PHARMION CORP
Form 8-K
January 24, 2008

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

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FORM 8-K

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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 24, 2008

Pharmion Corporation
(Exact name of Registrant as specified in its charter)

| Delaware | 000-50447 | 84-1521333 |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

| 2525 28th Street, Boulder, Colorado | 80301 |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

720-564-9100
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Registrant under any of the following provisions (see General Instruction A.2 below):

[ ] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

[ ] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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Item 8.01 Other Events.

On January 24, 2008, Pharmion Corporation ("Pharmion" or the "Company") announced that the European Medicines Agency ("EMEA") has issued a positive opinion to recommend approval of Thalidomide Pharmion(R) for use in combination with melphalan and prednisone as first line treatment for patients with untreated multiple myeloma, aged 65 years or older or ineligible for high dose chemotherapy. The marketing authorization application for Thalidomide Pharmion was submitted to the EMEA in January 2007.

The EMEA's Committee for Medicinal Products for Human Use ("CHMP") reviewed the application, and its positive opinion will be forwarded to the European Commission ("EC"), which generally follows, but is not obligated to follow, the recommendation of the CHMP, and issues final marketing approval within two to three months. Once ratified by the EC, a single marketing authorization would be granted to Pharmion to market Thalidomide Pharmion for first line multiple myeloma in the 27 member states of the European Union ("EU") as well as Norway and Iceland.

The marketing authorization application reviewed by the EMEA is based upon a clinical data package comprised of studies of nearly 1400 patients in total, including the Intergroupe Francophone du Myelome ("IFM") 99-06 survival study. The three-arm study conducted by IFM demonstrated the superiority of melphalan/prednisone plus Thalidomide ("MPT") over standard therapy of melphalan/prednisone ("MP") or a combination of chemotherapies (vincristine/adriamycin/dexamethasone) followed by melphalan and transplantation ("MEL 100") in the treatment of newly diagnosed multiple myeloma patients, aged 65 to 75 who were ineligible for intensive bone marrow transplantation. A total of 447 patients were randomized to one of the three treatment arms. At final analysis, the overall median survival in the MPT arm was 51.6 months, compared to 33.2 and 38.3 months, respectively, for the MP and MEL 100 arms. The hazard ratios were 0.59 and 0.69, respectively. Thalidomide treatment was generally well-tolerated by the majority of patients. The most frequently reported adverse events associated with MPT included neutropenia, somnolence and constipation. The Thalidomide combination was also associated with a 5-10% greater risk of Grade 3 and 4 venous thromboembolism and peripheral neuropathy.

Multiple myeloma, the second most common cancer of the blood, affects approximately 82,000 people in the EU, and approximately 25,000 people in the EU are diagnosed with multiple myeloma each year.

Thalidomide Pharmion has been designated as an Orphan Medicinal Product in the EU for the treatment of multiple myeloma, which, if approved, entitles the drug to ten years of market exclusivity for the approved indications.

Thalidomide Pharmion must be prescribed and dispensed through the Thalidomide Pharmion Pregnancy Prevention Programme, a risk management plan that includes a number of actions intended to prevent pregnancies in women being treated with thalidomide and exposure of unborn children to the medicine. Treatment with Thalidomide Pharmion, only available by prescription, will be initiated and monitored by a doctor who has experience in the treatment of

multiple myeloma. A clear warning will be printed on the boxes containing the medicine, indicating that Thalidomide Pharmion causes birth defects and fetal death. Prior to the launch of Thalidomide Pharmion, Pharmion will provide healthcare professionals and patients with educational materials about the treatment-related risks and the precautions required to ensure the safe use of the product.

Thalidomide Pharmion is approved in Australia, New Zealand, Turkey, Israel, South Korea, Thailand and South Africa for the treatment of multiple myeloma after the failure of standard therapies.

Thalidomide is currently provided by Pharmion on a named patient/compassionate use basis in most of the EU and under an Autorisation Temporaire d'Utilisation in France while the Company seeks an approval. Pharmion is the only provider of Thalidomide outside of the U.S. with a comprehensive safety program in place.

The Company holds exclusive marketing and distribution rights from Celgene Corporation for Thalidomide in markets outside of North America, Japan and certain other Asian countries.

Thalidomide is a powerful human teratogen, inducing a high frequency of severe and life threatening birth defects. Thalidomide must never be used by women who are pregnant or could become pregnant. The conditions of the Thalidomide Pharmion Pregnancy Prevention Programme must be fulfilled for all male and female patients.

The common adverse reactions associated with the use of Thalidomide in combination with other anti-myeloma therapies are: deep vein thrombosis, constipation, peripheral oedema, tremor, dizziness, fatigue, asthenia, somnolence, peripheral neuropathy, neutropenia, lymphopenia, leucopenia, anaemia, thrombocytopenia, paraesthesia and dysaesthesia. Serious or severe reactions associated with Thalidomide use are: deep vein thrombosis and pulmonary embolism, bradycardia, cerebrovascular accident, peritonitis, orthostatic hypotension, and severe skin reactions including Stevens Johnson Syndrome and toxic epidermal necrolysis. Thromboprophylaxis should be used when Thalidomide is prescribed in combination with other anti-myeloma therapies. Peripheral neuropathy is a potentially severe, adverse effect of treatment with Thalidomide that may result in irreversible damage. Thalidomide may also potentially aggravate existing neuropathy and should therefore not be used in patients with clinical signs or symptoms of peripheral neuropathy unless the clinical benefits outweigh the risks. Symptoms may occur some time after thalidomide treatment has been stopped and may resolve slowly or not at all. Thalidomide frequently causes drowsiness, somnolence and sedation. Patients should be instructed to avoid situations where drowsiness may be a problem.

Multiple myeloma (also known as myeloma or plasma cell myeloma) is a cancer of the blood in which malignant plasma cells are overproduced in the bone marrow. Plasma cells are white blood cells that help produce antibodies called immunoglobulins that fight infection and disease. However, most patients with multiple myeloma have cells that produce a form of immunoglobulin called paraprotein (or M protein) that does not benefit the body. In addition, the malignant plasma cells replace normal plasma cells and other white blood cells important to the immune system. Multiple myeloma cells can also attach to other tissues of the body, such as bone, and produce tumors. The cause of the disease is unknown.

Pharmion is a leading global oncology company uniquely focused on acquiring, developing and commercializing innovative products for the treatment of hematology and oncology patients in the U.S., Europe and additional

international markets. Pharmion has a number of products on the market including the world's first approved epigenetic drug, Vidaza(R), a DNA demethylating agent. For additional information about Pharmion, please visit the company's website at http://www.pharmion.com.

This report contains forward-looking statements, which express the current beliefs and expectations of management. Such statements are based on current expectations and involve a number of known and unknown risks and uncertainties that could cause Pharmion's future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include the regulatory status and timing of regulatory approvals for Thalidomide Pharmion; the impact of competition from other products sold by Pharmion's competitors in the EU; the regulatory environment and changes in the health policies and structure of various countries; acceptance and demand for new pharmaceutical products and new therapies, uncertainties regarding Pharmion's ability to enforce market exclusivities in member states of the EU; failure of third-party manufacturers to produce the product volumes required on a timely basis, fluctuations in currency exchange rates, and other factors that are discussed in Pharmion's filings with the U.S. Securities and Exchange Commission. Forward-looking statements speak only as of the date on which they are made, and Pharmion undertakes no obligation to update publicly or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: January 24, 2008

PHARMION CORPORATION

By: /s/ Steven N. Dupont
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Name: Steven N. Dupont
Title: Executive Vice President and General Counsel