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ENZON PHARMACEUTICALS INC

Form 8-K

January 06, 2003

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) January 6, 2003

ENZON Pharmaceuticals, INC.

(Exact name of registrant as specified in its charter)

Delaware	0-12957	22-2372868
(State or other jurisdiction	(Commission	(IRS Employer
of incorporation)	File Number)	Identification)

685 Route 202/206, Bridgewater, New Jersey 08807  
(Address of principal executive offices) (Zip Code)

(Registrant's telephone number, including area code: (908) 541-8600

ENZON, INC.

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

Item 5. Other Events

Enzon Pharmaceuticals, Inc. and SkyePharma PLC announced on January 2, 2003 a strategic alliance based on a broad technology access agreement. The two companies will draw on their combined drug delivery technology and expertise to jointly develop, up to three products for future commercialization. These products will be based on SkyePharma's proprietary platforms in the areas of oral, injectable and topical drug delivery, supported by technology to enhance drug solubility and Enzon's proprietary PEG modification technology, for which Enzon will receive a US\$3.5 million technology access fee. SkyePharma will receive a milestone payment for each product based on its own proprietary technology that enters Phase II clinical development. Research and development costs related to the technology alliance will be shared equally, as will future revenues generated from the commercialization of any jointly-developed products.

Effective December 31, 2002, Enzon also obtained an exclusive license for the right to sell, market and distribute SkyePharma's DEPOCYT(R), an injectable chemotherapeutic approved for the treatment of patients with lymphomatous meningitis in the United States and Canada.

Enzon will pay a license fee of US\$12 million for the North American rights to DEPOCYT. SkyePharma will manufacture DEPOCYT and Enzon will purchase finished product at 35% of net sales, which percentage of net sales can be reduced should a defined sales target be exceeded. SkyePharma is also entitled to milestone payments based on the achievement of certain sales levels and the approval of additional indications. Enzon is required to meet certain minimum sales levels for the product which are based on historical sales levels. Enzon's license is for an initial term of ten years and is automatically renewable for

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successive two year terms thereafter.

Approximately 25,000 cases of neoplastic meningitis occur annually, of which approximately 40 percent are lymphomatous meningitis and 60 percent are neoplastic meningitis in patients with solid tumors. SkyePharma is currently conducting Phase IV clinical studies that seek to expand the DEPOCYT label to include the latter, neoplastic meningitis, indication.

Enzon plans to market DEPOCYT through its focused, specialty oncology sales representatives currently responsible for marketing ONCASPAR(R). The marketing strategy will aim to increase awareness of the benefits of DEPOCYT in treating lymphomatous meningitis, a serious, disabling and potentially fatal complication of cancer.

DEPOCYT is an injectable, sustained-release formulation of the chemotherapeutic agent, cytarabine or Ara-C. Using SkyePharma's proprietary lipid-based drug delivery technology, DEPOFOAMO, DEPOCYT gradually releases cytarabine into the cerebral spinal fluid and extends the dosing interval to once every two weeks, as compared to the standard twice-weekly intrathecal chemotherapy dosing of cytarabine.

In addition, Enzon announced on January 3, 2003 that the Company will suspend its PEG-paclitaxel development program.

The decision to suspend the program, which is in Phase I, is based on a strategic analysis of the program's potential investment returns against the associated costs, competitive risks, resource allocation and development time.

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 Enzon's Form 10-K, Form 10-Q's, Form 8-K's and other documents on file with the SEC, including without limitation, risks in obtaining and maintaining regulatory approval for existing, new or expanded indications for DEPOCYT and other regulatory risks, risks relating to SkyePharma's ability to manufacture pharmaceutical products on a large scale, risks that customer inventory will be greater than previously thought, risks concerning Enzon's ability to manage growth, market a pharmaceutical product on a large scale and integrate and manage an internal sales and marketing organization and maintain or expand sales and market share for DEPOCYT, risks relating to the achievement of actual 2002 North American sales of DEPOCYT, risks relating to the ability to ensure regulatory compliance, risks related to the research, development and regulatory approval of new pharmaceutical products, risks related to research and development costs and capabilities, market acceptance of and continuing demand for Enzon's products and the impact of increased competition, risks associated with anticipated top and bottom line growth and the possibility that upside potential will not be achieved, competitive products and pricing, and risks associated with the ownership and use of intellectual property rights.

### 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

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undersigned hereunto duly authorized.

Dated: January 6, 2003

By: /s/ Kenneth J. Zuerblis

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