# UNITED STATES 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): September 16, 2004

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

Delaware (State or other jurisdiction of (Commission incorporation)

22-2372868 (IRS Employer File Number) Identification)

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

0-12957

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

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

Item 8.01 Other Events

Enzon Pharmaceuticals, Inc. (NASDAQ:ENZN) and Pharmagene plc (LSE: PGN) announced today they have signed an agreement for the development of a long-acting version of Pharmagene's drug candidate, PGN0052. PGN0052 is a peptide hormone that is initially being investigated as a treatment for cystic fibrosis and may have additional applications for other respiratory disorders.

 ${\tt PGN0052}$  , a synthetic version of human secretin, has been successfully advanced through three Phase 1 studies, and is currently being evaluated in a Phase 2a proof of concept trial. Clinical trial results to date have demonstrated a favorable safety and tolerability profile and importantly, PGN0052 has proven effective in improving airway function following intravenous administration. These results, together with Pharmagene's preclinical findings using human tissue, demonstrate the potential of this drug candidate to treat cystic fibrosis. Company researchers believe that extending the duration of action of PGN0052 may provide greater overall effectiveness and improve its potential as a therapeutic.

Under the agreement, Enzon will apply its proprietary PEGylation technology to engineer a molecule with optimized pharmacokinetic properties and an extended duration of action. Enzon will receive an initial fee upon signing and a milestone payment upon the molecule meeting certain pre-determined criteria. Subject to achievement of such criteria, the companies have the option to enter into a worldwide joint development and commercialization agreement for the product. Should the companies exercise this option, they would share equally in development costs and profits and Pharmagene would be eligible to receive future licensing and milestone payments, which could reach approximately (pound)26.5 million. Should the companies not elect to enter into a joint development and commercialization agreement, Pharmagene will be entitled to use the PEGylated molecule for development and commercialization purposes and Enzon will receive certain co-marketing rights and royalties on worldwide sales for all indications. While cystic fibrosis has been chosen as the lead indication for PGN0052, the companies also believe there is potential for the treatment of chronic obstructive pulmonary disease (COPD) and asthma.

In May 2004 at the American Thoracic Society conference, Pharmagene presented data from Phase 1 studies in which PGN0052 was administered by either the inhaled or intravenous route. The results demonstrated that in the intravenous form, the drug was well tolerated and effective in producing measurable effects on airway function. There is also supporting in vitro evidence of a relaxant effect on bronchial smooth muscle. Based in part on these positive results, Pharmagene has initiated a Phase 2a proof of concept study in cystic fibrosis patients designed to assess the impact of the drug on mucociliary clearance (the ability of the lining of the airways lungs to clear the protective mucus secreted by the epithelial cells), using specific objective indicators. If the

study confirms the therapeutic principle, the development program will continue with a version of PGN0052 with an optimized pharmacokinetic profile. Results from the Phase 2a study are anticipated in the fourth quarter of calendar 2004.

#### About Cystic Fibrosis

Cystic fibrosis is the most common terminal genetic condition among Caucasians. About 30,000 people in the United States and about 70,000 people worldwide have cystic fibrosis. Cystic fibrosis patients' epithelial cells produce a defective form of a protein called CFTR or Cystic Fibrosis Transmembrane Conductance Regulator. The CFTR forms a channel that controls the movement of salt and water into and out of cells. In cystic fibrosis, the protein is altered due to a genetic mutation and, as a consequence, not functional in the cell membrane of cells lining mucosal epithelial. Cystic fibrosis is characterized by a disruption in the essential balance of salt and water that is needed to maintain a normal thin coating of fluid and mucus inside the lungs, pancreas, and passageways in other organs, causing the organs to function improperly. In the lungs, the accumulation of thick mucus results in chronic lung complications, such as wheezing, coughing, pneumonia or infections. In the pancreas, the thick mucus can block the channels that would normally carry pancreatic enzymes to the intestines to digest foods, resulting in the improper processing and digestion of foods.

Death from cystic fibrosis is mainly due to pulmonary complications. The condition is commonly treated with inhaled medications that aim to minimize infection of the lung.

#### About Secretin

Secretin is a 27-amino acid polypeptide hormone (about half the size of insulin) that promotes the secretion of electrolytes and water from epithelial cells. Secretin also stimulates the release of pancreatic juice by the pancreas and bile by the liver, both of which contain bicarbonate (a salt) and change the pH of the duodenum (the first or proximal portion of small intestine) from acid to alkaline, thereby facilitating the action of intestinal digestive enzymes.

# About Pharmagene

Founded in 1996, Pharmagene is a drug discovery company whose aim is to identify and develop novel treatments for human disease. To achieve this objective, Pharmagene focuses solely on the use of fully consented human tissue for which it has established, and maintains, one of the most effective tissue supply networks in the world. By the provision of products and services that add value throughout the drug discovery process, Pharmagene has built a solid reputation and a growing customer base, including many of the major pharmaceutical companies. Pharmagene is also actively undertaking internal research programs to generate substantial intellectual property. Its lead therapeutic programs are in cystic fibrosis, irritable bowel syndrome and migraine, all with novel mechanisms of action elucidated by the company.

# About Enzon

Enzon Pharmaceuticals is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics to treat life-threatening diseases. The Company has developed or acquired a number of marketed products, including PEG-INTRON(R), marketed by Schering-Plough, and ABELCET(R), ONCASPAR(R), ADAGEN(R), and DEPOCYT(R), marketed in North America by Enzon's specialized sales force. Enzon's science-focused strategy includes an

extensive drug development program that leverages the Company's macromolecular engineering technology platforms, including PEG modification and single-chain antibody (SCA(R)) technologies. Internal research and development efforts are complemented by strategic transactions that provide access to additional products and technologies. Enzon has several drug candidates in various stages of development, independently and with partners, including Marqibo(R), for which a U.S. marketing application is currently being reviewed by the FDA for the treatment of relapsed aggressive non-Hodgkin's lymphoma. Further information about Enzon and this press release can be found on the Company's web site at www.enzon.com.

There are forward-looking statements contained herein that are not based on

historical fact, including without limitation statements containing the words "believes," "may," "plans," "will," "estimates," "continue," "anticipates," "intends," "expects," and similar expressions. Examples include statements above (i) regarding the potential benefits of extending the duration of action of PGN0052, (ii) anticipating the optimization of the pharmacokinetic properties of PGN0052 through the application of PEG technology, (iii) regarding the potential receipt of milestone and royalty payments, (iv) regarding the potential formation of a joint development and commercialization agreement, (v) contemplating the potential usefulness of PGN0052 in cystic fibrosis and other indications and (vi) predicting the timing of Phase 2 study results. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results, events or developments to be materially different from the future results, events or developments discussed above. Such factors include the risks that the application of PEG technology may not improve the pharmacokinetic properties of PGN0052, that the Phase 2 study may be delayed or that PGN0052 may not emerge successfully from it, that PGN0052 may not receive regulatory approval from the FDA, and that Pharmagene and/or Enzon may not be able to successfully commercialize PGN0052 if it does receive regulatory approval from the FDA, as well as those described in Enzon's Form 10-K and Forms 10-Q on file with the SEC, such as, Enzon's ability to sustain profitability, and positive cash flow; market acceptance of and continuing demand for Enzon's products; and the impact of competitive products and pricing. These factors should be considered carefully and readers are cautioned not to place undue reliance on such forward-looking statements. All information in this press release is as of September 16, 2004 and the Company undertakes no duty to update this information.

Item 9.01 Financial Statements and Exhibits

Exhibit 99.1 Press Release dated September 16, 2004

## 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: September 16, 2004

By: /s/ Kenneth J. Zuerblis Kenneth J. Zuerblis Vice President, Finance and Chief Financial Officer

## [LEETERHEAD OF ENZON PHARMACEUTICALS, INC.]

For Immediate Release

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PRESS RELEASE

Contacts:	
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ENZON AND PHARMAGENE ANNOUNCE AGREEMENT TO DEVELOP PEGYLATED SECRETIN FOR CYSTIC FIBROSIS

Bridgewater, NJ and Royston, UK - September 16, 2004 - Enzon Pharmaceuticals, Inc. (NASDAQ:ENZN) and Pharmagene plc (LSE: PGN) announced today they have signed an agreement for the development of a long-acting version of Pharmagene's drug candidate, PGN0052. PGN0052 is a peptide hormone that is initially being investigated as a treatment for cystic fibrosis and may have additional applications for other respiratory disorders.

PGN0052, a synthetic version of human secretin, has been successfully advanced through three Phase 1 studies, and is currently being evaluated in a Phase 2a proof of concept trial. Clinical trial results to date have demonstrated a favorable safety and tolerability profile and importantly, PGN0052 has proven effective in improving airway function following intravenous administration. These results, together with Pharmagene's preclinical findings using human tissue, demonstrate the potential of this drug candidate to treat cystic fibrosis. Company researchers believe that extending the duration of action of PGN0052 may provide greater overall effectiveness and improve its potential as a therapeutic.

Under the agreement, Enzon will apply its proprietary PEGylation technology to engineer a molecule with optimized pharmacokinetic properties and an extended duration of action. Enzon will receive an initial fee upon signing and a milestone payment upon the molecule meeting certain pre-determined criteria. Subject to achievement of such criteria, the companies have the option to enter into a worldwide joint development and commercialization agreement for the product. Should the companies exercise this option, they would share equally in development costs and profits and Pharmagene would be eligible to receive future licensing and milestone payments, which could reach approximately (pound)26.5 million. Should the companies not elect to enter into a joint development and commercialization agreement, Pharmagene will be entitled to use the PEGylated molecule for development and commercialization purposes and Enzon will

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receive certain co-marketing rights and royalties on worldwide sales for all indications. While cystic fibrosis has been chosen as the lead indication for PGN0052, the companies also believe there is potential for the treatment of chronic obstructive pulmonary disease (COPD) and asthma.

In May 2004 at the American Thoracic Society conference, Pharmagene presented data from Phase 1 studies in which PGN0052 was administered by either the inhaled or intravenous route. The results demonstrated that in the intravenous form, the drug was well tolerated and effective in producing measurable effects on airway function. There is also supporting in vitro evidence of a relaxant effect on bronchial smooth muscle. Based in part on these positive results, Pharmagene has initiated a Phase 2a proof of concept study in cystic fibrosis patients designed to assess the impact of the drug on mucociliary clearance (the ability of the lining of the airways lungs to clear the protective mucus secreted by the epithelial cells), using specific objective indicators. If the

study confirms the therapeutic principle, the development program will continue with a version of PGN0052 with an optimized pharmacokinetic profile. Results from the Phase 2a study are anticipated in the fourth quarter of calendar 2004.

Uli Grau, Enzon's Chief Scientific Officer, said: "We have been impressed with the data we have seen on PGN0052 and its potential for treating respiratory disorders. We look forward to working with the team at Pharmagene to apply Enzon's PEG expertise to engineer an optimized version of secretin for clinical development."

Dr Alastair Riddell, Chief Executive Officer of Pharmagene, added: "With their expertise in PEGylated reformulation and specialized sales and marketing capabilities in North America, Enzon is an excellent partner for this product. The agreement announced today will enable the rapid progression of the product's development whilst at the same time maximizing its value for our shareholders."

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of action of PGN0052, (ii) anticipating the optimization of the pharmacokinetic properties of PGN0052 through the application of PEG technology, (iii) regarding the potential receipt of milestone and royalty payments, (iv) regarding the potential formation of a joint development and commercialization agreement, (v) contemplating the potential usefulness of PGN0052 in cystic fibrosis and other indications and (vi) predicting the timing of Phase 2 study results. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results, events or developments to be materially different from the future results, events or developments discussed above. Such factors include the risks that the application of PEG technology may not improve the pharmacokinetic properties of PGN0052, that the Phase 2 study may be delayed or that PGN0052 may not emerge successfully from it, that PGN0052 may not receive regulatory approval from the FDA, and that Pharmagene and/or Enzon may not be able to successfully commercialize PGN0052 if it does receive regulatory approval from the FDA, as well as those described in Enzon's Form 10-K and Forms 10-Q on file with the SEC, such as, Enzon's ability to sustain profitability, and positive cash flow; market acceptance of and continuing demand for Enzon's products; and the impact of competitive products and pricing. These factors should be considered carefully and readers are cautioned not to place undue reliance on such forward-looking statements. All information in this press release is as of September 16, 2004 and the Company undertakes no duty to update this information.

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