ENZON INC
Form 8-K
June 13, 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) June 7, 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

On June 11, 2001, Enzon, Inc. ("Enzon") reported that Schering-Plough Corporation's Phase III study comparing its PEG-INTRON(TM) (peginterferon alfa-2b) Injection to its INTRON(R) A (interferon alfa-2b) Injection in patients with newly diagnosed chronic myelogenous leukemia (CML) has been completed. In this study, PEG-INTRON administered once weekly demonstrated clinical comparability to INTRON A administered daily, with a comparable safety profile. Despite demonstrating clinical comparability, the efficacy results for PEG-INTRON did not meet the protocol-specified statistical criteria for non-inferiority - the primary endpoint in the study. The major cytogenetic response rates at month 12 for both products were similar to those previously reported in the literature for alpha interferon.

Results of this Phase III study have not yet been presented or published, and, therefore, are not publicly available at this time. Presentations of these data by study investigators at appropriate medical meetings are anticipated, followed by the subsequent publication of the study results.

In addition to conducting this Phase III study of PEG-INTRON in CML, Schering-Plough is working with independent investigators to pursue novel research initiatives with PEG-INTRON in oncology indications through a comprehensive Medical Affairs program. This program includes large ongoing

studies with PEG-INTRON in high-risk melanoma, myeloma and non-Hodgkin's lymphoma, both as monotherapy and in combination with other agents.

PEG-INTRON is currently marketed by Schering-Plough in major world markets for the treatment of chronic hepatitis C. It is the first and only pegylated interferon approved for marketing in the world. PEG-INTRON (peginterferon alfa-2b) is a longer-acting form of Schering-Plough's INTRON 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.

Peter Tombros resigned as a Director of Enzon as of June 7, 2001. Mr. Tombros, former President and Chief Executive Officer of Enzon, was recently replaced as President and Chief Executive Officer by Arthur J. Higgins. Mr. Higgins officially started as President and Chief Executive Officer on May 31, 2001. Mr. Higgins was also elected to Enzon's Board of Directors as of May 31, 2001.

ADAGEN, our first FDA-approved PEG product, is used to treat patients afflicted with a type of Severe Combined Immunodeficiency Disease, or SCID, also known as the Bubble Boy Disease, which is caused by the chronic deficiency of the adenosine deaminase enzyme. The adenosine deaminase or ADA enzyme in ADAGEN is obtained from bovine intestine. We purchase this enzyme from the world's only FDA approved supplier, which, until recently, has obtained it from cattle of German origin. Bovine spongiform encephalopathy (BSE or mad cow disease) has been detected in cattle herds in the United Kingdom and more recently, in other European countries. In November 2000, BSE was identified for the first time in cattle in Germany. There is evidence of a link between the agent that causes BSE in cattle and a new variant form of Creutzfeld-Jakob, or nvCJD disease, in humans. The ADA that has been used in ADAGEN and will be used through early 2002, is derived from bovine intestines harvested prior to November 2000, when herds were identified in Germany as BSE-free. The BSE agent has not been detected in the herds from which ADA was derived for ADAGEN and we have no reason to believe that these herds were infected with that agent. Based upon the timing of the harvest of the intestines, the use of certain purification steps taken in the manufacture of ADAGEN, and from our analysis of relevant information concerning this issue, we consider the risk of product contamination to be extremely low. However, the lengthy incubation period of BSE, and the absence of a validated test for the BSE agent in pharmaceutical products, makes it impossible to be absolutely certain that ADAGEN is free of the agent that causes nvCJD. To date, cases of nvCJD have been rare in the United Kingdom, where large numbers of BSE-infected cattle are known to have entered the human food chain. To date, no cases of nvCJD have been linked to ADAGEN or, to our knowledge, any other pharmaceutical product, including vaccines manufactured using bovine derived materials from countries where BSE has been detected.

We have been in discussions with the FDA concerning our continued distribution of ADAGEN. Given the significant benefit to the patients who take this product, and the likely significant adverse consequences to these patients if this product were not available, we have agreed with the FDA to continue to distribute the product. In order to avoid any potential BSE-related risk from ADAGEN and to be consistent with recommendations from the FDA, our supplier has secured a new source of bovine intestines from New Zealand, which has no confirmed cases of BSE. We are working closely with our supplier to expedite the delivery of ADA from New Zealand herds, but do not anticipate being able to supply ADAGEN derived from this source until early in 2002. In the longer term, we are pursuing development of a recombinant form of human ADA, but a product based on this technology will not be available for several years, if ever.

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, Form 10-K/A, Form 10-Q's 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.

Item 7. Exhibits

10.30 Employment Agreement between Enzon, Inc. and Arthur J. Higgins dated May 9, 2001.

10.31 Amendment dated May 23, 2001 to Employment Agreement between Enzon, Inc. and Arthur J. Higgins dated May 9, 2001.

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: June 12, 2001

ENZON, INC.

(Registrant)

By: /s/ Kenneth J. Zuerblis

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