ENZON PHARMACEUTICALS INC
Form 8-K
July 24, 2003

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) July 24, 2003

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

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

Item 5. Other Events

Enzon Pharmaceuticals, Inc. today announced that the Company's ongoing Phase II trial for PEG-Camptothecin for the treatment of gastric and gastroesophageal junction cancers has met its interim safety and efficacy criteria and will be advanced for that indication.

During the first stage of the trial, the Company treated 15 patients. Two patients showed a partial response and 8 attained stable disease. In addition, this drug appears to be well tolerated for a cytotoxic agent. Based on these clinical results, Enzon has opened the study's second stage and will enroll an additional 20 patients.

In parallel, a second study will be initiated within several months that will evaluate PEG-Camptothecin in patients whose disease progressed following prior chemotherapy. One of the 2 patients who achieved a partial response in the Phase II study had a tumor that reoccurred following prior chemotherapy. Enzon is focusing the PEG-Camptothecin development program on second line therapy for gastric and gastroesophageal junction cancers, as there are no single-agent drug approvals for this indication.

The Company intends to seek Orphan Drug designation for PEG-Camptothecin under the Orphan Drug Act. Orphan drug designation is administered by the United States Food and Drug Administration (FDA) and is granted to applicants when the prevalence of the disease is less than 200,000 patients in the United States. The Orphan Drug Act provides for seven-years of marketing exclusivity in the United States upon FDA approval of the product, as well as certain potential additional financial and tax benefits.

The annual worldwide incidence of adenocarcinoma of the stomach and gastroesophageal junction is approximately 800,000 new cases, with approximately 24,000 of these cases occurring in the United States. The median survival for patients with advanced cancers from the time of diagnosis is approximately 7-8 months.

Based on these successful results, the company plans to focus its current clinical trial program on gastric and gastroesophageal junction cancers and therefore will no longer pursue its work in the areas of pancreatic, small-cell lung, and non-small cell lung cancers. The company will continue to consider other potential indications, as warranted, as clinical data becomes available.

PEG-Camptothecin is a novel cytotoxic drug of the topoisomerase I inhibitor class. PEG-Camptothecin appears to be passively targeted to certain tumors due to their enhanced vascular permeability. This leads to increased retention within these tumors (EPR effect). PEG-Camptothecin is administered as a one-hour infusion every 3 weeks.

Except for the historical information herein, the matters discussed in this report include forward-looking statements that may involve a number of risks and uncertainties. Actual results may vary significantly based upon a number of factors, which are described in the Company's Form 10-K, Form 10-Q's and Form 8-K's on file with the SEC, including without limitation, Enzon's dependence on Schering-Plough's effective marketing of PEG-INTRON; Enzon's ability to sustain profitability; risks in obtaining and maintaining regulatory approval for indications and expanded indications for Enzon's products; market acceptance of and continuing

demand for Enzon's products; timing and results of clinical trials and the impact of competitive products and pricing. All information in this report is as of July 24, 2003, and the Company undertakes no duty to update this information.

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: July 24, 2003

By: /s/ Kenneth J. Zuerblis

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