

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) May 22, 2001

ENZON, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)	0-12957 (Commission File Number)	22-2372868 (IRS Employer Identification)
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20 Kingsbridge Road, Piscataway, New Jersey 08854  
(Address of principal executive offices) (Zip Code)

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

N/A

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

Item 5. Other Events.

ENZON ANNOUNCES INTERIM RESULTS OF  
PEG-INTRON(TM) PLUS REBETOL(R) STUDIES IN HEPATITIS C PATIENTS  
REPORTED AT DIGESTIVE DISEASES WEEK MEETING

Enzon, Inc. announced today that Schering-Plough Research Institute has reported interim results of two ongoing investigational clinical studies with once-weekly PEG-INTRON(TM) (peginterferon alfa-2b) Injection plus daily REBETOL(R) (Ribavirin, USP) Capsules in patients with chronic hepatitis C who did not respond to, or had relapsed following, previous interferon-based therapy. These data are being presented for the first time at the 2001 Digestive Diseases Week (DDW) conference in Atlanta, Georgia.

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

In a study led by Dr. Ira M. Jacobson, M.D., chief, division of gastroenterology and hepatology, Weill Medical College of Cornell University, New York, evaluating two different doses of both PEG-INTRON and REBETOL, combined results of the two dosing regimens for the subset of patients who did not respond to prior combination therapy showed that 35 percent of these patients had a virologic response after 24 weeks of treatment (half way through therapy). PEG-INTRON and REBETOL combination therapy is currently undergoing priority review by the U.S. Food and Drug Administration (FDA) for the treatment of chronic hepatitis C in patients not previously treated with alpha interferon who have compensated liver disease and are at least 18 years of age.

As previously reported by Schering-Plough, analysis of a pivotal Phase III study with PEG-INTRON and REBETOL in previously untreated (naive) adult patients with chronic hepatitis C showed that the combination therapy analyzed on an optimized dose/body-weight basis (1.5 mcg/kg of PEG-INTRON once weekly and >10.6 mg/kg of REBETOL daily) achieved a 61 percent rate of sustained virologic response(1) overall (48% for genotype 1 and 88% for genotypes 2 and 3).

This Phase III study serves as the basis for Schering-Plough's worldwide registration program for PEG-INTRON and REBETOL combination therapy. These results in previously untreated patients have led to further investigations involving PEG-INTRON and REBETOL in patients who had failed treatment with currently available therapies.

PEG-INTRON and REBETOL combination therapy in March 2001 was granted centralized marketing authorization in the European Union (EU) for the treatment of both relapsed and naive (previously untreated) adult patients with histologically proven chronic hepatitis C.

In the United States, Schering-Plough in February 2001 submitted a supplemental Biologics License Application (sBLA) to the FDA seeking marketing approval of PEG-INTRON for use in combination therapy with REBETOL for the treatment of chronic hepatitis C in patients not previously treated with interferon alpha who have compensated liver disease and are at least 18 years of age. FDA has granted this application priority review status, which provides for FDA action within six months from the date of filing.

The FDA on Jan. 19, 2001, granted marketing approval to PEG-INTRON as once-weekly monotherapy for the treatment of chronic hepatitis C in patients not previously treated with alpha interferon who have compensated liver disease and are at least 18 years of age. PEG-INTRON is the first and only pegylated interferon approved for marketing in the United States.

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

REBETOL had been previously approved in the United States for use in combination with INTRON A (interferon alfa-2b, recombinant) Injection for the treatment of chronic hepatitis C in patients with compensated liver disease previously untreated with alpha interferon or who have relapsed following alpha interferon therapy. REBETOL is marketed in the United States as a component of REBETRON(TM) Combination Therapy, which contains REBETOL Capsules and INTRON A Injection in a single package. Schering-Plough on Nov. 7, 2000, submitted a supplemental application to FDA seeking approval to market REBETOL separately for use in combination with INTRON A. The REBETOL application is currently undergoing FDA review.

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.

INTRON A is a recombinant version of naturally occurring alpha interferon, which has been shown to exert both antiviral and immunomodulatory effects. Schering-Plough markets INTRON A, the world's largest-selling alpha interferon, for 16 major antiviral and anticancer indications worldwide.

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-Q's and Form 8-K's 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.

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: May 22, 2001

ENZON, INC.

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(Registrant)

By: /s/ KENNETH J. ZUERBLIS

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