

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 12, 2001

ENZON, 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)

20 Kingsbridge Road, Piscataway, New Jersey 08854
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (732) 980-4500

NA

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

Item 5. Other Events

ENZON ANNOUNCES RESULTS OF CLINICAL STUDIES
OF PEG-INTRON(TM) AND REBETOL(R) COMBINATION THERAPY FOR HEPATITIS C
REPORTED BY SCHERING-PLOUGH AT AMERICAN ASSOCIATION FOR THE
STUDY OF LIVER DISEASES MEETING

DATA PRESENTED ON WIDE VARIETY OF PATIENT POPULATIONS

Enzon, Inc. announced today that Schering-Plough Corporation has reported results of several clinical studies presented at the 52nd Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in Dallas, Texas on PEG-INTRON(TM) (peginterferon alfa-2b) Powder for Injection in combination with REBETOL(R) (ribavirin, USP) Capsules for the treatment of chronic hepatitis C. In all, clinical investigators presented 28 studies with PEG-INTRON.

PEG-INTRON is a longer-acting form of INTRON(R) A (interferon alfa-2b, recombinant) Injection that uses proprietary PEG technology developed by Enzon. Under the Company's licensing agreement with Schering-Plough, Enzon is entitled to royalties on worldwide sales of PEG-INTRON.

PEG-INTRON and REBETOL combination therapy received U.S. Food and Drug Administration (FDA) approval in August 2001 for the treatment of chronic hepatitis C in patients with compensated liver disease who have not been previously treated with interferon alpha and are at least 18 years of age. The combination therapy was approved for hepatitis C in the European Union (EU) in March 2001.

In an oral presentation, investigators reviewed clinical data indicating that PEG-INTRON and REBETOL combination therapy reduces the rate of fibrosis progression in patients with chronic hepatitis C. The extent of liver fibrosis is known to be an important prognostic factor in patients infected with the hepatitis C virus (HCV). Researchers pooled data from four randomized studies involving 3,010 previously untreated patients with pre- and post-treatment biopsies who received one of 10 different regimens utilizing either standard or pegylated alpha interferon and ribavirin. The histological impact of each regimen was estimated by the percentage of patients with at least one grade improvement in liver necrosis and inflammation, the percentage of patients with at least one stage worsening in fibrosis and by the fibrosis progression rate

per year. While all regimens reviewed in this study reduced fibrosis progression rates in comparison to rates before treatment, PEG-INTRON and REBETOL combination

therapy showed the greatest improvement in liver necrosis and inflammation and the lowest rate of fibrosis worsening among these treatment regimens.

"The development of pegylated interferon is a significant advance in the treatment of hepatitis C, especially when used in combination with oral ribavirin," said Ira Jacobson, M.D., chief, division of gastroenterology and hepatology, Weill Medical College of Cornell University, New York. "It is imperative for us now to better define optimal treatment regimens using these therapies and further explore their use in treating specific patient populations," he said. Jacobson is the lead investigator for the largest prospective hepatitis C study undertaken to date, which is expected to enroll more than 4,000 U.S. patients. Schering-Plough is supporting this study.

PEG-INTRON Studies Presented at AASLD

A large randomized study is ongoing to evaluate two different dosing regimens of PEG-INTRON and REBETOL in nonresponders to interferon monotherapy or combination therapy with ribavirin, or in patients who relapsed following combination therapy. Of the 330 patients enrolled in this study to date, 152 have completed 24 weeks of treatment (half way through therapy). Combined results of the two dosing regimens for the subset of patients who did not respond to prior combination therapy showed that 26% of these patients (29/112) had a virologic response after 24 weeks of treatment, including patients with genotype 1 (22/98), the predominant genotype worldwide and the most difficult to treat.

In another large ongoing study involving patients who failed to clear the hepatitis C virus following interferon-based therapy, the first 250 patients enrolled are being treated with PEG-INTRON (1.5 mcg/kg/week) and REBETOL (800 mg/kg/day) for 48 weeks. The next 250 patients enrolled will receive the same dose of PEG-INTRON, but in combination with a weight-based dose of REBETOL. Of the 132 patients to date who have received at least 24 weeks of treatment with PEG-INTRON (1.5 mcg/kg/week) and REBETOL (800 mg/kg/day), 41% are HCV negative. Of these patients, 31% with genotype 1a and 49% with genotype 1b, as well as 22% of previous nonresponders and 25% of African Americans, are HCV negative.

In a study designed to evaluate the effect of adherence to therapy on treatment outcome for HCV patients receiving PEG-INTRON and REBETOL, researchers performed an analysis on data from the pivotal clinical study involving 1,530 patients that served as the basis for U.S. and EU regulatory approval of the combination therapy. Analysis of sustained viral response(1) (SVR) rates according to patient compliance during therapy showed that patients receiving $\geq 80\%$ of their total interferon dose and $\geq 80\%$ of

their ribavirin dose for $>80\%$ of the expected duration of therapy had enhanced SVR rates compared to patients who were not adherent to therapy.

New treatment strategies are needed to maximize HCV viral clearance in the growing number of patients with chronic hepatitis C who did not respond to, or had relapsed following, previous interferon-based therapy. Researchers at AASLD presented interim data from eight separate ongoing prospective studies evaluating the safety and efficacy of PEG-INTRON and REBETOL combination therapy in this treatment setting.

Treatment of chronic hepatitis C in patients co-infected with HIV has become a major issue in the last few years as the prognosis of HIV disease has improved dramatically with the development of highly active antiretroviral therapy (HAART). As a consequence, an increasing number of co-infected patients are prone to develop cirrhosis and end-stage liver disease. Investigators reported interim results of an ongoing open-label study evaluating the safety and efficacy of PEG-INTRON (150 mcg/week) and REBETOL (800 mg/day) in 31 co-infected patients previously untreated with interferon, many of whom are receiving antiretroviral drugs for HIV. After 12 weeks of treatment, serum

HCV-RNA was undetectable in 22 patients (75%) and liver enzyme levels normalized in 27 patients (85%), with three patients stopping therapy due to adverse effects. These interim results indicate that longer follow up is warranted.

In a study comparing the public health burden of chronic hepatitis C and HIV infection in France, researchers using mortality data and natural history estimates applied the back-calculation method to make projections about incidence and mortality from HCV and HIV up to 1997. The HCV model applied natural history and hepatocellular carcinoma mortality data from French national statistics. The HIV model used AIDS cases reported to the French National Institute for Public Health Surveillance and HIV/AIDS deaths reported to the French Institute of Health and Medical Research. These data indicate that the public health burden of HCV is on the rise in France, while the burden of HIV may be on the decline.

Hepatitis C virus recurrence after liver transplantation is common and poses one of the greatest challenges to transplantation for this indication. In a small study, PEG-INTRON and REBETOL combination therapy was evaluated in six patients who developed aggressive recurrent HCV after receiving transplants for HCV-related cirrhosis. Researchers noted that additional clinical studies are necessary to define duration of therapy and whether treatment will lead to improved overall patient and graft survival.

A significant number of patients chronically infected with hepatitis C have cirrhosis or transition to cirrhosis at the time of diagnosis. In order to define the impact of severe liver

disease on the pharmacokinetics and pharmacodynamics of PEG-INTRON and REBETOL combination therapy, pharmacokinetic data for REBETOL (1,367 patients) and pharmacodynamic data for PEG-INTRON in combination with REBETOL (627 patients) were collected from the pivotal clinical study involving 1,530 patients that served as the basis for U.S. and EU regulatory approval of the combination therapy. Additionally, pharmacokinetic data for PEG-INTRON (894 patients) were collected from the pivotal clinical study involving 1,219 patients that served as the basis for U.S. and EU regulatory approval of PEG-INTRON monotherapy. The population models for PEG-INTRON and REBETOL were developed separately and the severity of hepatic fibrosis was determined by Knodell HAI score. Results of this analysis suggest that baseline fibrosis score had no effect on the apparent clearance of REBETOL. For PEG-INTRON, the baseline fibrosis score had no effect on week 4 clearance. Furthermore, the baseline fibrosis score had no effect on other pharmacokinetic parameters, (end of treatment) and the time that the clearance of PEG-INTRON declines to half of the baseline clearance (T50).

Researchers also presented results of a cost-effectiveness study of PEG-INTRON and REBETOL combination therapy in the initial treatment of hepatitis C. For this analysis, summary data from the pivotal clinical study involving 1,530 patients that served as the basis for U.S. and EU regulatory approval of the combination therapy was applied to a previously published and validated computer cohort simulation to project lifelong clinical outcomes. Their analysis suggested that PEG-INTRON and REBETOL combination therapy should be considered cost effective, providing good economic value for its clinical benefit.

PEG-INTRON, which is approved for dosing according to patient body weight, is the first and only pegylated interferon product approved for marketing in the United States. PEG-INTRON, recombinant interferon alfa-2b linked to a 12,000 dalton polyethylene glycol (PEG) molecule, is a once-weekly therapy designed to optimize the balance between antiviral activity and elimination half-life. Schering-Plough holds an exclusive worldwide license to PEG-INTRON.

Some 4 million Americans are infected with the hepatitis C virus (HCV) and approximately 70 percent of infected patients go on to develop chronic liver disease, according to the Centers for Disease Control and Prevention (CDC). Hepatitis C infection contributes to the deaths of an estimated 8,000 to 10,000 Americans each year. This toll is expected to triple by the year 2010 and exceed the number of annual deaths due to AIDS, according to the CDC. The CDC has reported that HCV-associated end-stage liver disease is the most frequent

indication for liver transplantation among adults. It is predicted that direct U.S. medical costs to treat HCV-related disease will exceed \$13 billion for the years 2010 through 2019, according to a study published in the American Journal of Public Health.

Except for the historical information herein, the matters discussed in this Form 8-K 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/A, Form 10-Qs and Form 8-Ks on file with the SEC, including without limitation, risks in obtaining and maintaining regulatory approval for indications and expanded indications, market acceptance of and continuing demand for Enzon's products and the impact of competitive products and pricing.

- (1) Defined as HCV-RNA below limit of detection using a research-based RT-PCR assay at 24 weeks post-treatment.

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 26, 2001

ENZON, INC

(Registrant)

By: /s/ Kenneth J. Zuerblis

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