

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) December 20, 2000

ENZON, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)	0-12957 (Commission File Number)	22-237286 (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

PEGINTRON(TM) and REBETOL(R) Recommended for Approval as Combination Therapy by European Union's CPMP for the Treatment of Hepatitis C

Enzon, Inc. (the "Company") announced on December 20, 2000 that the European Union's (EU) Committee for Proprietary Medicinal Products (CPMP) of the European Agency for the Evaluation of Medicinal Products (EMEA) has issued a positive opinion to Schering-Plough Corporation (NYSE:SGP) recommending approval of PEGINTRON(TM) (peginterferon alfa-2b) Injection and REBETOL(R) (ribavirin) Capsules as combination therapy for the treatment of both relapsed and naive (previously untreated) adult patients with histologically proven chronic hepatitis C.

The CPMP opinion serves as the basis for a European Commission approval, which is typically issued within three to four months. Commission approval of the centralized Type II variations to the Marketing Authorizations for PEGINTRON and REBETOL would result in unified labeling that would be immediately valid in all 15 EU-Member States.

PEGINTRON has previously received centralized marketing authorization in the EU and is marketed as monotherapy in cases of intolerance or contraindication to ribavirin for the treatment of adult patients with histologically proven chronic hepatitis C. PEGINTRON is a longer-acting form of Schering-Plough's interferon alfa-2b recombinant injection (marketed as INTRON(R) A in certain countries), developed using Enzon's proprietary PEG technology licensed to Schering-Plough. Under the Company's licensing agreement with Schering-Plough, Enzon is entitled to royalties on worldwide sales of PEGINTRON and milestone payments.

REBETOL has previously received centralized marketing authorization in the EU and is marketed for use in combination with Schering-Plough's interferon

alfa-2b injection for the treatment of both relapsed and naive adult patients with hepatitis C.

The centralized Type II variations propose that PEGINTRON should be administered as a once-weekly subcutaneous injection at a dose of 1.5 mcg/kg when used in combination with REBETOL capsules. The dose of REBETOL to be used in combination with PEGINTRON is based on patient body weight (<65kg/800 mg/daily; 65-85 kg/1,000 mg/daily; >85 kg/1,200 mg/daily). Ribavirin capsules are to be administered orally each day in two divided doses with food (morning and evening). It is recommended that patients be treated initially with the combination therapy for six months. In patients showing loss of HCV-RNA1 at six months, treatment is to be continued for an additional six months, i.e., one year of treatment.

Clinical Trials

In a pivotal Phase III, randomized, controlled clinical study of two dosing regimens of PEGINTRON in combination with REBETOL compared to interferon alfa-2b (INTRON A) in combination with REBETOL, a total of 1,530 previously untreated patients from 62 sites worldwide (33 U.S., 5 Canada, 22 Europe, 2 other) were randomized to three treatment arms:

- (A) PEGINTRON Injection 1.5 mcg/kg once weekly (QW) plus REBETOL Capsules 800 mg/daily for 48 weeks (PEG 1.5/R);
- (B) PEGINTRON 1.5 mcg/kg QW plus REBETOL 1000-1200 mg/daily for four weeks followed by PEGINTRON 0.5 mcg/kg QW plus REBETOL 1000-1200 mg/daily for 44 weeks (Peg 0.5/R); or
- (C) Interferon alfa-2b (INTRON A) Injection 3 MIU/three times weekly plus REBETOL Capsules 1000-1200 mg/daily for 48 weeks (I/R). In this study, the combination of PEGINTRON (1.5 mcg/kg once weekly) and REBETOL was significantly more effective than the combination of interferon alfa-2b and REBETOL, particularly in patients infected with Genotype 1 virus. Sustained virologic response (SVR) was assessed by the response rate six months after the cessation of treatment.
- (D) Sustained virologic response rates in this study were shown to be dependent on the dose of REBETOL administered in combination with PEGINTRON or interferon alfa-2b (INTRON A). In those patients who received >10.6 mg/kg/daily REBETOL (800 mg dose in typical 75 kg patient), regardless of genotype or viral load, response rates were significantly higher than in those patients who received <10.6 mg/kg/daily REBETOL.

Optimized Weight-Based Dosing

(>10.6 mg/kg/daily REBETOL*)

RESULTS:	(A) PEG 1.5/R	(B) PEG 0.5/R	(C) I/R
SVR (overall)	61%	48%	47%
SVR Genotype 1	48%	34%	34%
SVR Genotypes 2 & 3	88%	80%	80%

* 10.6 mg/kg/daily REBETOL About Equals REBETOL 800 mg/daily for patient weighing 75 kg.

Sustained virologic response rates in this study were increased if patients were able to maintain compliance. Regardless of genotype, patients who received the recommended combination regimen and received >|=80% of their treatment with PEGINTRON and REBETOL had a higher sustained response six months after one year of treatment than those who received <80% of their treatment (72% vs. 46%).

In clinical studies, the combination of PEGINTRON and REBETOL had comparable safety profiles as the combination of interferon alfa-2b and REBETOL. The most frequently reported adverse events with PEGINTRON and REBETOL combination therapy (fatigue, fever, headache and rigors) were also the most

frequently reported adverse events with interferon alfa-2b and REBETOL combination therapy.

PEGINTRON (peginterferon alfa-2b), interferon alfa-2b linked to a 12,000 dalton polyethylene glycol (PEG) molecule, is a once-weekly product designed to optimize the balance between antiviral activity and elimination half-life. Schering-Plough holds an exclusive worldwide license to PEGINTRON.

Chronic hepatitis C is estimated to affect some 10 million people in major world markets. As many as 5 million Europeans (1 to 2 percent of the general population) are chronically infected with the hepatitis C virus, according to a study conducted by the World Health Organization (WHO). In Europe, chronic hepatitis C is the leading cause of chronic liver disease and the most common reason for liver transplant.

Except for the historical information herein, the matters discussed herein 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-Qs and Form 8-K on file with the SEC, including without limitation, risks in obtaining and maintaining regulatory approval for 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: December 20, 2000

ENZON, INC.

(Registrant)

By: /s/ Kenneth J. Zuerblis

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