health Canada in 12 to 18 months.

The NDS follows a New Drug Application that was submitted to the US Food and Drug Administration (FDA) seeking marketing approval for the same indication. The NDA was completed in March of this year, and the FDA will include in its review an evaluation by the Oncologic Drugs Advisory Committee (ODAC) on December 1, 2004. INEX and Enzon expect the FDA's response on the NDA by January 15, 2005.

About Marqibo(TM) (vincristine sulfate liposomes injection)

Marqibo(TM) 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

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side effects of the encapsulated drug.

In the completed multi center pivotal phase 2/3 clinical trial, 119 patients with aggressive NHL who had not responded to their previous therapy or had responded and subsequently relapsed were treated with Marqibo(TM). Prior to enrolment in this study, patients had received on average four other therapies. After treatment with Marqibo(TM) as a single-agent, an overall response rate of 25% was attained. Currently, there is no standard treatment for patients with aggressive NHL who have not responded to or have relapsed following at least two prior treatment regimens.

The results of this pivotal trial were released in June 2003 and presented in December 2003 at the American Society of Hematology annual conference along with interim results from two ongoing phase 2 trials in relapsed Hodgkin's disease and relapsed B-cell lymphoma.

In addition to the lead indication, Enzon and INEX are also exploring the development of Marqibo(TM) for use as a single-agent therapy or in combination therapy for several cancers in which vincristine is now used.

### About Non-Hodgkin's Lymphoma (NHL)

NHL is the fifth-leading cause of cancer deaths in the Canada (2,900 estimated in 2004) and the fifth-leading cause of cancer deaths in United States (19,400 estimated in 2004), according to estimates of the Canadian Cancer Society and the American Cancer Society. Approximately 6,400 and 53,400 new cases were diagnosed in Canada and the U.S. and respectively in 2003.

### About INEX

INEX is a Canadian biopharmaceutical company developing and commercializing proprietary drugs and drug delivery systems to improve the treatment of cancer. Further information about INEX and this news release can be found at [www.inexpharm.com](http://www.inexpharm.com).

### About Enzon

Enzon Pharmaceuticals is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics to treat life-threatening diseases. Further information about Enzon and this news release can be found at [www.enzon.com](http://www.enzon.com).

There are forward-looking statements contained herein that are not based on historical fact, including without limitation statements containing the words "believes," "may," "plans," "will," "estimate," "continue," "anticipates," "intends," "expects," and similar expressions. Examples of such statements above include the statements regarding expectations of the time frames within which Health Canada will act. 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 future results, events or developments described in the forward looking statements. Such factors include the risk that Health Canada's acceptance of the New Drug Submission and its ultimate decision regarding approval may be delayed and, the risk that Marqibo may not receive regulatory approval from the Therapeutics Products Directorate of Health Canada or the U.S. FDA under Subpart H of the Food and Drug Act for the lead indication and the fact that any such approval, if granted, will include post approval commitments, as well as those risks described in Enzon's Form 10-K and Forms 10-Q on file with the SEC and INEX's publicly filed periodic reports. These factors should be considered carefully and readers are cautioned not to place undue reliance on such forward-looking statements. All information

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in this press release is as of November 5, 2004, and Enzon and INEX undertake no duty to update this information.

Item 9.01 Financial Statements and Exhibits

Exhibit 99.1 Press Release dated November 5, 2004

### 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: November 5, 2004

By: /s/ Kenneth J. Zuerblis

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Kenneth J. Zuerblis  
Vice President, Finance and  
Chief Financial Officer