ALPHARMA INC
Form 8-K
March 08, 2002

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

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FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

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Date of Report (Date of earliest event reported):
March 8, 2002

Alpharma Inc.

(Exact name of registrant as specified in its charter)

| Delaware | 1-8593 | 22-2095212 |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

One Executive Drive, Fort Lee, New Jersey 07024
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code
(201) 947-7774

Not Applicable

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

Item 5. Other Events

Alpharma Inc. (the "Company") wishes to disclose the following risk factors relating to the Company and its business:

Risk Factors

This report includes certain forward looking statements. Like any company subject to a competitive and changing business environment, the Company cannot guarantee the results predicted in any of the Company's forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements include (but are not limited to) the following:

The acquisition of the U.S. oral solid dose pharmaceutical business of F.H. Faulding & Co. from Mayne Nickless Limited which was completed on December 12, 2001 (the "Acquisition") and the integration of the acquired business, as well as related management changes, could adversely affect the Company's business and results of operations.

The success of the Acquisition depends in part on the Company's ability to integrate the acquired business into the Company's business and to realize the anticipated benefits. The integration process may be disruptive to the Company's operations and those of the acquired business and may cause an interruption of, or a loss of momentum in, the businesses as a result of a number of obstacles such as the:

- loss of key employees or customers;
- failure to maintain the quality of customer service that the Company's historical businesses or the acquired business has historically provided;
- need to coordinate research and development and quality control functions in order to keep the Company's new product pipeline adequately developed;
- need to comply with governmental regulations;
- resulting diversion of management's attention from the Company's day-to-day business to the integration process; and
- unfamiliarity of management with the needs of the acquired business.

If the Company is not successful in this integration or if it takes longer than anticipated, the Company's business could be adversely affected.

As part of the Company's review of its operations at the time of the Acquisition, the Company added new presidents of its U.S. Human Pharmaceutical business and Animal Health business, as well as other senior employees. On an ongoing basis, the Company reviews its business and may make other senior management changes. These changes may disrupt the Company's business by diverting the attention of management and displacing resources as it focuses on new initiatives.

The Company is subject to government regulations and actions that increase the Company's costs and could prevent it from marketing or selling some of its products in certain countries.

The research, development, manufacturing and marketing of the Company's products are subject to extensive government regulation. Government regulation includes inspection of and controls over testing, manufacturing, safety, efficacy, labeling, record keeping, pricing, sale and distribution of pharmaceutical products.

The U.S. and other governments regularly review manufacturing operations. The Company is presently responding to regulatory concerns as a result of these reviews. Failure to adequately address these concerns could have a material adverse effect on the Company.

During 2001 the Company received inspection observations (483 Reports) from the FDA at its USHP facilities in Elizabeth and Baltimore and its Willow Island and Chicago Heights AHD plants. The Elizabeth review resulted in the

issuance of a warning letter and the inspection at Baltimore resulted in an allegation from the FDA that the Company was not in compliance with a 1992 Consent Decree requiring general compliance with cGMP. The Company believes that it has taken action satisfactory to the FDA at its Elizabeth plant. As to each of the other plants, the inspections have been more recent and, as a result the Company is still in the process of discussing and implementing actions which it believes will be satisfactory to the FDA. At the Baltimore plant, this action includes a temporary slowdown in production which will have an effect on earnings in the first quarter of 2002. Additionally, the Company is presently engaging in a recall and other similar actions with respect to two of its USHP products. In addition to the charges for these actions taken in the fourth quarter of 2001, further charges are expected in the first quarter of 2002. There can be no assurance that the FDA will not require further actions at an additional cost.

The Company also has affiliations, license agreements and other arrangements with third parties that depend on regulatory approvals sought by such third parties. The Company's vendors and third party contract manufacturers are subject to these same regulatory restrictions. If any one of these third parties is found to have violations of a regulatory significance, the Company would be materially negatively impacted as its supply to API and/or product would be threatened. While the Company takes measures to secure back-up suppliers, there can be no assurance that such contingency plans will be able to provide adequate and timely product to eliminate any threat of interruption of supply of the Company's products to its customers or that these problems will not otherwise materially impact the Company's business.

Non-compliance with applicable requirements can result in fines, recall or seizure of products, suspension of production or distribution and debarment of individuals or the Company from providing services to drug companies in any capacity or obtaining new drug approvals. Government regulation substantially increases the cost of manufacturing, developing and selling the Company's products.

The Company has filed, and continues to file, applications to market its products with the FDA and other regulatory agencies both in the U.S. and internationally. The timing of receipt of approvals of these applications can significantly affect the Company's future revenues and income. This is particularly significant with respect to human pharmaceuticals where the Company is, in certain instances, using procedures, known as "paragraph IV certification," to seek marketing approvals prior to the latest date as to which a third party may claim patent protection, including, among others, with respect to Gabapentin. The use of this strategy may involve lengthy litigation, frequently with substantially larger, well-financed pharmaceutical companies. There can be no assurance that the Company will obtain new product approvals in a timely manner, if ever, through litigation or otherwise. Failure to obtain approvals when expected, or at all, could have a material adverse effect on the Company's business. The Company also has affiliations, license agreements and other arrangements with companies that depend on regulatory approvals sought by those companies.

The issue of the potential for increased bacterial resistance to certain antibiotics used in certain food producing animals is the subject of discussions on a worldwide basis and, in certain instances, has led to government restrictions on the use of antibiotics in these food producing animals. While most of the government activity in this area has involved products other than those that the Company offers for sale, effective July 1, 1999, the European Union and five non-EU countries have banned the use of bacitracin zinc, a feed antibiotic and growth promoter manufactured by the Company and others which has been used in livestock feeds for over 40 years. The EU ban is based upon the "Precautionary Principle" which states that a product may be withdrawn from the market based upon a finding of a potential threat of serious or irreversible damage even if such finding is not supported by scientific certainty. The Company's initial effort to reverse this action by means of a court injunction from the Court of First Instance of the European Court was denied. The Company is continuing to pursue the Company's efforts in the European Court and based upon scientific evidence available for the product the Company is engaged in certain other initiatives to limit the effects of this ban. Although the EU actions negatively impact the Company's business, they were not material to the Company's financial position or its results of operations. The discussions concerning resistance to antibiotics used in certain food producing animals have recently become more active in the U.S. Various sources have published reports concerning possible adverse effects of the use of antibiotics in food animals. Some of these reports have

asserted that major animal producers, some of whom are the Company's customers or the end-users of its products, are reducing the use of antibiotics. It is uncertain what actions, if any, the FDA may take in connection with drug resistant bacteria in animal health products. The loss of the U.S. market for, or negative publicity regarding, the Company's bacitracin-based products would be materially adverse to the Company.

The Company cannot predict whether the present bacitracin zinc ban will be expanded. If either (a) the EU or countries or customers within the EU, act to prevent the importation of meat products from countries that allow the use of bacitracin-based products, or (b) there is an expansion of the ban to additional countries, such as the U.S., where the Company has material sales of bacitracin-based products or (c) there is an increase in public pressure to discontinue the use of antibiotic feed additives, the resultant loss of sales could be material to the Company's financial condition, cash flows and results of operations. The Company also cannot predict whether this antibiotic resistance concern will result in expanded regulations adversely affecting other antibiotic-based animal health products manufactured by the Company of which it has significant sales.

The Company's foreign operations are subject to additional economic and political risks

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The Company's foreign operations are subject to currency exchange fluctuations and restrictions, political instability in some countries, and uncertainty as to the enforceability of, and government control over, commercial rights.

The Company sells products in many countries that are susceptible to significant foreign currency fluctuations. The Company's products are generally sold for U.S. dollars, which eliminates the direct exposure to currency fluctuations, but increases credit risk if the local currency devalues significantly and it becomes more difficult for customers to purchase U.S. dollars required to pay the Company.

Some of the Company's foreign operations are being affected by wide currency fluctuations and decreased economic activity in these regions and, in case of Indonesia and Argentina, by social and political unrest. While our present exposure to economic factors in these regions is not material, they are important areas for anticipated future growth.

Regulation of, and competition in, the generic pharmaceuticals industry in the United Kingdom and Germany may decrease the Company's prices and sales volume in these countries.

The United Kingdom Department of Health is currently reviewing proposed legislative changes to the United Kingdom generic pharmaceuticals market, and as part of this review introduced in August 2000 interim maximum pricing legislation for the sale of generic pharmaceuticals in the United Kingdom. These price controls are expected to remain in place at least until October 2002. This interim pricing legislation, as well as competitive factors, has resulted in lower prices for the Company's human generic pharmaceutical products in the United Kingdom.

The United Kingdom generic pharmaceuticals market in 1999 and the first half of 2000 had historically high prices and volume due to product shortages. These market conditions have not continued through 2001 due to increased competition and the United Kingdom government's interim maximum pricing legislation and increased competition. The Company is unable to predict the long-term impact these circumstances will have on the Company's United Kingdom operations and the pricing and sales of generic pharmaceuticals in the United Kingdom.

In Germany new legislation was introduced in January, 2002 which adjusted the existing fixed price system, requiring price reductions for a large number of human generic pharmaceutical products in Germany including a number of the Company's products. Additionally, while the new German law does permit pharmacist substitution of generics for certain branded drugs there are several exceptions to this law which, in the Company's view, will make it less than fully effective in requiring such substitution on a broad basis. Overall the Company expects this legislation to result in lower prices for human generic pharmaceutical products in Germany and this is expected to result in

decreased profitability for all industry participants including the Company. The Company is unable to predict the long-term impact these circumstances will have on the Company's German operations and the pricing and sales of generic pharmaceuticals in Germany.

An interruption in the supply of the Company's raw materials or products or an adverse event at one of the Company's manufacturing facilities could adversely effect its operations.

The Company currently purchases many of its raw materials and other products from single suppliers and many of its products are manufactured at a single facility. Any interruption in the supply of these materials or an adverse event at the facilities which manufacture and blend the Company's products, could decrease sales of the affected products. In this event, the Company may seek to enter into agreements with third parties to purchase raw materials or products or to lease or purchase new manufacturing facilities. The Company may be unable to find a third party willing or able to provide the necessary products or facilities suitable for manufacturing pharmaceuticals on terms acceptable to the Company. If the Company had to obtain substitute materials or products, the Company would require additional regulatory approvals, as approvals are specific to a single product produced by a specified manufacturer. The use of new facilities similarly would require regulatory approvals. Any significant interruption of supply from the Company's suppliers or adverse event at any of its manufacturing facilities could have a material adverse effect on the Company's operations.

The Company has been and will continue to be affected by competitive factors, including price restrictions in certain markets.

The Company's generic pharmaceuticals business has historically been subject to intense competition. As patents and other bases for market exclusivity expire, prices typically decline as generic competitors, such as the Company, enter the marketplace. Normally, there is a further unit price decline as the number of generic competitors increases. The timing of these price decreases is unpredictable and can result in a significantly curtailed period of profitability for a generic product. In addition, brand-name and patented pharmaceuticals manufacturers frequently take actions to prevent or discourage the use of generic equivalents. These actions may include:

- filing new patents on drugs whose original patent protection is about to expire;
- developing patented controlled-release products or other product improvements; and
- increasing marketing initiatives and filing of additional litigation.

Generic pharmaceuticals market conditions, particularly, in the U.S., were further affected in recent years by a fundamental shift in industry distribution, purchasing and stocking patterns resulting from increased importance of sales to major wholesalers and a concurrent reduction in sales to private label generic distributors. Wholesaler programs generally require lower prices on products sold, lower inventory levels kept at the wholesaler and fewer manufacturers selected to provide products to the wholesaler's own marketing programs.

The factors which have adversely affected the U.S. generic pharmaceuticals industry may also affect some or all of the markets in which the Company operates internationally. In addition, in Europe the Company is encountering price pressure from parallel imports of identical products from lower priced markets under EU laws of free movement of goods. Parallel imports could lead to lower revenue for the Company. The Company's international pharmaceuticals business is also affected by general governmental initiatives to reduce drug prices, including price controls or other restrictions on the Company's industry. Parallel imports, governmental cost containment and other regulatory efforts could cause lower prices in certain markets, including the United Kingdom, Germany and the Nordic countries, where the Company has significant sales.

In all the Company's businesses, it may become more difficult for the Company to respond to competitive challenges because of the significance of relatively few major customers, such as large wholesalers, animal producers and chain stores, a rapidly changing market and uncertainty of timing of new product approvals.

The bulk antibiotic, international generic human pharmaceutical and animal pharmaceutical industries are highly competitive and many of the Company's competitors in these areas are substantially larger and have greater financial, technical and marketing resources than the Company possesses. The increased focus on pharmaceutical prices in Europe may lead to increased competition and price pressures for suppliers of all types of pharmaceuticals, including patented generics. In addition, in certain countries such as France, because of the Company's size and product mix, the Company may not be able to capitalize on such changes as fully as the Company's competitors.

The Company's business is affected by the reimbursement policies of third party payors, such as insurers and managed care organizations.

The Company's commercial success with respect to generic products depends, in part, on the availability of adequate reimbursement from third party health care payors, such as government and private health insurers and managed care organizations. Third party payors are increasingly challenging the pricing of medical products and services and their reimbursement practices may prevent the Company from maintaining the Company's present product price levels. In addition, the market for the Company's products may be limited by third party payors who establish lists of approved products and do not provide reimbursement for products not listed. Medicaid legislation requires all pharmaceutical manufacturers to rebate state governments a percentage of the average manufacturer's selling price on sales of certain prescription drugs reimbursed under the state Medicaid programs. Certain states, such as Michigan and Florida, have adopted measures to contain further the costs incurred for prescription drugs under their Medicaid programs. These measures include placing certain prescription drugs on a restricted list and negotiating additional discounts in the prices paid for prescription drugs.

The Company's liability from accidents, product liability or other claims may exceed the Company's insurance coverage.

The Company seeks to obtain liability insurance to protect it from liability due to accidents, product liability and other claims which arise during the course of doing business. The insurance that the Company obtains to protect itself against these potential liabilities may be inadequate, or such insurance may be unobtainable or prohibitively expensive. The Company must renew some of its insurance policies each year. In recent months the Company has experienced significant increases in its insurance costs. In addition, the Company's insurance policies may contain exceptions which do not protect it from liabilities it may incur due to products it now manufactures or may manufacture in the future. The Company's inability to obtain and maintain sufficient insurance coverage on reasonable terms could materially adversely affect the Company's business, financial condition and results of operations.

The Company's Animal Health business is in the process of making changes in its business strategy.

The Company recently announced new management of its Animal Health business and immediately began exploring changes in market strategy in this business. The clear objectives of any new strategy will include strengthening customer and market focus, stabilizing pricing, and significantly improving working capital management. As a first step, the Company has reduced the use of certain U.S. sales incentives in this division. These incentives had the effect of increasing the Company's level of accounts receivable. In addition to previously announced charges in the fourth quarter of 2001, these evolving strategies could require future actions necessitating charges against income including divestitures, decisions to curtail or terminate activities with respect to the development of certain products in its pipeline, the necessity to alter or terminate certain existing contractual arrangements and organizational restructuring.

The Company does not know the ultimate impact of the infringement claims brought by Pfizer relating to Gabapentin and does not know with any certainty if it will have to write-off inventory relating to Gabapentin.

The Company has filed a Paragraph IV certification challenging the patents protecting Pfizer's Gabapentin, a drug used to treat epilepsy. While not assured, this filing could provide the Company with generic market exclusivity for a period of up to six months. Given the size of the Gabapentin market (close to $2.0 billion in 2001) and the market price and share normally anticipated during a period of generic exclusivity, the Company's profit potential (which it is initially obligated to share equally with its supplier of the drug's active ingredient) could be significant.

However, Pfizer has filed several lawsuits challenging the Company's position that it can introduce the product prior to the expiration of the last to expire of the Pfizer patents. Under the Hatch-Waxman Act, the Company may be able to commence the sale of the product in December of 2002 whether or not the Pfizer litigation has been finally decided. The Company could also wait to commence sales until the receipt of a court decision or any appeal. While the Company has made no decision on this issue, a launch at anytime before a final decision on Pfizer claims would leave the Company exposed to potential material infringement damages if Pfizer were to ultimately prevail in the litigation. In addition, in order to be prepared to take advantage of the six month period of exclusivity, the Company would be required to produce significant amounts of inventory during 2002. In the event that Pfizer prevails in the litigation, or the Company decides to delay its launch to a date significantly after December 2002, this inventory may no longer be commercially saleable which would result in a write-off and a charge against the Company's income in the relevant period.

The Company is highly leveraged. The Company's substantial indebtedness limits cash flow available for operations and could adversely affect our ability to service debt or obtain additional financing if necessary

As of December 31, 2001, after giving effect to the Acquisition and related financing transactions and the initial actions under the Company's deleveraging strategy, the Company's total debt was $1,060.6 million and its total consolidated shareholders' equity was $891.6 million. The Company's operating income relative to its level of indebtedness will continue to restrict its operations. Among other things, the Company's indebtedness and the restrictive covenants contained in the agreements governing its indebtedness:

- require a substantial portion of the Company's cash flow from operations for the payment of interest on the Company's debt;
- limit the Company's ability to use its cash flow, or to obtain additional financing, to fund future working capital, capital expenditures, acquisitions and other general corporate purposes;
- limit the Company's flexibility to plan for and react to changes and take advantage of opportunities in its business and industry;
- increase the Company's vulnerability to adverse economic and industry conditions; and
- place the Company at a competitive disadvantage to less leveraged competitors.

In addition, the Company may incur additional debt. Subject to specified limitations, the agreement governing the notes and the Company's senior credit facilities permit the Company and its subsidiary guarantors to incur substantial additional debt.

Servicing the Company's debt will require a significant amount of cash, and its ability to generate sufficient cash depends on many factors, some of which are beyond the Company's control.

The Company's ability to make payments on and to refinance its debt depends on the Company's ability to generate cash flow. This, to a significant extent, is subject to general economic, financial, competitive, legislative, regulatory

and other factors that are beyond the Company's control. In addition, the Company's ability to borrow funds in the future to make payments on its debt will depend on its satisfaction of the financial covenants in the issuer's senior credit facilities and other debt agreements.. The Company's business may not generate sufficient cash flow from operations, and future borrowings may not be available to the Company under its senior credit facilities or otherwise, in an amount sufficient to enable the Company to pay its debt or fund other liquidity needs. If the Company is unable to generate sufficient cash, it may need to refinance all or a portion of its debt on or before maturity. The Company may not be able to refinance any of its debt on favorable terms, or at all. Any inability to generate sufficient cash flow or refinance the Company's debt on favorable terms could have a material adverse effect on its financial condition.

Covenant restrictions under the Company's outstanding debt instruments may limit the Company's ability to operate its business.

The Company's outstanding debt instruments contain covenants that restrict the ability of the Company and the guarantors to finance future operations and capital needs and engage in certain other business activities. For example, the Company's senior credit facilities require it to maintain specified financial ratios and satisfy financial condition tests consisting of a maximum total leverage ratio test, a maximum senior leverage ratio test, a fixed charge coverage ratio test, a minimum interest coverage ratio test and a minimum net worth test.

As of December 31, 2001, the Company was in compliance with each of these ratios and the net worth test. Based upon the Company's estimates of near-term performance, there is only a small margin of compliance with some of these covenants, therefore continued compliance with these covenants may require that the Company take action to reduce its debt or to act in a manner that may not be in accord with its business objectives. In addition, events beyond its control, including changes in general economic and business conditions, may affect its ability to satisfy these covenants. The Company might not meet these covenants, and the lenders might not waive any failure to meet these covenants. A breach of any of these covenants, if not cured or waived, could result in a default under the Company's senior credit facilities and under the agreement governing the notes. If an event of default under the Company's senior credit facilities occurs, the lenders under these facilities could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. The Company's senior credit facilities are also subject to early maturity and termination in certain cases.

To better assure the Company's continued debt covenant compliance, it has implemented a strategy to de-leverage its balance sheet. Pursuant to this strategy, the Company has undertaken a series of initiatives to improve working capital, and an aggressive focus on operating expense reduction and capital management. The Company may also issue additional common stock for cash or in exchange for existing convertible debt. Additionally, in December, 2001, the Company repaid $65.0 million of the term loans under its senior credit facilities and completed the exchange of its Class A common stock for a portion of its 5.75% convertible subordinated notes due 2005 having an approximate principal value of $34.1 million.

The interests of the Company's controlling stockholder may conflict with interests of the Company.

A.L. Industrier AS, or Industrier, is the beneficial owner of 11,872,897 shares of Alpharma Inc.'s Class B common stock as of December 31, 2001, which represented 100% of the outstanding shares of the Class B Common Stock as of that date. Shares of Class B common stock are convertible into an equal number of shares of Class A common stock. As a result of its ownership of all of the outstanding shares of Class B Common Stock, Industrier controls Alpharma Inc. and is presently entitled to elect two-thirds of the members of its board of directors. As to matters other than the election of directors, each share of Class B common stock is entitled to four votes. Einar Sissener, Chairman of the board of directors of Alpharma Inc., controls a majority of Industrier's outstanding shares and is Chairman of Industrier. In addition, Mr. Sissener beneficially owns 328,667 shares of Class A common stock.

Industrier has the ability to make decisions affecting the Company's capital structure including, in some instances, the issuance of additional indebtedness. Industrier may pursue future transactions that could enhance its equity

investment while involving risks to the interest of the Company. All contractual arrangements between the Company and Industrier are subject to review by, or ratification of, the audit committee of the Company's board of directors as to the fairness of the terms and conditions of such arrangements to the Company. The committee consists of one or more directors who are unaffiliated with Industrier.

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.

ALPHARMA INC.

By: /s/Jeffrey E. Smith

Jeffrey E. Smith
Executive Vice President and
Chief Financial Officer

Date: March 8, 2002