ENZON INC
Form 8-K
March 30, 2001

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) March 28, 2001

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

Delaware	0-12957	22-237286
(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

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

Item 5. Other Events

ENZON ANNOUNCES EUROPEAN UNION APPROVAL OF PEGINTRON(TM)
AND REBETOL(R)COMBINATION THERAPY FOR HEPATITIS C

Enzon, Inc. announced today that Schering-Plough Corporation was informed that the European Commission of the European Union (EU) has granted centralized marketing authorization to 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. PEGINTRON is a longer acting form of Schering-Plough's INTRON(R) A 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 PEGINTRON.

Commission approval of PEGINTRON and REBETOL results in unified labeling that is immediately valid in all 15 EU-Member States and Iceland and Norway. The Commission's decision follows recommendation for approval in December 2000 by the EU's Committee for Proprietary Medicinal Products (CPMP) of the European Agency for the Evaluation of Medicinal Products (EMEA).

The pivotal clinical study on which the marketing authorization is based demonstrated that PEGINTRON and REBETOL combination therapy was significantly more effective (61% vs. 47%) in achieving a sustained virologic response (SVR)

in patients receiving the recommended combination regimen than the combination of interferon alfa-2b (INTRON(R) A) and REBETOL, particularly in patients infected with Genotype 1 virus (48% vs. 33%). SVR is defined as sustained loss of detectable1 hepatitis C virus (HCV-RNA2) at six months after the cessation of treatment.

The study showed that SVR rates 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 SVR than those who took