PHARMION CORP
Form 10-K
March 26, 2004

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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**

for the fiscal year ended December 31, 2003.

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**

For the transition period from to .

Commission file number 000-50447

Pharmion Corporation

(Exact name of Registrant as specified in its charter)

Delaware	**84-1521333**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

2525 28th Street, Suite 200
Boulder, Colorado 80301
(720) 564-9100
(Address, including zip code, and telephone number, including area code, of principal executive offices)

Securities registered pursuant to Section 12(b) of the Act:

None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock $.001 Par Value
(Title of Class)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (Section 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. þ

Indicate by check mark whether the Registrant is an accelerated filer (as defined by Exchange Act Rule 12b-2). Yes o No þ

There was no established public trading market for the Registrant s Common Stock as of the last business day of the Registrant s most recently completed second fiscal quarter.

As of March 25, 2004, there were 25,293,930 shares of the Registrant s Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant s definitive Proxy Statement for its 2004 Annual Meeting of Stockholders are incorporated by reference into Part III of this report on Form 10-K to the extent stated therein.

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PART I

Unless the context requires otherwise, references in this report to Pharmion, the Company, we, us, and our refer to Pharmion Corporat

All statements, trend analysis and other information contained in this Form 10-K and the information incorporated by reference which are not historical in nature are forward-looking statements within the meaning of the Private-Securities Litigation Reform Act of 1995. These forward-looking statements include, without limitation, discussion relative to markets for our products and trends in revenue, gross margins and anticipated expense levels, as well as other statements including words such as anticipate, believe, plan, estimate, expect and intend and c similar expressions. All statements regarding our expected financial position and operating results, business strategy, financing plans, forecast trends relating to our industry are forward-looking statements. These forward-looking statements are subject to business and economic risks and uncertainties, and our actual results of operations may differ materially from those contained in the forward-looking statements. Although we may elect to update forward-looking statements in the future, we specifically disclaim any obligation to do so, even if our estimates change, and readers should not rely on those forward-looking statements as representing our views as of any date subsequent to the date of this annual report.

Item 1. ***Business***
Overview

We are creating a global pharmaceutical company focused on acquiring, developing and commercializing innovative products for the treatment of hematology and oncology patients. We have established our own regulatory, development and sales and marketing organizations covering the U.S., Europe and Australia. We have also developed a distributor network to serve the hematology and oncology markets in 20 additional countries throughout the Middle East and Asia. To date, we have acquired rights to two marketed products, Innohep® and Refludan®. We also have two products, Thalidomide Pharmion 50mg and Vidaza, in registration that we believe represent significant market opportunities. With our combination of regulatory, development and commercial capabilities, we intend to continue to build a balanced portfolio of approved and pipeline products targeting the hematology and oncology markets.

Our current product portfolio consists of the following four products:

Thalidomide Pharmion 50mg (thalidomide) Thalidomide has become a standard of care for the treatment of relapsed and refractory multiple myeloma, a cancer of the plasma cells in the bone marrow. We have licensed the marketing rights to thalidomide from Celgene Corporation and Penn T Limited for all countries outside of North America and certain Asian markets. We began selling thalidomide in Europe on a compassionate use or named patient basis under a stringent risk management program in the third quarter of 2003 while we actively seek full regulatory approval for this drug in Europe and several additional countries. In the fourth quarter of 2003, Thalidomide Pharmion 50mg was approved as a treatment for relapsed and refractory multiple myeloma and erythema nodosum leprosum, or ENL, in Australia and New Zealand. These approvals were the first regulatory approval of thalidomide for the treatment of multiple myeloma anywhere in the world.

Vidaza (azacitidine) Vidaza is the subject of a completed and published Phase III study indicating its safety and efficacy in the treatment of myelodysplastic syndromes, or MDS, a bone marrow disorder characterized by the production of abnormally functioning, immature blood cells. We obtained worldwide rights to this product from Pharmacia & Upjohn Company, now a part of Pfizer, Inc. We submitted a New Drug Application, or NDA, to the Food and Drug Administration, or FDA, for Vidaza in December 2003 and anticipate making comparable filings in Europe and Australia later this year. In February 2004, the FDA accepted for filing, and granted Priority Review classification to, our Vidaza NDA. Priority Review status of the NDA reduces the standard FDA response time to six months, and targets an agency response on or before June 29, 2004. In connection with these

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submissions in the fourth quarter of 2003, we initiated a confirmatory study of Vidaza in MDS, which will be one of the largest studies in MDS to date.

Innohep® (tinzaparin) Innohep® is a low molecular weight heparin approved in the U.S. for the treatment of deep vein thrombosis, or DVT, which occurs when a blood clot develops in the deep veins of the legs. We obtained the U.S. rights to this product from LEO Pharma A/S, which markets Innohep® in Europe and several additional countries. We relaunched Innohep® as a treatment for DVT in cancer patients in the fourth quarter of 2002, and used this drug to establish our U.S. sales and marketing organization.

Refludan® (lepirudin) Refludan® is an antithrombin agent approved in the U.S., Europe and several additional countries for the treatment of heparin-induced thrombocytopenia, or HIT, an allergic, adverse immune response to heparin, resulting in an absence of sufficient cell platelets to enable blood clotting. We obtained rights to this product in all countries outside of the U.S. and Canada from Schering AG. We began selling Refludan®in Europe and Australia in the third quarter of 2002, and used this drug to establish our European and Australian sales and marketing organizations.

We were incorporated in Delaware in August 1999 and commenced operations in January 2000. Our principal executive offices are located at 2525 28th Street, Boulder, Colorado 80301, and our telephone number is (720) 564-9100. Our website is located at www.pharmion.com. The reference to our website does not constitute incorporation by reference of the information contained on our website into this annual report on Form 10-K.

Our periodic and current reports, and all amendments to those reports, are available free of charge, on our website at www.pharmion.com, as soon as reasonably practicable after we have electronically filed them with, or furnished them to, the Securities and Exchange Commission.

Our Strategy

We believe that there are significant opportunities available for a global pharmaceutical company with a focus on the hematology and oncology markets. Our strategy for taking advantage of these opportunities includes the following key elements:

Focusing on the hematology and oncology markets. We focus on the hematology and oncology markets for several reasons. The hematology and oncology markets are characterized by a number of disorders with high rates of recurrence and a limited response from current therapies or treatments, many of which include severe side effects. New hematology and oncology product candidates addressing unmet medical needs or providing a superior safety profile are frequently the subject of expedited regulatory reviews and, if approved and effective, can experience rapid adoption rates. While the overall global hematology and oncology markets are substantial, many drugs directed at hematology and oncology patients treat relatively small patient populations or subsets of patients with a specific cancer type. Because large, multinational pharmaceutical companies are increasingly seeking products with very large revenue potential, they often do not devote resources to develop drugs they discover with the potential to treat these patient populations, presenting us the opportunity to acquire, develop and market these drugs. There are also a large number of emerging biotechnology companies doing research in hematology and oncology, many of which do not have the global commercial and regulatory capabilities that we have. We believe we can be a regional or global partner for these companies, particularly for compounds that target smaller patient populations. There are approximately 11,000 hematologists and oncologists practicing in each of the U.S. and Europe. In addition, a small number of opinion leaders significantly influence the types of drugs prescribed by this group of physicians. We believe that we can effectively reach the hematology and oncology markets with a relatively small sales organization focused on these physicians and opinion leaders.

Expanding and leveraging our global sales and marketing capabilities. We believe that our U.S., European and Australian sales and marketing organizations, combined with our distributor network in other countries, distinguish us from other pharmaceutical companies of our size. In each of these markets, we are continuing to develop highly-trained sales forces that target the hematology and oncology communities in

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conjunction with medical education specialists focused on advocate development, educational forums, clinical data publications and clinical development strategies. The licensing of Refludan® and Innohep® were strategically important as they provided the means for us to establish our current sales and marketing organizations. Having these teams in place calling on key hematologists and oncologists will facilitate the commercial launch of our two drugs in registration and makes us a more attractive partner for companies with drugs targeted to this group of physicians. We expect to expand the size of our sales force as we increase sales of Thalidomide Pharmion 50mg in Europe and as needed to support the launch of Vidaza and products licensed in the future from other companies. By managing the global sales and marketing of our products on our own and with our partners, we believe we can provide uniform marketing programs and consistent product positioning and labeling. In addition, we seek consistent pricing across these markets to maximize the commercial potential of our products and reduce the risk of parallel imports and reimportation.

Leveraging our global regulatory expertise. We have assembled a team of highly-experienced regulatory professionals with multinational expertise in obtaining regulatory approvals for new drugs and maintaining compliance with the regulations governing the sales, marketing and distribution of pharmaceutical products. While some early stage biotechnology and pharmaceutical companies have developed regulatory capabilities in the country in which they are located, we have built an organization with multinational regulatory expertise. We believe our regulatory experience enables us to devise time and cost-efficient strategies to obtain regulatory approvals for new drugs, and to choose the regulatory pathway that allows us to get a product to market as quickly as possible. We can use our resources efficiently to generate a regulatory submission that can be used in multiple jurisdictions. Our global regulatory expertise is an essential element of effectively evaluating and developing late-stage product candidates. We believe that this provides us with a competitive advantage in attracting biotechnology and pharmaceutical companies with products in development that they want to out-license.

Acquiring attractive late-stage development or approved products. We intend to continue to acquire or in-license rights to late-stage development and approved products to more fully exploit our regulatory, sales and marketing capabilities. We are focused on acquiring products that satisfy significant unmet medical needs and that provide us with a period of sales, regulatory or geographic exclusivity.

Our Products

Our product portfolio is focused on addressing unmet needs in the hematology and oncology markets. We believe these markets present us with significant commercial opportunities. Our current product portfolio consists of the following:

Product	Disease/Indication	Phase of Development	Licensor	Licensed Territory
Thalidomide Pharmion 50mg (thalidomide)	Relapsed and refractory multiple myeloma	In registration in Europe and approved in Australia and New Zealand; recently initiated compassionate use and named patient sales in Europe	Celgene Corporation and Penn T Limited	All countries outside North America, Japan, China, Taiwan and Korea
	Newly-diagnosed multiple myeloma	Phase III study ongoing		

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Product	Disease/Indication	Phase of Development	Licensor	Licensed Territory
Vidaza (azacitidine)	Myelodysplastic syndromes	In registration in the U.S. with a Subpart H NDA priority review granted. Pre- registration in Europe	Pharmacia & Upjohn Company (Pfizer, Inc.)	Global rights
Innohep® (tinzaparin)	Deep vein thrombosis with or without pulmonary embolisms	Marketed	LEO Pharma A/S	U.S.
Refludan® (lepirudin)	Heparin-induced thrombocytopenia type II	Marketed	Schering AG	All countries outside North America

Thalidomide Pharmion 50mg

In November 2001, we entered into agreements with Celgene Corporation and Penn T Limited to obtain the exclusive marketing and distribution rights to Celgene s formulation of thalidomide, Thalomid®, in all countries outside of North America, Japan, China, Taiwan and Korea. Under the agreement with Celgene, we also obtained an exclusive license in our territory to utilize Celgene s current and future thalidomide-related patents, including its patented System for Thalidomide Education and Prescribing Safety, or S.T.E.P.S.® program, and its current and future thalidomide-related dossiers, including clinical and pharmaceutical formulation data. We recently began selling thalidomide on a compassionate use and named patient basis in Europe while we actively seek full regulatory approval for this drug in Europe and several additional countries. In the fourth quarter of 2003, Thalidomide Pharmion 50mg was approved as a treatment for relapsed and refractory multiple myeloma and ENL in Australia and New Zealand. These approvals were the first regulatory approval of thalidomide for multiple myeloma anywhere in the world. In our markets, we sell Thalomid® as Thalidomide Pharmion 50mg and we call the Celgene S.T.E.P.S.® program the Pharmion Risk Management Program, or PRMP.

Since acquiring these rights from Celgene and Penn, we have undertaken the following activities to commercialize thalidomide in Europe and our additional markets:

Filed marketing authorization applications Beginning in March 2002, we submitted marketing authorization applications to the European Agency for the Evaluation of Medicinal Products, or the EMEA, and the Therapeutic Goods Administration, or the TGA, in Australia and to regulatory authorities in New Zealand, South Africa, Saudi Arabia and Turkey. We are seeking approval for thalidomide as a treatment for relapsed and refractory multiple myeloma and for ENL. In the fourth quarter of 2003, Thalidomide Pharmion 50mg was approved in Australia and New Zealand for these indications.

Acquired Laphal Développement, S.A. In March 2003, we acquired Laphal, the only other company that has submitted a marketing authorization application for thalidomide in Europe. In addition, Laphal was selling its formulation of thalidomide on a compassionate use or named patient basis in France, Belgium and Luxembourg, and we are continuing to sell thalidomide in these markets on a compassionate use or named patient basis.

Assumed Penn s compassionate use and named patient sales in the U.K., Ireland and Denmark Under our initial license agreement with Penn, they were permitted to continue compassionate use and named patient sales of their formulation of thalidomide in the U.K., Ireland and Denmark until we received a marketing authorization from the EMEA. In June 2003, Penn agreed to discontinue its sales of thalidomide in these countries and we initiated sales of Thalidomide Pharmion 50mg on a compassionate use or named patient basis in these countries.

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Initiated compassionate use and named patient sales in Europe In late June 2003, we began compassionate use and named patient sales in the markets previously served by Grünenthal Group, the original manufacturer of thalidomide. Through June 2003, Grünenthal distributed thalidomide free of charge in all European markets, except for those served by Laphal and Penn. In June 2003, Grünenthal announced that it would no longer be providing thalidomide due to the exhaustion of its supply and it referred healthcare professionals seeking thalidomide supply to us.

Developed and implemented the Pharmion Risk Management Program Given thalidomide s history and risk, the development of the PRMP was a critical element to our planned commercialization of thalidomide and enrollment is obligatory for all patients receiving the drug. Shortly after our acquisition of the thalidomide rights from Celgene in 2001, we began to develop the PRMP consistent with Celgene s S.T.E.P.S. This process included the development of software and educational materials in 15 languages for use by physicians, pharmacists and patients throughout Europe and our other markets. We implemented PRMP in June 2003 in connection with the commencement of our compassionate use and named patient sales.

Thalidomide was developed in the late 1950 s as an oral, non-barbiturate sedative and was prescribed throughout Europe for use as a sleep aid and for the treatment of morning sickness in pregnancy. Shortly thereafter, use of thalidomide was found to be associated with severe birth defects and it was virtually withdrawn from the worldwide market, without ever receiving approval in the U.S. In 1964, thalidomide was discovered to be effective in the treatment of ENL, which is an inflammatory complication of leprosy. As a result, thalidomide remained in use as a treatment for ENL. In the 1990s, it was further discovered to act as an anti-angiogenic agent, which is an agent that prevents the formation of new blood vessels. Since many types of tumors are associated with the formation of new blood vessels, physicians began to explore thalidomide s use as a treatment to prevent the growth of tumor-associated blood vessels on the theory that this would result in starvation of the tumor.

In 1998, Celgene s Thalomid® was approved in the U.S. for the treatment of acute cutaneous manifestations of moderate to severe ENL and as maintenance therapy for prevention and suppression of cutaneous manifestation recurrences. Thalomid® was the first drug approved by the FDA under a special restricted distribution for safety regulation. In connection with FDA approval, given the known propensity of thalidomide for causing birth defects, Celgene developed its patented S.T.E.P.S.® program, which is a comprehensive compliance and risk management program designed to support the safe and appropriate use of Thalomid® by ensuring that women of child-bearing potential do not come into contact with Thalomid®. While the treatment of ENL is the only currently approved indication for thalidomide in the U.S., the drug is used primarily in the treatment of multiple myeloma and other forms of cancer, including renal cell carcinoma, which is a cancer of the kidneys, glioblastoma, which is a cancer of the brain, and colon cancer.

Multiple myeloma is the second most common hematological cancer after non-Hodgkin s lymphoma. It is a cancer of the plasma cells in the bone marrow, which is characterized by lytic bone lesions or the production of elevated levels of M-protein, an abnormal monoclonal antibody, in the blood or urine of patients. The symptoms of multiple myeloma include painful bone deterioration, bone marrow failure (anemia, leukopenia and thrombocytopenia), plasma cell leukemia, infections, kidney damage or failure and hyperviscosity of the blood. Although the median age of onset of multiple myeloma is 65 to 70 years of age, according to the Multiple Myeloma Research Foundation, recent statistics indicate both increasing incidence and earlier age of onset. The incidence of multiple myeloma in most western industrialized countries is approximately 4 in every 100,000 persons. We estimate that there are approximately 65,000 multiple myeloma patients in the E.U., with approximately 21,000 new cases annually, and 4,000 to 5,000 multiple myeloma patients in Australia, with approximately 800 new cases annually. While current treatment regimens provide some therapeutic benefit, multiple myeloma patients continue to have high rates of relapse and suffer high mortality rates.

Thalidomide is currently being evaluated as a potential therapy for all stages of multiple myeloma, in particular, newly diagnosed and relapsed and refractory. Several leading investigators at cancer research

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centers have published data on the response rate, the median effective dose and the average duration of response for multiple myeloma patients treated with thalidomide in clinical trials.

Newly Diagnosed Multiple Myeloma. Peer-reviewed studies from MD Anderson Cancer Center and the Mayo Clinic evaluating the use of the orally administered combination of thalidomide and dexamethasone for newly diagnosed multiple myeloma were published in November 2002 in the *Journal of Clinical Oncology.* Dr. S. Vincent Rajkumar of the Mayo Clinic reported that 32 of 50 patients (64 percent) achieved a greater than 50% reduction in M-protein, and an additional 14 patients (28 percent) achieved a reduction in M-protein of between 25 and 50%. These reductions in M-protein are an indication of a positive effect of the drug on the course of this disease. The regimen was generally well-tolerated, and the most commonly reported grade one or two adverse events were constipation, sedation, fatigue, neuropathy, rash, tremor, edema and elevated alkaline phosphatase, a kidney enzyme. Based on this data, Celgene is sponsoring, and we are helping to fund, a Phase III registration study to confirm the benefits of thalidomide plus dexamethasone in newly diagnosed multiple myeloma patients. If successful, we intend to submit this data to the EMEA in support of an indication for Thalidomide Pharmion 50mg as a treatment for newly diagnosed multiple myeloma.

Relapsed and Refractory Multiple Myeloma. Thalidomide s effect on long-term survival in multiple myeloma was published in *Blood* in July 2001 in an article entitled Extended Survival in Advanced and Refractory Multiple Myeloma After Single-agent Thalidomide: Identification of Prognostic Factors in a Phase II Study of 169 Patients. The study is a follow-up of a Phase II trial of 169 advanced and refractory multiple myeloma patients with progressive disease treated with thalidomide, and it extends results of 84 patients previously reported in *The New England Journal of Medicine.* The Phase II study was initiated to evaluate the use of thalidomide in multiple myeloma patients who relapsed after high dose chemotherapy. Of the study s 169 patients, 37% demonstrated a 25% or greater reduction in M-protein, 30% demonstrated a 50% or greater reduction and 14% of patients achieved a complete or near complete response.

The trial s principal investigator, Bart Barlogie, M.D., Ph.D., and researchers at the Arkansas Cancer Research Center reported that high-risk patients who received greater than or equal to 42 grams of thalidomide in a three-month period experienced higher response rates (54% vs. 21%) and longer survival time (63% vs. 45%). In addition, for the entire patientgroup, event-free survival after two years of follow-up was 20%, and two year overall survival was 48%.

The study s most commonly reported side effects included one or more grade three toxicities, which reflect more severe side effects. Approximately 25% of patients experienced events affecting the central nervous system, such as sedation and somnolence, confusion, depression and tremor. Approximately 16% of patients experienced gastrointestinal toxicities, mainly constipation. Neuropathy was seen in 9% of patients, and less than 2% of patients developed deep vein thrombosis. These toxicities were found to be dose related.

In addition to these studies evaluating thalidomide as a therapy for multiple myeloma, there are various Phase II studies ongoing in respect of solid tumors, including renal cell, colorectal cancer, non-small cell lung cancer, prostate cancer, glioblastoma and metastatic melanoma.

Despite the lack of any formal regulatory approval for thalidomide outside the U.S., as a result of compassionate use and named patient sales and the publication of articles reporting on investigator-led clinical trials, thalidomide has become a widely used therapy for the treatment of multiple myeloma and certain other forms of cancer. In Europe, we estimate over 10,000 patients were treated with thalidomide during 2002, with substantially all drug product distributed by three companies. Grünenthal Group, the German company that was the original developer of thalidomide, distributed approximately two-thirds of the overall volume used in Europe free of charge upon physician request through various special regulatory authorizations. In June 2003, Grünenthal announced that due to the exhaustion of its supply, it was discontinuing the distribution of thalidomide. We believe that the remaining thalidomide used in Europe during 2002 was supplied primarily by Penn T Limited and Laphal, the French pharmaceutical development, regulatory and marketing organization that we acquired in March 2003. Both Penn and Laphal supplied thalidomide pursuant to the regulatory

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provisions allowing for sale of unlicensed drugs on a compassionate use or named patient basis. While the thalidomide supplied by Penn and Laphal was not given free of charge, it was sold at a significant discount to the price charged by Celgene in the U.S.

In March 2002, working with the data packages that we had obtained from Celgene and Penn, we submitted to the EMEA, under its centralized procedure, two marketing authorization applications for thalidomide for the treatment of relapsed and refractory multiple myeloma and for ENL. In February 2003, we withdrew our marketing authorization application for ENL to focus our efforts with the EMEA on obtaining the marketing authorization for relapsed and refractory multiple myeloma. This decision was made in consultation with the EMEA, which, given their belief that thalidomide would have widespread off-label use in the treatment of multiple myeloma, was not comfortable approving thalidomide for the much narrower indication of ENL, especially given the history of thalidomide in Europe.

In addition to these EMEA regulatory approval activities, we have submitted regulatory approval applications for thalidomide in Australia, South Africa, Saudi Arabia and Turkey for the indications of multiple myeloma and ENL. In the fourth quarter of 2003, the TGA approved the use of Thalidomide Pharmion 50mg for treatment of relapsed and refractory multiple myeloma and ENL in Australia. This was the first approval of Thalidomide for the treatment of multiple myeloma, after failure of standard therapies, anywhere in the world.

We were granted orphan drug designation for thalidomide in Europe by the EMEA for the multiple myeloma indication, which, if the marketing authorization application is approved and the criteria for orphan drug designation continue to be met, would provide a ten year period of exclusivity from the date of the marketing authorization application s approval. During this period the EMEA would be prohibited, except in very limited circumstances, from approving another formulation of thalidomide for treatment of relapsed and refractory multiple myeloma. We were also granted orphan drug designation for thalidomide in Australia, as well as data exclusivity, which provides similar protection for a five year period from the date of approval.

In March 2003, through our purchase of all of the outstanding stock of Gophar S.A.S., we acquired Laphal, which sells its formulation of thalidomide, known as Thalidomide Laphal, in France and Belgium under an *autorisation temporaire d utilisation,* or ATU, which is a temporary authorization for compassionate use sales.

For its fiscal year ended December 31, 2002, Laphal had aggregate net sales of $5.5 million, substantially all of which were sales of Thalidomide Laphal. Our acquisition of Laphal, also allowed us to obtain its two marketing authorization applications on file with the EMEA for thalidomide. These two marketing authorization applications are for thalidomide as a treatment for ENL and for relapsed and refractory multiple myeloma, both of which have been granted orphan drug status by the EMEA. Laphal had also undertaken a number of clinical trials of thalidomide, the data from which may be useful to us in connection with our efforts to seek marketing approval from the EMEA. We are currently responding to questions posed by the EMEA to each of our active marketing authorization applications on file. We anticipate submitting our responses for the two multiple myeloma applications during the second quarter of 2004. With our acquisition of Laphal, to our knowledge we are now the only company with applications with the EMEA for a thalidomide marketing authorization.

We believe that an integral component of our applications is our undertaking to develop and implement the PRMP throughout Europe and our other markets. The PRMP requires adherence to strict guidelines both prior to and during the course of thalidomide therapy, including comprehensive physician, pharmacist and patient registration and education, emphasizing, among other things, the need for adequate contraception in patients taking thalidomide and pregnancy tests for female patients of child-bearing potential. Under the PRMP, automatic prescription refills are prohibited, and prescriptions may not exceed four weeks dosing. The PRMP also permits authorization of each prescription only upon confirmation of compliance with the PRMP guidelines.

We became aware of Grünenthal s intention to discontinue distributing thalidomide in the fourth quarter of 2002 and recognized that this would create a large void in the supply of thalidomide for the thousands of

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patients currently being treated with the drug in Europe, Australia and many Asian countries. We also believed that patients and medical professionals would benefit from a more tightly controlled distribution system for thalidomide, such as the PRMP. As such, in the fourth quarter of 2002, we began to actively work with the regulatory authorities in each of the major European countries to fully explain to them the benefits of the PRMP and to obtain authorizations, where required, to allow us to sell thalidomide on a compassionate use or named-patient basis prior to the issuance of a formal marketing authorization. Following negotiations with the health authorities of individual countries, while we pursue a marketing authorization, we began selling Thalidomide Pharmion 50mg in June 2003 on a compassionate use and named patient basis in Europe, South Africa and Egypt and we have made the PRMP program available in over 20 languages. Since receiving regulatory approval to market Thalidomide Pharmion 50 mg in Australia and New Zealand during the fourth quarter of 2003, we have been actively marketing the product in each of those countries. In addition, we are continuing to sell Thalidomide Laphal in France and Belgium until such time as we are permitted to replace this formulation with Thalidomide Pharmion 50mg.

Under our original agreement with Penn, they were permitted to continue compassionate use and named patient sales of their formulation of thalidomide in the U.K., Ireland and Denmark. In June 2003, Penn agreed to discontinue its sales of thalidomide in these countries and we initiated sales of Thalidomide Pharmion 50mg on a compassionate use or named patient basis in these countries. This revised arrangement reflected Penn s recognition of the merits of using the PRMP in connection with thalidomide sales in these countries.

Vidaza

In June 2001, we entered into an agreement with Pharmacia & Upjohn Company, now part of Pfizer, Inc., to obtain the exclusive worldwide manufacturing, marketing and distribution rights to azacitidine, which we intend to market as Vidaza. Under the agreement with Pharmacia, we also obtained an exclusive worldwide license to use Pharmacia s azacitidine technology and patents, including its clinical data. Azacitidine was the subject of a completed and published Phase III study demonstrating its safety and efficacy in the treatment of myelodysplastic syndromes, or MDS, a group of hematologic conditions caused by abnormal blood-forming cells of the bone marrow.

Azacitidine, a pyrimidine nucleoside analog, was originally developed by Upjohn Corporation as a cytotoxic agent, which is an agent that indiscriminately kills actively multiplying cells. Azacitidine was studied at high doses as a treatment for various malignancies, including acute myelogenous leukemia, or AML. An NDA was submitted by Upjohn in 1982 for the treatment of AML, but was deemed not approvable by the FDA, due to a lack of controlled studies adequately demonstrating clinical benefit. In addition, there were severe side effects observed in the high dosage studies. Researchers at the NCI, The Mount Sinai Medical Center and other institutions continued to study azacitidine and determined that it could be used effectively at much lower doses than originally studied by Upjohn, thereby reducing the side effects experienced in the earlier clinical studies. The results of subsequent clinical studies suggest that azacitidine is an effective treatment for MDS.

The recognition that azacitidine could be effective at lower doses was based on the discovery that azacitidine acts not only as a cytotoxic agent, but also through an additional mechanism of action. Azacitidine is a member of a class of drugs in development known as hypomethylating or demethylating agents. Methylation of DNA is a major mechanism regulating gene expression. Researchers have determined that an increase in specific methylation of DNA results in blockage of the activity of genes that regulate cell division and differentiation, known as suppressor genes. With suppressor genes blocked, cell division becomes unregulated, causing cancer. In studies, researchers have demonstrated that azacitidine can reverse the methylation of DNA, leading to reexpression of suppressor genes and a resulting redifferentiation and maturation of the cancer cells back to normal.

MDS occurs when blood cells remain in an immature, or blast, stage within the bone marrow and never develop into mature cells capable of performing their necessary functions. The five types of MDS are refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation and chronic myelomonocytic leukemia. Approximately 90% of

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MDS cases occur in persons aged 60-80. According to the American Cancer Society, or ACS, the exact number of cases of MDS in the U.S. is unknown, as there is no registry tracking this information, but most estimates are between 10,000 and 20,000 new cases each year. According to the ACS, these numbers appear to be increasing each year. Currently, we estimate there are approximately 50,000 to 60,000 MDS patients throughout the U.S. and Europe. According to the ACS, survival rates range from six months to six years for the different types of MDS. MDS can result in death from bleeding and infection in the majority of patients, while transformation to AML occurs in up to 40% of patients. Following transformation to AML, these patients have an exceptionally poor prognosis. MDS may occur without any identifiable cause, may be related to chemotherapy or radiation therapy being administered to treat other diseases, or may result from exposure to petrochemicals, benzene or rubber. Despite having been the subject of significant clinical development activity, there is currently no approved treatment for MDS. Patients generally receive best supportive care, which typically consists of a combination of transfusions, antibiotics and growth factors, such as erythropoietin and granulocyte colony stimulating factor. In addition, clinicians may add low-dose chemotherapies to best supportive care if they feel that their patients can tolerate the side effects. Patients under 60 years of age may receive bone marrow transplants.

In a Phase III study, azacitidine demonstrated superior efficacy compared to best supportive care, including improved response rates and delayed time to leukemic transformation or death. Azacitidine s effect on MDS was published in the Journal of Clinical Oncology in an article entitled Randomized Controlled Trial of azacitidine in Patients With the Myelodysplastic Syndrome: A Study of the Cancer and Leukemia Group B. Dr. Lewis R. Silverman of the Mount Sinai Medical Center and his colleagues reported that they conducted a randomized controlled trial in 191 patients comparing the effects of azacitidine and best supportive care on various hematological parameters. Azacitidine was given by subcutaneous injection. Responses occurred in 60% of patients in the azacitidine group (7% complete response, 16% partial response, 37% improved) compared with 5% (improved) of the patients receiving best supportive care, a statistically significant response. Median time to leukemic transformation or death was 21 months for azacitidine and 13 months for best supportive care, also a statistically significant response. The most common toxicity of azacitidine was myelosuppression, a reduction in the ability of the bone marrow to produce blood cells, and nausea.

In addition to the efficacy data from the Silverman study, several quality of life parameters were also reported and showed statistically significant improvement in the azacitidine patient group compared to patients receiving best supportive care. In particular, azacitidine patients showed statistically significant improvement over time in fatigue, physical functioning and shortness of breath. In patients receiving best supportive care who showed stable or worsening quality of life prior to crossover to azacitidine, statistically significant improvement occurred in fatigue, physical functioning, shortness of breath and general well-being after crossover to azacitidine.

In December 2003, we submitted an NDA for Vidaza, under Subpart H of the New Drug Application regulations, which allows for conditional approval of a drug to treat serious or life-threatening diseases based on a surrogate endpoint, a relatively simple measure of the effect of a drug on the course of a disease, as long as the drug provides a meaningful therapeutic benefit over existing treatments. In addition, under Subpart H a drug can be approved on the basis of one Phase I or Phase II study, conditioned upon the sponsor agreeing to complete a confirmatory Phase IV study. Since there are currently no drugs approved for the treatment of MDS and best supportive care is the only existing treatment, the Subpart H approval option is available. In February 2004, the FDA accepted for filing and granted Priority Review classification for our Vidaza NDA. Priority Review status of the NDA reduces the standard FDA response time to six months, and targets an agency response on or before June 29, 2004.

Our submission is based upon the previously cited Silverman study for the treatment of MDS that was conducted by the Cancer and Leukemia Group B, or CALGB, and the NCI and two supportive Phase II CALGB/ NCI studies. Due to the fact that the Phase III CALGB study was not prospectively designed as a registration study, over the last 24 months we have engaged in a lengthy process of collecting and analyzing data from the CALGB studies to confirm their published results and to compile the information needed to submit an NDA for Vidaza in MDS. This activity involved visiting nearly 75 treatment centers and accessing

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and auditing nearly 400 patient records from the CALGB studies. In addition, working with third party manufacturers, we have successfully developed a fully scaled up manufacturing process for the active ingredient and finished product.

As required under Subpart H in the U.S., we have initiated a comparative confirmatory clinical trial that will examine survival outcomes and other secondary end points, using a multicenter, randomized, open-label, parallel group format. The aim of this study is to compare the effect of Vidaza plus best supportive care against conventional care regimens plus best supportive care on survival in MDS patients. As a result of the fact that this study is global in nature and MDS treatment practices vary among countries, there will be three comparative conventional care treatments: best supportive care only; low dose cytarabine, plus best supportive care; or standard chemotherapy, plus best supportive care. This design takes into account the actual conventional care used to treat MDS patients in each country targeted for trial participation and should also help to enhance timely enrollment. The study will recruit over 350 patients and will be one of the largest studies to date in this disease.

The primary objective of this confirmatory study is to look at survival in these MDS patients. All other relevant endpoints, such as time to transformation to AML, time to relapse after complete remission or partial remission, disease progression, hematological status (peripheral blood counts, need for platelet and red blood cell transfusions and hematological response), episodes of infections requiring intravenous antibiotics and safety parameters will be assessed.

Innohep®

Innohep®, the tradename for tinzaparin, is a low molecular weight heparin that is approved in the U.S. and 63 other markets. In July 2002, we entered into an agreement with LEO Pharma A/S to obtain the exclusive U.S. marketing and distribution rights to Innohep®. Since LEO Pharma does not have a presence in the U.S., it sought to market the product in the U.S. through a marketing partner. It originally chose DuPont Pharmaceuticals Company, which launched Innohep® in the U.S. in late 2000 following its approval by the FDA in June of that year. Shortly after Innohep® s launch, DuPont s pharmaceutical business was acquired by Bristol Myers Squibb, which elected to return the U.S. rights to the product back to LEO Pharma. As a result, while the product has achieved substantial sales in Europe and elsewhere around the world, Innohep® received minimal marketing support in the U.S. throughout 2001 and 2002.

Innohep® is a member of a broad class of drugs known as anticoagulants, which are generally prescribed to prevent or treat blood clotting in patients. In the U.S., Innohep® is approved for the treatment of acute, symptomatic deep vein thrombosis, or DVT, which is a subset of the overall anticoagulant market. DVT occurs when a blood clot develops in the deep veins of the legs. If not effectively treated, DVT can lead to pulmonary embolisms that, in turn, can result in death. Cancer patients are particularly at risk to develop DVT, either from the disease itself or as a side effect of certain cancer treatments. The estimated prevalence of DVT in cancer patients ranges from 15-20%. Further, according to the ACS, approximately 1.3 million new cases of cancer occur in the U.S. each year. We believe that 21%, or approximately 277,000, of these patients are highly predisposed to DVT occurrence.

The acquisition of the marketing and distribution rights to Innohep® allowed us to establish our sales and marketing organization in the U.S. in a cost-effective manner, and provided us with access and exposure to the opinion leaders that influence product sales in the hematology and oncology markets. We completed the hiring and training of our U.S. sales force and relaunched Innohep® in October 2002. Innohep® is administered through a subcutaneous injection once daily for at least a six day cycle.

We attribute the growth we have experienced in Innohep® sales to our strategy of focusing our marketing efforts on hematologists and oncologists, groups often overlooked by pharmaceutical companies marketing other anticoagulants. Hematologists and oncologists are among the top three prescribers of DVT treatments. We believe, however, that only a small number of the sales calls made to DVT treatment prescribers are made to hematologists and oncologists. Innohep® does not require a dosing adjustment for weight-compromised, elderly or renally-impaired patients. Because these are common conditions for cancer patients, we believe that

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this feature, combined with the convenience of its once per day dosing, makes Innohep®the treatment of choice for a cancer patient with DVT.

Innohep® is used predominantly as a treatment for DVT since this is its only approved indication. In order to achieve the long-term sales potential that we believe Innohep® has, use of the drug will need to be expanded into other areas. One area of particular interest is the use of Innohep® for the prevention of DVT in high-risk cancer patients. Our development strategy for Innohep® includes funding clinical studies, that examine the use of Innohep® in prevention and treatment of DVT in cancer patients to generate data suitable for publication.

Refludan®

Refludan®, the tradename for lepirudin, is an antithrombin agent for patients with heparin-induced thrombocytopenia type II, or HIT type II. Refludan® is approved in 42 countries outside of North America. In May 2002, we entered into an agreement with Schering AG to obtain the exclusive marketing and distribution rights to Refludan® in all markets outside of North America. Hoechst Marion Roussel, or HMR, originally developed Refludan®. As a condition to the merger of HMR with Rhone Poulenc Rorer to form Aventis Pharmaceuticals, Aventis divested itself of Refludan® on a global basis to Schering AG, which continues to market the product in the U.S. and Canada through its subsidiary, Berlex Laboratories, Inc. Although approved in 42 countries outside of North America, Aventis had actively marketed the product only in Germany. We are currently marketing Refludan® principally in Europe and Australia.

HIT is an allergic, adverse immune response to heparin. Generally this response occurs after 2 to 4 days of heparin exposure, resulting in an absence of sufficient cell platelets to enable blood clotting. HIT occurs in 2-3% of patients treated with unfractionated heparin and 1-2% of patients treated with low molecular weight heparins. There are two forms of HIT. The first is relatively benign. The second, known as HIT type II, is a more serious form with the potential for significant impact on patient morbidity and mortality. Refludan® is prescribed for the treatment of HIT type II. Refludan® is administered through subcutaneous injection or infusion.

We believe that increasing the awareness of HIT and the clinical importance of effectively treating this condition will positively impact its diagnosis and treatment. Beginning in October 2002 and continuing through February 2004, we organized a number of symposia among leading hematologists in Europe, which we called HIT Schools, to provide these specialists with the latest information about HIT and its impact, as well as appropriate treatment regimens. These medical education programs have been our primary marketing activity as we work to build awareness of HIT. Nevertheless, given the relatively low incidence rate for HIT, we do not expect Refludan® sales to grow significantly above the current level. In addition, we expect the potential for Refludan® sales growth to be limited as a result of the warning letter Schering issued to doctors in Germany, following the advice of the EMEA, regarding the incidence of anaphylaxis, a severe allergic reaction, in approximately a dozen patients treated with Refludan® in both the U.S. and Europe, five of which cases resulted in fatalities. Although the possibility of anaphylaxis from Refludan® is a known possible reaction and is indicated in the product s label, the occurrences referenced in the warning letter appeared to be at a higher frequency than had previously been reported.

In addition to adding a marketed product to our portfolio, the acquisition of Refludan® allowed us to achieve our objective of establishing a sales and marketing organization throughout Europe and our other non-U.S. markets. The primary target physician audience for Refludan® is hematologists. With the planned launch of thalidomide and, later, Vidaza, it was important that we develop our commercial organization and establish relationships with the key prescribers of these products. We were able to achieve that objective in Europe through our acquisition of Refludan®. Today we have sales and marketing organizations established in each of the primary European markets, Australia, and, through third party distributors, in 20 additional countries throughout Europe and Asia.

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Sales, Marketing and Distribution

We have established sales and marketing organizations in the U.S., Europe and Australia. Our U.S. field-based sales organization consists of 31 professionals, including 22 clinical account specialists, three sales managers, three medical science liaisons, and three national account specialists. Our clinical account specialists and sales managers average over 10 years pharmaceutical sales experience and are based in or around major metropolitan areas with large inpatient and outpatient cancer treatment centers. Currently, they target hematologists and oncologists who prescribe high volumes of cancer therapies as well as low molecular weight heparin products. The concentration of high volume prescribers enables us to promote Innohep® with a small, dedicated sales and marketing organization. In anticipation of a Vidaza approval in the U.S., we expect to increase the number of field-based professionals to approximately sixty. While the number of target physicians would expand, we believe we can still access key opinion leaders and prescribers with a relatively small sales force.

In Europe, we employ a general manager in each of the U.K., France, Germany, Spain, Italy, and Denmark. These general managers are responsible for all commercial activities in each of their home countries, and may also have responsibility for commercial activities in smaller nearby countries. Each of our subsidiaries employs, in addition to the general manager, a trained physician, regulatory specialists if required by local law, sales representatives, PRMP experts and administrative support staff. In general, we only employ nationals in each of our local subsidiaries. All marketing activities are centrally directed from our U.K. office to ensure consistency across regional markets. In addition, clinical development, regulatory affairs and information technology functions are centrally managed from our U.K. office. In this manner, we seek to develop globally consistent programs but ensure that they are implemented according to local practices. Our Australian sales and marketing organizational structure is consistent with our European structure. Information regarding geographic areas is included in Note 3 to the Consolidated Financial Statements.

In addition to our own sales organizations, we have access to the hematology and oncology markets in 20 additional countries through relationships with our distributors. Pursuant to the agreements governing our relationships with our distributors, we are prohibited from selling or marketing our products on our own behalf in a country covered by one of these agreements until the applicable agreement expires.

The chart below identifies the countries which are served directly by our sales organizations and those which we access using our third-party distribution network.

Direct Sales Countries

Australia	Germany	Spain
Belgium	Ireland	Sweden
Denmark	Italy	Switzerland
Finland	Netherlands	U.K.
France	Norway	U.S.
	Portugal	

Distribution Countries

Cyprus	Lebanon	South Africa
Egypt	Malaysia	Syria
Greece	Malta	Taiwan
Hong Kong	New Zealand	Thailand
Israel	Oman	Turkey
Jordan	Saudi Arabia	United Arab Emirates
Kuwait	Singapore	

By working closely with top scientists, physicians and association leaders, our sales and marketing professionals are able to create science-based marketing materials of interest to key opinion leaders. In addition, our product acquisition strategy has been designed to maximize the success of our sales and marketing efforts by focusing on the acquisition of products and product candidates that make a clinical

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difference to patients in markets responsive to key opinion leaders. We intend to seek new countries in which to promote our products and we will continue the expansion of our sales and marketing organization as product growth or product acquisitions warrant.

In the U.S., we sell to pharmaceutical wholesalers, who in turn distribute product to retail pharmacies, hospitals, and other institutional customers. In Europe and Australia, we sell directly to retail and hospital pharmacies. Sales into countries where we have partnered with third party distributors are made directly to our partners. Net sales generated from three wholesale customers in the U.S. totaled approximately 13% of our total net sales for the year ended December 31, 2003.

Regulatory and Medical Affairs

Our regulatory affairs group is comprised of professionals with experience from both large pharmaceutical companies and biotechnology companies. The difference between an attractive drug candidate and one which is not economically viable for development often hinges on our assessment of the time and expense required to get the drug approved and sold in a particular jurisdiction. Determining the optimal regulatory pathway for commercialization is an integral part of our product candidate selection. We believe that our combination of country-specific regulatory expertise and our focus on the hematology and oncology markets provide a significant advantage as we seek to acquire additional product candidates through in-license, and move our existing product candidates forward through the approval process.

Collaborations and License Agreements

Celgene and Penn Agreements. In 2001, we licensed rights relating to thalidomide from both Celgene and Penn T Limited for all countries outside of North America, Japan, China, Korea and Taiwan. Under agreements with Celgene, we obtained the rights in this territory to Celgene s formulation of thalidomide, Thalomid®, exclusive licenses or sublicenses for use in this territory of all intellectual property owned or licensed by Celgene relating to thalidomide, as well as all existing and future clinical data relating to thalidomide developed by Celgene, and an exclusive license to employ Celgene s patented S.T.E.P.S.® program as our PRMP. Under agreements with Penn, we became Penn s exclusive distributor in this territory of any formulation of thalidomide manufactured by Penn, which included an exclusive supply and requirements relationship with respect to Penn s manufacture of thalidomide for this territory. We will pay Penn and Celgene a combined royalty of 36% of net sales, less our purchase price from Penn of the units of product sold, on all of our sales of thalidomide once thalidomide is approved by the appropriate health regulatory authority for sale in any country within our license territory. In the interim, our combined royalty payment obligations to Celgene and Penn are generally lower than 36%. Our royalty payment obligations to Celgene and Penn are also subject to certain minimum yearly payment thresholds. In connection with our ongoing relationship with Celgene, and to further the clinical development of thalidomide, particularly in multiple myeloma, we have also agreed to fund an aggregate of $8.0 million of Celgene s clinical trial development costs for clinical studies of thalidomide, with this amount payable in installments through 2005. Through December 31, 2003, we had funded $3 million of this $8 million commitment. The agreements with Celgene and Penn each have a ten year term running from the date of receipt of our first regulatory approval for thalidomide in the United Kingdom, subject, in the case of the Celgene agreement to Celgene having a right to terminate the agreement if we have not obtained that approval by November 2006.

Pharmacia Agreement

We licensed worldwide rights to azacitidine from Pharmacia & Upjohn Company, now a part of Pfizer, Inc., in June 2001. Under the terms of our agreement, we are obligated to pay Pharmacia a royalty of 20% on net sales of Vidaza, except if the data from the clinical trials of the NCI and CALGB on the use of Vidaza as a treatment for MDS patients is deemed insufficient by the FDA to support an approval of Vidaza and we are required to conduct another Phase III clinical trial for MDS prior to initial FDA approval, then the royalty rate will be 8%. The license from Pharmacia has a term extending for the longer of the last to expire of valid patent claims in any given country or ten years from our first commercial sale of the product in a particular country.

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LEO Pharma Agreement

In July 2002, we obtained an exclusive license from LEO Pharma A/S to distribute Innohep® in the U.S., as well as an exclusive supply and requirements agreement with LEO Pharma for their supply to us of Innohep®. Under our agreement with LEO Pharma, we made an up-front payment for this license of $7.5 million, up to $2.5 million of which is creditable against royalty payments otherwise due during the period ending March 1, 2005. In addition, we are obligated to pay LEO Pharma royalties at the rate of 30% on annual net sales of up to $20.0 million and at the rate of 35% of annual net sales exceeding $20.0 million, less in each case our purchase price from LEO Pharma of the units of product we sell. The agreement has a term of ten years.

Schering AG Agreement

In May 2002, we obtained the exclusive rights from Schering AG to distribute Refludan® in all countries outside of North America. Schering produces the product for us under contract with a third-party manufacturer and sells it to us at its acquisition cost plus 5%. Our agreements with Schering, as amended, transfer to us all of the marketing authorizations and product registrations for Refludan® in the individual countries within our territory. We have paid Schering an aggregate of $5.0 million and are obligated to make an aggregate of $8 .0 million of additional fixed payments to Schering, payable in quarterly installments of $1.0 million through the end of 2005. We are obligated to make up to $7.5 million of additional payments upon the achievement of certain milestones. We paid to Schering, in addition to our product acquisition costs, a royalty of 8% of our net sales of Refludan® during the period through December 31, 2003 and pay a royalty of 14% of our net sales of Refludan® thereafter. However, when we have paid $12.0 million in royalties measured from January 2004, the royalty rate would then be reduced to 6%.

CALGB Agreement

In November 2001, we entered into a collaboration agreement with the CALGB pursuant to which the CALGB agreed to provide us with the data produced by its azacitidine studies in exchange for aggregate payments of approximately $1.1 million. We incorporated the data provided to us by the CALGB in our December 2003 NDA submission. The CALGB has agreed not to permit any other party to use its azacitidine data in connection with an NDA until such time as we cease our efforts to commercialize azacitidine.

Manufacturing

We currently use, and expect to continue to be dependent upon, contract manufacturers to manufacture each of our products. We do not maintain alternative manufacturing sources for any of our products. Our contract manufacturers and distributors are subject to extensive governmental regulation. Regulatory authorities in our markets require that drugs be manufactured, packaged and labeled in conformity with Good Manufacturing Practices, or cGMPs. We have established a quality control and quality assurance program, including a set of standard operating procedures and specifications, designed to ensure that our products are manufactured in accordance with cGMPs, and other applicable domestic and foreign regulations.

Thalidomide. We obtain our two formulations of thalidomide from two different suppliers. Thalidomide Pharmion 50mg is formulated, encapsulated and packaged for us by Penn Pharmaceuticals Services Limited of Great Britain in a facility that is in compliance with the regulatory standards of each of the countries where we sell and expect to sell the product. Under the terms of this agreement we purchase from Penn all of our requirements of the product. Pricing is subject to an annual adjustment based upon the fully allocated cost of manufacture. This agreement terminates upon the tenth anniversary of the date upon which we receive regulatory approval for thalidomide in the U.K.

Thalidomide Laphal is formulated, encapsulated and packaged for us by Laphal Industrie, an unaffiliated Company, in a facility that is in compliance with the regulatory standards of each of the countries where we sell and expect to sell the product. Pricing is subject to an annual adjustment based upon a formula that accounts for increases in the cost of manufacture. In addition, in the event that prior to the expiration of the agreement we decide to discontinue ordering Thalidomide Laphal from Laphal Industrie, we are obligated to

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provide twelve months advance notice and pay 300,000. If our notice to discontinue ordering Thalidomide Laphal is not timely, the fee may increase to as much as 500,000. This agreement terminates in March 2013.

Vidaza. Under the terms of two development agreements, Ash Stevens, Inc. and Ben Venue Labs provide us with clinical supplies and manufacturing services for azacitidine. Azacitidine drug substance is manufactured for us by Ash Stevens, who sends the product in its raw form to Ben Venue Labs. Ben Venue Labs then formulates the product, fills the product into vials and labels the finished product for us. Both Ash Stevens and Ben Venue Labs operate facilities that are in compliance with the regulatory standards of each of the countries where we expect to sell the product. We expect to enter into commercial supply agreements with both Ash Stevens and Ben Venue prior to receiving regulatory market approval for azacitidine.

Innohep®. Innohep® is formulated and packaged for us by LEO Pharmaceutical Products Ltd. in a facility that is in compliance with FDA requirements. Under our agreement, we are required to purchase our Innohep® requirements exclusively from LEO. Pricing may be adjusted annually based upon changes in the Danish Pay Index. This agreement terminates in June 2012.

Refludan®. Refludan® is manufactured in a facility that meets the standards of each of the countries where we sell and expect to sell the product by a third-party manufacturer, who then supplies the drug to our supplier, Schering AG. Under our agreement, we are required to purchase our Refludan® requirements exclusively from Schering. The pricing is subject to an annual adjustment under the existing supply agreement between Schering and the third-party manufacturer. This agreement terminates in 2022.

Raw Materials

Raw materials and supplies are normally available in quantities adequate to meet the needs of our business.

Government Regulation

Regulation by governmental authorities in the U.S. and other countries is a significant factor in the manufacture and marketing of our products and in ongoing research and product development activities. All of our products require regulatory approval by governmental agencies prior to commercialization. In particular, our products are subject to rigorous preclinical and clinical testing and other approval requirements by the FDA and similar regulatory authorities in other countries. Various statutes and regulations also govern or influence the manufacturing, safety, reporting, labeling, storage, record keeping and marketing of our products. The lengthy process of seeking these approvals, and the subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could harm our business.

The regulatory requirements relating to the manufacturing, testing and marketing of our products may change from time to time. For example, at present, member states in the E.U. are in the process of incorporating into their domestic laws the provisions contained in the E.U. Directive on the implementation of good clinical practice in the conduct of clinical trials. The Directive imposes more onerous requirements in relation to certain aspects of clinical trial conduct than are currently in place in many member states. This may impact our ability to conduct clinical trials and the ability of independent investigators to conduct their own research with support from us. In addition, the E.U. rules concerning the authorization of medicinal products are in the process of being amended. We do not expect the new rules to apply until 2005. The final rules are not yet available and as such the impact upon our business cannot be known at this time.

Product Approval

The clinical development, manufacturing and marketing of our products are subject to regulation by various authorities in the U.S., the E.U. and other countries, including, in the U.S., the FDA, and, in the E.U., the EMEA. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act in the U.S. and numerous directives, regulations, local laws and guidelines in the E.U. govern the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of our products. Product

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development and approval within these regulatory frameworks takes a number of years and involves the expenditure of substantial resources.

Regulatory approval will be required in all the major markets in which we, or our licensors, seek to test our products in development. At a minimum, such approval requires the evaluation of data relating to the quality, safety and efficacy of a product for its proposed use. The specific types of data required and the regulations relating to this data will differ depending on the territory, the drug involved, the proposed indication and the stage of development.

In general, new chemical entities are tested in animals until adequate proof of safety is established. Clinical trials for new products are typically conducted in three sequential phases that may overlap. In Phase I, the initial introduction of the pharmaceutical into healthy human volunteers, the emphasis is on testing for safety (adverse effects), dosage tolerance, metabolism, distribution, excretion and clinical pharmacology. Phase II involves studies in a limited patient population to determine the initial efficacy of the pharmaceutical for specific targeted indications, to determine dosage tolerance and optimal dosage and to identify possible adverse side effects and safety risks. Once a compound shows evidence of effectiveness and is found to have an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to more fully evaluate clinical outcomes.

In the U.S., specific preclinical data and chemical data, as described above, needs to be submitted to the FDA as part of an Investigational New Drug application, or IND, which, unless the FDA objects, will become effective 30 days following receipt by the FDA. Phase I studies in human volunteers may commence only after the application becomes effective. Prior regulatory approval for human healthy volunteer studies is also required in member states of the E.U. Currently, in each member state of the E.U., following successful completion of Phase I studies, data is submitted in summarized format to the applicable regulatory authority in the member state in respect of applications for the conduct of later Phase II studies. The regulatory authorities in the E.U. typically have between one and three months in which to raise any objections to the proposed study, and they often have the right to extend this review period at their discretion. In the U.S., following completion of Phase I studies, further submissions to regulatory authorities are necessary in relation to Phase II and III studies to update the existing IND. Authorities may require additional data before allowing the studies to commence and could demand that the studies be discontinued at any time if there are significant safety issues. In addition to the regulatory review, a study involving human subjects has to be approved by an independent body. The exact composition and responsibilities of this body will differ from country to country. In the U.S., for example, each study will be conducted under the auspices of an independent Institutional Review Board at the institution at which the study is conducted. This board considers among other things, the design of the study, ethical factors, the safety of the human subjects and the possible liability risk for the institution. Equivalent rules apply in each member state of the E.U. where one or more independent ethics committees, which typically operate similarly to an Institutional Review Board, will review the ethics of conducting the proposed research. Other authorities around the rest of the world have slightly differing requirements involving both the execution of clinical trials and the import/export of pharmaceutical products. It is our responsibility to ensure we conduct our business in accordance with the regulations of each relevant territory.

Information generated in this process is susceptible to varying interpretations that could delay, limit or prevent regulatory approval at any stage of the approval process. The failure to demonstrate adequately the quality, safety and efficacy of a therapeutic drug under development would delay or prevent regulatory approval of the product. There can be no assurance that if clinical trials are completed, either we or our collaborative partners will submit applications for required authorizations to manufacture and/or market potential products (including a marketing authorization application, NDA or abbreviated NDA) or that any such application will be reviewed and approved by the appropriate regulatory authorities in a timely manner, if at all.

In order to gain marketing approval we must submit a dossier to the relevant authority for review, which is known in the U.S. as an NDA and in the E.U. as a marketing authorization application, or MAA. The format is usually specific and laid out by each authority, although in general it will include information on the

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quality of the chemistry, manufacturing and pharmaceutical aspects of the product as well as the non-clinical and clinical data. The FDA undertakes the review for the U.S. In the E.U. there is, for many products, a choice of two different authorization routes: centralized and decentralized. Under the centralized route one marketing authorization is granted for the entire E.U., while under the decentralized route a series of national marketing authorizations are granted. In the centralized system the application will be reviewed by members of the Committee for Proprietary Medicinal Products, or the CPMP, on behalf of the EMEA. The EMEA will, based upon the review of the CPMP, provide an opinion to the European Commission on the safety, quality and efficacy of the product. The decision to grant or refuse an authorization is made by the European Commission. In circumstances where use of the centralized route is not mandatory, we can choose to use the decentralized route, in which case the application will be reviewed by one member state s regulatory agency. If the regulatory agency grants the authorization, other member states regulatory authorities are asked to mutually recognize the authorization granted by the first member state s regulatory agency. Approval can take several months to several years, or be denied. The approval process can be affected by a number of factors. Additional studies or clinical trials may be requested during the review and may delay marketing approval and involve unbudgeted costs. The regulatory authorities may conduct an inspection of relevant facilities, and review manufacturing procedures, operating systems and personnel qualifications. In addition to obtaining approval for each product, in many cases each drug manufacturing facility must be approved. Further inspections may occur over the life of the product. An inspection of the clinical investigation sites by a competent authority may be required as part of the regulatory approval procedure. As a condition of marketing approval, the regulatory agency may require post-marketing surveillance to monitor for adverse effects, or other additional studies as deemed appropriate. After approval for the initial indication, further clinical studies are usually necessary to gain approval for any additional indications. The terms of any approval, including labelling content, may be more restrictive than expected and could affect the marketability of a product.

The FDA offers an accelerated approval procedure for certain drugs under Subpart H of the agency s NDA approval regulations. Subpart H provides for accelerated NDA approval for new drugs intended to treat serious or life-threatening diseases where the drugs provide a meaningful therapeutic advantage over existing treatment. Under this accelerated approval procedure, the FDA may approve a drug based on evidence from adequate and well-controlled studies of the drug s effect on a surrogate endpoint that reasonably suggest clinical benefits, or on evidence of the drug s effect on a clinical endpoint other than survival or irreversible morbidity. This approval is conditioned on the favorable completion of trials to establish and define the degree of clinical benefits to the patient. These post-approval clinical trials, known as Phase IV trials, would usually be underway when the product obtains this accelerated approval. If, after approval, a Phase IV trial establishes that the drug does not perform as expected, or if post-approval restrictions are not adhered to or are not adequate to ensure the safe use of the drug, or other evidence demonstrates that the product is not safe or effective under its conditions of use, the FDA may withdraw approval. This accelerated approval procedure for expediting the clinical evaluation and approval of certain drugs may shorten the drug development process by as much as two to three years. The E.U. rules relating to marketing authorizations permit, in exceptional circumstances, the regulatory authorities to grant a marketing authorization where the applicant is not able to provide the usual comprehensive set of data relating to safety and efficacy, because the targeted disease state is rarely encountered or because there is a lack of scientific knowledge about the disease, or because it would be unethical to collect such data. Marketing authorizations granted on an exceptional circumstances basis are normally subject to the holder fulfilling certain obligations, such as completion by the applicant of particular clinical studies.

In many markets outside of the U.S., regulations exist that permit patients to gain access to unlicensed pharmaceuticals, particularly for severely ill patients where other treatment options are limited or non-existent. Generally, the supply of pharmaceuticals under these circumstances is termed compassionate use or named patient supply. In the E.U., each member state has developed its own system under an E.U. directive that permits the exemption from traditional pharmaceutical regulation of medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with specifications of an authorized health care professional and for use by his individual patients on his direct personal responsibility. Essentially, two systems operate among E.U. member states: approval can be given for cohort supply, meaning more than one patient can be supplied in accordance with an agreed treatment protocol; or,

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alternatively, as is the case in the majority of E.U. member states, supply is provided on an individual patient basis. Some countries, such as France, have developed other systems, where an ATU involves a thorough review and approval by the regulator of a regulatory data package. In France, the company then receives an approval to supply. All E.U. member states require assurance of the quality of the product, which is usually achieved by provision of good manufacturing practice, or GMP, certification. In the majority of markets, the prescribing physician is responsible for the use for the product and in some countries the physician in conjunction with the pharmacist must request approval from the regulator to use the unlicensed pharmaceutical. Outside of the E.U., many countries have developed named patient systems similar to those prevalent in Europe.

The U.S., the E.U. and Australia may grant orphan drug designation to drugs intended to treat a rare disease or condition, which, in the U.S., is generally a disease or condition that affects no more than 75 in 100,000 persons or fewer than 200,000 individuals. In the E.U., orphan drug designation can be granted if: the disease affects no more than 50 in 100,000 persons in the E.U. or the drug is intended for a life-threatening, seriously debilitating or serious and chronic condition; without incentive it is unlikely that the drug would generate sufficient return to justify the necessary investment; and no satisfactory method of treatment for the condition exists or, if it does, the new drug will provide a significant benefit to those affected by the condition. In Australia, orphan drug designation can be granted to drugs intended to treat a disease that affects no more than 11 in 100,000 persons or fewer than 2,000 individuals. If a product that has an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, meaning that the applicable regulatory authority may not approve any other applications to market the same drug for the same indication, except in certain very limited circumstances, for a period of seven years in the U.S., ten years in the E.U. and five years in Australia. Orphan drug designation does not prevent competitors from developing or marketing different drugs for an indication. Orphan drug designation must be requested before submitting an NDA or MAA. After orphan drug designation is granted, the identity of the therapeutic agent and its potential orphan use are publicly disclosed. Orphan drug designation does not convey an advantage in, or shorten the duration of, the review and approval process.

For both currently marketed and future products, failure to comply with applicable regulatory requirements after obtaining regulatory approval can, among other things, result in the suspension of regulatory approval, as well as possible civil and criminal sanctions. Renewals in Europe may require additional data, which may result in a license being withdrawn. In the U.S. and the E.U., regulators have the authority to revoke, suspend or withdraw approvals of previously approved products, to prevent companies and individuals from participating in the drug-approval process, to request recalls, to seize violative products and to obtain injunctions to close manufacturing plants not operating in conformity with regulatory requirements and to stop shipments of violative products. In addition, changes in regulation could harm our financial condition and results of operation.

Product Regulation

We are also subject to various federal and state laws pertaining to health care fraud and abuse, including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third party payors (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services.

As a drug marketer, we participate in the Medicaid rebate program established by the Omnibus Budget Reconciliation Act of 1990, and under amendments of that law that became effective in 1993. Participation in this program includes requirements such as extending comparable discounts under the Public Health Service, or PHS, pharmaceutical pricing program. Under the Medicaid rebate program, we pay a rebate for each unit of our product reimbursed by Medicaid. The amount of the rebate for each product is set by law as a minimum 15.1% of the average manufacturer price, or AMP, of that product, or if it is greater, the difference

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between AMP and the best price available from us to any customer. The rebate amount also includes an inflation adjustment if AMP increases faster than inflation. The PHS pricing program extends discounts comparable to the Medicaid rebate to a variety of community health clinics and other entities that receive health services grants from the PHS, as well as hospitals that serve a disproportionate share of poor Medicare and Medicaid beneficiaries. The rebate amount is recomputed each quarter based on our reports of our current average manufacturer price and best price for each of our products to the Health Care Financing Administration.

As a result of the Veterans Health Care Act of 1992, federal law requires that product prices for purchases by the Veterans Administration, the Department of Defense, Coast Guard, and the PHS (including the Indian Health Service) be discounted by a minimum of 24% off the AMP to non-federal customers, the non-federal average manufacturer price, or non-FAMP. Our computation and report of non-FAMP is used in establishing the price, and the accuracy of the reported non-FAMP may be audited by the government under applicable federal procurement laws.

Under the laws of the U.S., the member states of the E.U. and other countries, we and the institutions where we sponsor research are subject to certain obligations to ensure the protection of personal information of human subjects participating in our clinical trials. We have instituted procedures that we believe will enable us to comply with these requirements and the contractual requirements of our data sources. The laws and regulations in this area are evolving and further regulation, if adopted, could affect the timing and the cost of future clinical development activities.

We are subject to the U.S. Foreign Corrupt Practices Act which prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. Under this act, it is illegal to pay, offer to pay, or authorize the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity.

Pricing Controls

Before a pharmaceutical product may be marketed and sold in certain foreign countries the proposed pricing for the product must be approved. The requirements governing product pricing vary widely from country to country and can be implemented disparately at the national level.

The E.U. generally provides options for its member states to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. For example, the regulation of prices of pharmaceuticals in the United Kingdom is generally designed to provide controls on the overall profits that pharmaceutical companies may derive from their sales to the U.K. National Health Service. The U.K. system is generally based on profitability targets or limits for individual companies which are normally assessed as a return on capital employed by the company in servicing the National Health Service market, comparing capital employed and profits.

In comparison, Italy generally establishes prices for pharmaceuticals based on a price monitoring system. The reference price is the European average price calculated on the basis of the prices in four reference markets: France, Spain, Germany and the U.K. Italy typically establishes the price of medicines belonging to the same therapeutic class on the lowest price for a medicine belonging to that category. Spain generally establishes the selling price for new pharmaceuticals based on the prime cost, plus a profit margin within a range established each year by the Spanish Commission for Economic Affairs. Promotional and advertising costs are limited.

There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceuticals will allow favorable reimbursement and pricing arrangements for our products. In addition, in the U.S. there have been, and we expect that there will continue to be, a number of federal and state proposals to implement governmental pricing control.

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Third Party Reimbursement

In the U.S., E.U. and elsewhere, sales of therapeutic and other pharmaceutical products are dependent in part on the availability of reimbursement to the consumer from third party payers, such as government and private insurance plans. Third party payors are increasingly challenging the prices charged for medical products and services. The E.U. generally provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement. Member states in the E.U. can opt to have a positive or a negative list. A positive list is a listing of all medicinal products covered under the national health insurance system, whereas a negative list designates which medicinal products are excluded from coverage. In the E.U., the U.K. and Spain use a negative list approach, while France uses a positive list approach. In Canada, each province decides on reimbursement measures. In some countries, in addition to positive and negative lists, products may be subject to a clinical and cost effectiveness review by a health technology assessment body. A negative determination by such a body in relation to one of our products could affect the prescribing of the product. For example, in the U.K., the National Institute for Clinical Excellence, or the NICE, provides guidance to the National Health Service on whether a particular drug is clinically effective and cost effective. Although presented as guidance, doctors are expected to take the guidance into account when choosing a drug to prescribe. In addition, health authorities may not make funding available for drugs not given a positive recommendation by the NICE. There is a risk that a negative determination by the NICE will mean fewer prescriptions. Although the NICE will consider drugs with orphan status, there is a degree of tension in the application by the NICE of the standard cost assessment for orphan drugs, which are often priced more highly to compensate for the limited market. It is unclear whether the NICE will adopt a more relaxed approach toward the assessment of orphan drugs. We cannot assure you that any of our products will be considered cost effective and that reimbursement to the consumer will be available or will be sufficient to allow us to sell our products on a competitive and profitable basis.

Our present and future business has been and will continue to be subject to various other laws and regulations.

Patents and Proprietary Rights

Our success will depend in part on our ability to protect our existing products and the products we acquire or license by obtaining and maintaining a strong proprietary position both in the U.S. and in other countries. To develop and maintain such a position, we intend to continue relying upon orphan drug status, trade secrets, know-how, continuing technological innovations and licensing opportunities. Although patent protection for each of our existing products has expired, together with Ash Stevens, Inc. we jointly hold two patents that protect certain manufacturing processes and technological innovations. In addition, we intend to seek patent protection whenever available for any products or product candidates and related technology we acquire in the future.

The patent positions of pharmaceutical firms like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, we do not know whether any of the products or product candidates we acquire or license will result in the issuance of patents or, if any patents are issued, whether they will provide significant proprietary protection or will be challenged, circumvented or invalidated. Because patent applications in the U.S. and certain other jurisdictions are maintained in secrecy until patents issue, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office or a foreign patent office to determine priority of invention, or in opposition proceedings in a foreign patent office, either of which could result in substantial cost to us, even if the eventual outcome is favorable to us. There can be no assurance that the patents, if issued, would be held valid by a court of competent jurisdiction. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using such technology.

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In the absence of patent protection for our existing products and any products or product candidates we should acquire in the future, we have sought and intend to continue seeking orphan drug status whenever it is available. To date, we have been granted orphan drug status in the U.S. for Vidaza for the indication MDS, in the E.U. for Vidaza for the indication MDS and for Thalidomide Pharmion 50mg for the indications multiple myeloma and ENL and in Australia for Vidaza for the indication MDS and for Thalidomide Pharmion 50mg for the indications multiple myeloma and ENL. If a product which has an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, meaning that the applicable regulatory authority may not approve any other applications to market the same drug for the same indication, except in certain very limited circumstances, for a period of seven years in the U.S. and ten years in the E.U. Orphan drug designation does not prevent competitors from developing or marketing different drugs for an indication. See Government Regulation for a more detailed description of orphan drug status.

We also rely on trade secret protection for our confidential and proprietary information. No assurance can be given that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technology, or that we can meaningfully protect our trade secrets. However, we believe that the substantial costs and resources required to develop technological innovations, such as the PRMP, will help us to protect the competitive advantage of our products.

It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual s relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual shall be our exclusive property. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

Competition

The development and commercialization of new drugs is competitive and we will face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Our competitors may develop or market products or other novel technologies that are more effective, safer or less costly than any that have been or are being developed by us, or may obtain regulatory approval for their products more rapidly than we may obtain approval for ours.

The acquisition or licensing of pharmaceutical products is also very competitive, and a number of more established companies, which have acknowledged strategies to license or acquire products, may have competitive advantages as may other emerging companies taking similar or different approaches to product acquisitions. In addition, a number of established research-based pharmaceutical and biotechnology companies may acquire products in late stages of development to augment their internal product lines. These established companies may have a competitive advantage over us due to their size, cash flows and institutional experience.

Many of our competitors will have substantially greater financial, technical and human resources than we have. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances made in the commercial applicability of technologies and greater availability of capital for investment in these fields. Our success will be based in part on our ability to build and actively manage a portfolio of drugs that addresses unmet medical needs and create value in patient therapy.

Thalidomide Pharmion 50mg. We believe that the primary competition for Thalidomide Pharmion 50mg are Velcade™ from Millennium Pharmaceuticals Inc., a proteasome inhibitor, and Revlimid™ from Celgene, a small molecule compound that affects multiple cellular pathways and is currently

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being evaluated for a wide range of hematological cancers, including relapsed and refractory multiple myeloma and MDS.

Vidaza. We believe that the primary competition for Vidaza are Decitabine from Supergen Inc., which like Vidaza, is a demethylating agent, and Thalomid® and Revlimid, each from Celgene.

Innohep®. We believe that the primary competition for Innohep® are two low molecular weight heparins, Lovenox® from Aventis, the top-selling low molecular weight heparin worldwide, and Fragmin® from Pharmacia Corporation, as well as Arixtra® from Sanofi-Synthelabo, the first of a new class of anti-thrombotic drugs which are factor Xa inhibitors.

Refludan®. We believe that the primary competition for Refludan® is Argatroban from GlaxoSmithKline plc, an anticoagulant indicated for both the prevention and treatment of HIT.

Clinical, Development and Regulatory Expense

In the years ended December 31, 2003, 2002 and 2001, we incurred clinical, development and regulatory expense of $24.6 million, $15.0 million and $6.0 million, respectively. Since each of our four products was either already marketed or at a late-stage of development at the time we acquired rights to it, we have not, to date, incurred any research expense.

Employees

As of December 31, 2003, we had 177 employees, consisting of 61 in regulatory affairs and clinical development, 87 in sales and marketing and 29 in general and administrative. We believe that our relations with our employees are good and we have no history of work stoppages.

Item 2. ***Facilities***

We lease approximately 29,000 square feet of space in our headquarters in Boulder, Colorado under a lease that expires in 2008. We also lease clinical development, sales and marketing, and support offices in other parts of the U.S. and abroad. We have no laboratory, research or manufacturing facilities. We believe that our current facilities are adequate for our needs for the foreseeable future and that, should it be needed, suitable additional space will be available to accommodate expansion of our operations on commercially reasonable terms.

Item 3. ***Legal Proceedings***

We are not engaged in any material legal proceedings except as follows:

During the fourth quarter of 2003, we filed suit against Lipomed AG, and certain of its distributors, in the UK, Switzerland, Germany and Italy for infringement of European Patent EP 0 688 211, in connection with their sales of thalidomide for the treatment of angiogenesis-mediated disorders, including multiple myeloma, in these countries. We are the exclusive licensee under this patent in all countries outside of North America, Japan, China, Taiwan and Korea, pursuant to an agreement with Celgene Corporation. Celgene is a co-plaintiff to the proceedings in Switzerland, Italy and Germany. We are seeking injunctive relief that prevents the defendants from making any further sales of thalidomide for the treatment of angiogenesis-mediated disorders, including multiple myeloma, in the four countries in which we brought suit, and damages against the defendants. We are seeking preliminary injunctions in Italy and Switzerland pending a decision on the merits. We do not expect decisions on the merits to be rendered in the various proceedings until late 2004 at the earliest.

Item 4. ***Submission of Matters to a Vote of Security Holders***

In September 2003, we sent a written consent to our stockholders requesting their consent to our taking the following actions in connection with our initial public offering: (1) the approval and adoption of a certificate of amendment to our restated certificate of incorporation so as to effect a reverse stock split prior to

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our initial public offering, (2) the approval and adoption of our restated certificate of incorporation to become effective following the closing of our initial public offering, (3) the approval and adoption of our amended and restated bylaws to become effective upon the closing of our initial public offering, and (4) the approval and adoption of an amendment to our 2000 Stock Incentive Plan and our 2001 Non-Employee Director Stock Option Plan to allow for automatic annual share increases. All such actions were effected pursuant to an action by written consent of our stockholders in compliance with Section 228 of the Delaware General Corporation Law. We received the requisite consents on September 23, 2003.

A total of 17,668,872 shares of our stock out of 17,929,223 shares issued and outstanding as of September 8, 2003, including 16,815,636 common shares out of 17,030,948 shares of our Series A, Series B and Series C preferred stock issued and outstanding, all on an as converted basis, voted in favor of these matters.

PART II

Item 5. *Market for Registrant s Common Equity and Related Stockholder Matters*

Market Information and Holders

Our common stock is traded on the Nasdaq National Market under the symbol PHRM. Trading of our common stock commenced on November 6, 2003, following completion of our initial public offering. The following table sets forth, for the periods indicated, the high and low sales prices for our common stock as reported by the Nasdaq National Market:

Year Ended December 31, 2003	High	Low
Fourth Quarter	$15.25	$11.20

On March 24, 2004, the last reported sale price of our common stock on the Nasdaq National Market was $21.26 per share.

American Stock Transfer and Trust Company is the transfer agent and registrar for our common stock. On March 26, 2004, we had approximately 78 holders of record of our common stock. We believe there are in approximately 987 beneficial owners of our common stock.

Dividends

We have never paid any cash dividends on our capital stock and do not intend to pay any such dividends in the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

Equity Compensation Plan Information

As of December 31, 2003

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders(1)(2)	1,818,212	$4.28	1,074,112
Equity compensation plans not approved by security holders	849,693	$9.68	0

Total	2,667,905	$3.49	1,074,112

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(1) As of December 31, 2003, 2,758,000 shares were reserved for issuance under our 2000 Stock Incentive Plan. This number is subject to an automatic yearly increase pursuant to an evergreen formula. Each year, on the date of our annual meeting of stockholders, the amount of shares reserved for issuance under the 2000 Stock Incentive Plan will be increased by 500,000 shares, unless our board of directors determines that a smaller increase or no increase is necessary.

(2) As of December 31, 2003, 375,000 shares were reserved for issuance under our 2001 Non-Employee Director Stock Option Plan. This number is subject to an automatic yearly increase pursuant to an evergreen formula. Each year, on the date of our annual meeting of stockholders, the amount of shares reserved for issuance under the 2001 Non-Employee Director Stock Option Plan will be increased by 50,000 shares, unless our board of directors determines that a smaller increase or no increase is necessary.

We have authorized the issuance of equity securities under the compensation plans described below without the approval of stockholders. No additional options, warrants or rights are available for issuance under any of these plans, except for additional shares that may become purchasable pursuant to any anti-dilution provisions contained within the warrants.

Warrants dated November 30, 2001: provided common stock purchase warrants to a business partner to purchase an aggregate of 425,451 shares of common stock at an exercise price of $8.36 per share with an expiration date of November 30, 2008.

Convertible Debt Warrants dated April 8, 2003: provided common stock warrants to two lenders to purchase an aggregate of 424,242 shares of common stock at an exercise price of $11.00 per share with an expiration date of April 8, 2008.

Recent Sales of Unregistered Securities

During the three month period ended December 31, 2003, we issued and sold 2,224 shares of our common stock that were not registered under the Securities Act of 1933, as amended, to our employees upon the exercise of stock options for cash consideration with an aggregate exercise price of $1,490. During the same period, we granted options to purchase 368,500 shares of common stock at a weighted average exercise price of $13.58 per share. No underwriters were involved in the foregoing stock or option issuances. The issuance of these securities was exempt from registration under the Securities Act in reliance on Rule 701 promulgated under the Securities Act as transactions by an issuer under compensatory benefit plans and contracts relating to compensation within the parameters required by Rule 701.

Use of Proceeds from Sales of Registered Securities

On November 12, 2003, we closed the sale of 6,000,000 shares of our common stock in our initial public offering. The registration statement on Form S-1 (Reg. No. 333-108122), we filed to register our common stock in the offering was declared effective by the SEC on November 5, 2003. Our initial public offering commenced as of November 5, 2003 and did not terminate before any securities were sold. The offering has been completed and all shares were sold at an initial price per share of $14.00. The aggregate purchase price of the offering amount registered was $84,000,000.

The managing underwriters for the offering were Morgan Stanley & Co. Incorporated, J.P. Morgan Securities Inc., Pacific Growth Equities, LLC, and U.S. Bancorp Piper Jaffray Inc. We incurred expenses in connection with the offering of $7.8 million, which consisted of direct payments of: (i) $1.6 million in legal, accounting and printing fees; (ii) $5.9 million in underwriters discounts, fees and commissions; and (iii) $.3 million in miscellaneous expenses. No payments for such expenses were made directly or indirectly to (i) any of our directors, officers or their associates, (ii) any person(s) owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

After deducting expenses of the offering, we received net offering proceeds of approximately $76.2 million. From the time of receipt, November 12, 2003, through December 31, 2003, we have used approximately $6.7 million of the net proceeds from the offering to fund operations, capital expenditures, working capital and

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other general corporate purposes. The remainder of the proceeds have been invested into short-term investment-grade securities and money market accounts.

None of the net proceeds were directly or indirectly paid to (i) any of our directors, officers or their associates, (ii) any person(s) owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

Item 6. ***Selected Consolidated Financial Data***

We were formed in August 1999 and commenced operations in January 2000. In the table below, we provide you with our selected consolidated financial data which should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and the related notes appearing elsewhere in this annual report. We have prepared this information using our audited consolidated financial statements for the years ended December 31, 2000, 2001, 2002 and 2003. The pro forma net loss attributable to common stockholders per common share and shares used in computing pro forma net loss attributable to common stockholders per common shares reflect the conversion of all outstanding shares of our redeemable convertible preferred stock as of January 1, 2001 or the date of issuance, if later. The net loss per share data and pro forma net loss per share data do not include the effect of any options or warrants outstanding as they would be antidilutive. For further discussion of earnings per share, please see note 2 to our consolidated financial statements.

	2000	2001	2002	2003(1)
	(In thousands, except share and per share data)			
Consolidated Statement of Income Data:				
Net sales	$	$	$ 4,735	$ 25,539
Operating expenses:				
Cost of sales			1,575	11,462
Clinical, regulatory and development	972	6,009	15,049	24,616
Selling, general and administrative	3,664	8,322	23,437	36,109
Product rights amortization			375	1,972
Total operating expenses	4,636	14,331	40,436	74,159
Loss from operations	(4,636)	(14,331)	(35,701)	(48,620)
Other income (expense) net	190	621	1,109	(154)
Loss before taxes	(4,446)	(13,710)	(34,592)	(48,774)
Income tax expense			105	1,285
Net loss	(4,446)	(13,710)	(34,697)	(50,059)
Accretion to redemption value of redeemable convertible preferred stock	(409)	(2,458)	(8,576)	(10,091)
Net loss attributable to common stockholders	$ (4,855)	$ (16,168)	$ (43,273)	$ (60,150)
Net loss attributable to common stockholders per common share, basic and diluted	$ (7.28)	$ (23.99)	$ (57.58)	$ (14.70)
Shares used in computing net loss attributable to common stockholders per common share, basic and diluted	667,000	673,822	751,525	4,093,067
Pro forma net loss attributable to common stockholders per common share, assuming conversion of preferred stock, basic and diluted (unaudited)		$ (2.26)	$ (2.47)	$ (2.66)
Shares used in computing pro forma net loss attributable to common stockholders per common share, assuming conversion of		6,060,284	14,072,707	18,791,015

preferred stock, basic and diluted
(unaudited)

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	As of December 31,			
	2000	2001	2002	2003(2)
	(In thousands)			
Consolidated Balance Sheet Data:				
Cash and cash equivalents	$ 5,317	$ 68,444	$ 62,604	$ 88,542
Working capital	4,966	66,568	60,891	86,539
Total assets	6,055	70,278	80,847	145,473
Convertible notes				13,374
Other long-term liabilities			190	8,144
Redeemable convertible preferred stock	10,312	87,790	135,987	
Accumulated deficit	(4,590)	(19,697)	(62,950)	(120,559)
Total stockholders equity (deficit)	(4,709)	(19,783)	(62,216)	104,914

(1) We acquired Laphal Développement S.A. on March 25, 2003 and its operations are included in our results since that date.

(2) In November 2003 we completed our initial public offering, raising $76.2 million in net proceeds to us through the issuance of 6,000,000 shares of common stock. Concurrent with effective date of the IPO, all outstanding shares of our redeemable convertible preferred stock were converted into 17,030,956 shares of our common stock.

Item 7. ***Management s Discussion and Analysis of Financial Condition and Results of Operations***

Overview

Our goal is to create a global pharmaceutical company focused on in-licensing, developing and commercializing therapeutic products for the treatment of hematology and oncology patients. We were formed in August 1999 and commenced operations in January 2000 with the completion of our first round of equity financing. To date, we have licensed the rights to four products on either a global or regional basis. Two of these products are approved for marketing and are being sold by us, one in the U.S. and the second in Europe and Australia. The other two products are in registration, one of which has been approved for marketing in Australia and New Zealand and which we are currently selling in Europe on a compassionate use or named patient basis while we pursue full regulatory marketing approval.

Our operations focus on the clinical development of our late-stage product candidates and seeking regulatory marketing approvals for those products in the U.S., Europe, Australia and certain other countries in our licensed territories, and sales and marketing activities for our marketed products, primarily in the U.S., Europe and Australia. We began generating revenues from product sales in July 2002.

Since our inception we have generated significant losses. At December 31, 2003 our accumulated deficit was $120.6 million. We expect to continue to spend significant amounts on the development and sales and marketing of our existing products in 2004 and thereafter. In 2004, we plan on increasing our sales and marketing expenses to support the expected increase in sales of thalidomide and the anticipated launch of Vidaza in the U.S., subject to receiving FDA approval of our Vidaza NDA. We also plan to continue to invest in clinical studies to expand the use of thalidomide and to complete the Vidaza confirmatory trial. Additionally, we plan to continue to evaluate possible acquisitions of development-stage or approved products that would fit within our growth strategy. Accordingly, we will need to generate significantly greater revenues to achieve and then maintain profitability.

Most of our expenditures to date have been for clinical and development activities and selling, general and administrative expenses. Clinical and development expenses represent costs incurred for clinical trials and data analysis, activities related to regulatory filings and manufacturing development efforts. We outsource our clinical trials and manufacturing development activities to independent organizations to maximize efficiency and minimize our internal overhead. We expense our clinical and development costs as they are incurred.

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Selling, general and administrative expenses consist primarily of salaries and related expenses, general corporate activities and costs associated with promotion and marketing activities worldwide.

Acquisition

In March 2003, we acquired all the outstanding stock of Gophar S.A.S., the parent company of Laphal. Laphal is a French pharmaceutical company focused on the sale of orphan drugs in France and Belgium, including its own formulation of thalidomide. We paid cash in the amount of 12.3 million at closing. Two additional payments of 4.0 million each will be paid if certain aggregate sales targets are achieved. Operating results for Laphal after the date of acquisition are included in our consolidated financial results for the year ended December 31, 2003.

Critical Accounting Policies

Revenue Recognition

We sell our products to wholesale distributors and directly to hospitals, clinics, and retail pharmacies. Revenue from product sales is recognized when ownership of the product is transferred to our customer, the sales price is fixed and determinable, and collectibility is reasonably assured. Within the U.S. and certain foreign countries revenue is recognized upon shipment (freight on board shipping point) since title passes and the customers have assumed the risks and rewards of ownership. In certain other foreign countries it is common practice that ownership transfers upon receiving the product and, accordingly, in these circumstances revenue is recognized upon delivery (freight on board destination) when title effectively transfers.

We report revenue net of allowances for distributor chargebacks, product returns, rebates, and prompt-pay discounts. Significant estimates are required in determining such allowances and are based on historical data, industry information, and information from customers. If actual results are different from our estimates, we adjust the allowances in the period the difference becomes apparent.

Certain governmental health insurance providers as well as hospitals and clinics that are members of group purchasing organizations may be entitled to price discounts and rebates on the Company s products used by those organizations and their patients. When we record sales, we estimate the likelihood that products sold to wholesale distributors will ultimately be subject to a rebate or price discount and book our sales net of estimated discounts. This estimate is based on historical trends and industry data on the utilization of the Company s products.

Inventories

Inventories are stated at the lower of cost or market, cost being determined under the first-in, first-out method. We periodically review inventories and items considered outdated or obsolete are reduced to their estimated net realizable value. We estimate reserves for excess and obsolete inventories based on inventory levels on hand, future purchase commitments, product expiration dates and current and forecasted product demand. If an estimate of future product demand suggests that inventory levels are excessive, then inventories are reduced to their estimated net realizable value.

Long-Lived Assets

Our long-lived assets consist primarily of product rights and property and equipment. We estimate the useful lives of our long-term assets based on the period of time over which we expects to receive economic benefit. These estimates are based on industry information and product forecasts. In accordance with Statement of Financial Accounting Standards No. 144 (SFAS 144), *Accounting for the Impairment or Disposal of Long-Lived Assets,* we evaluate our ability to recover the carrying value of long-lived assets used in our business, considering changes in the business environment or other facts and circumstances that suggest their value may be impaired. If this evaluation indicates the carrying value will not be recoverable, based on the undiscounted expected future cash flows estimated to be generated by these assets, we reduce the carrying amount to the estimated fair value.

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Results of Operations

Comparison of Years Ended December 31, 2003, 2002 and 2001

Our operating activities in 2001 were limited as compared to 2002 and 2003 as we were focused on identifying and acquiring products during 2001 as well as hiring employees and establishing our corporate infrastructure. We began generating revenue from product sales in July 2002 following the acquisition of commercial rights to Refludan® and Innohep®.

Net sales. Net sales totaled $25.5 million for the year ended December 31, 2003 as compared to $4.7 million for the year ended December 31, 2002. Net sales included $3.8 million and $2.1 million in the U.S. and $21.7 million and $2.6 million in Europe and other countries for the years ended December 31, 2003 and 2002, respectively. The net sales growth in 2003 was due primarily to sales of thalidomide, which totaled $15.6 million for the year ended December 31, 2003. We began selling thalidomide in France and Belgium in April 2003 following our acquisition of Laphal. In July 2003, we began selling thalidomide on a compassionate use or named patient basis in additional countries in Europe. The remaining increase in sales in 2003 is due to the fact that Refludan and Innohep were sold by us for a partial year in 2002 compared to the full year of 2003.

Cost of sales. Cost of sales for the year ended December 31, 2003 totaled $11.5 million compared to $1.6 million for the year ended December 31, 2002. Cost of sales reflects the cost of product sold, royalties due on the sales of our products and the logistics costs related to selling our products. Our gross margin for the year ended December 31, 2003 was 55% as compared to 67% for 2002. Cost of sales for 2003 included two charges totaling $2.1 million which reduced our gross margin for this period by 8 percentage points. One of the charges totaled $.3 million and resulted from a retroactive adjustment to the cost of Refludan® sold in 2002. Under our supply agreement for Refludan®, the manufacturer is entitled to an adjustment to the cost of product supplied based on differences between estimated and actual volumes of Refludan® product supply purchased by us during the year. We were notified of the 2002 price adjustment in the second quarter of 2003 and, as a result, recorded the charge in 2003. The second charge recorded in 2003 was a $1.8 million charge to write-off the carrying value of obsolete or short-dated Refludan® inventory.

Clinical, development and regulatory expenses. Clinical, development and regulatory expenses increased from $6.0 million in 2001, to $15.0 million in 2002, and to $24.6 million in 2003. These expenses consist primarily of salaries and benefits, contractor fees, principally with organizations assisting us with our clinical development programs, and license fees for drugs in development. Generally, the increases in these expenses were due to the in-licensing of products in 2001 and 2002, particularly Thalidomide Pharmion 50 mg and azacitidine. Under our license agreements, we are responsible for all remaining development and regulatory costs for both of these products. Although clinical studies for both products were complete at the time we acquired the drugs, we have incurred and expect to continue to incur significant costs analyzing and auditing the data from these studies and initiating additional clinical studies for the products. In addition, we have increased our staffing significantly over the past two years to support the regulatory and development activities for all of our products. Of the $9.6 million increase in clinical, development and regulatory expenses in 2003, $3.7 million was due to increased salaries and benefits expenses and other non-product related costs. In 2003 we spent approximately $16.8 million on azacitidine and thalidomide development, primarily for clinical programs, analysis of data from previously completed Phase III studies, manufacturing and formulation development, pursuing regulatory authorizations to sell thalidomide in Europe on a compassionate use and named patient basis, and establishing a medical safety, education and distribution system to support our thalidomide sales. This represented an increase of $5.8 million over product development expenses in 2002.

Of the $9.0 million increase in clinical, development and regulatory expenses in 2002 over 2001, $1.3 million was due to increased salaries and benefits expenses. In 2002 we spent approximately $11.0 million on product development or an increase of $7.4 million over product development expenses in 2001.

Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, the cost to complete projects in development is not reasonably estimable. Results from clinical trials may not be favorable. Further, data from clinical trials is subject to varying interpretation, and may be deemed

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insufficient by the regulatory bodies reviewing applications for marketing approvals. As such, clinical development and regulatory programs are subject to risks and changes that may significantly impact cost projections and timelines.

Selling, general and administrative expenses. Selling, general and administrative expenses increased from $8.3 million in 2001, to $23.4 million in 2002, and to $36.1 million in 2003. Selling expenses include salaries and benefits for sales and marketing personnel, advertising and promotional programs, professional education programs and facility costs for our sales offices located throughout Europe, and in Thailand and Australia. General and administrative expenses include salaries and benefits for corporate staff, outside legal, tax and auditing services, and corporate facility and insurance costs.

Sales and marketing expenses totaled $20.8 million for 2003, an increase of $9.7 million over 2002. In the second half of 2002 and the first half of 2003, following the in-licensing of Refludan® and Innohep®, we began establishing our sales organizations in the U.S., Europe, and Australia and expanded our marketing staffing to support the commercialization of these products. This resulted in a $9.5 million increase in personnel related expenses, including salaries, benefits and travel, for the year ended December 2003 over 2002. Significant product marketing costs totaling $5.4 million were incurred to launch Refludan® and Innohep® in 2002, resulting in only a slight increase of $.2 million to on-going product related marketing costs in 2003.

Sales and marketing expenses increased $9.0 million from 2001 to $11.1 million in 2002. This increase reflects the growth of our sales organizations worldwide in 2002 as well as the marketing programs for the products licensed in 2002.

General and administrative expenses totaled $15.3 million for the year ended December 31, 2003, an increase of $3.0 million over 2002. The increase in 2003 of general and administrative expenses was due primarily to increased salaries, benefits and travel costs resulting from personnel hired to expand our corporate infrastructure and to support the additional responsibilities of becoming a public company. Of the $3.0 million increase, $1.9 million relates to facility and depreciation expenses, $.7 million to corporate staffing to support our business growth, $.8 million to product liability and directors and officers insurance costs, partially offset by a decrease of $.4 million in other corporate expenses.

General and administrative expenses increased by $6.0 million from 2001 to a total of $12.3 million in 2002. Of this increase, $2.6 million relates to increased personnel-related costs, $1.1 million to increased facility costs, and $1.8 million to increased tax, audit, legal and insurance costs. This growth in expenses resulted from increased corporate activities to support the in-licensing of our four products and the establishment of our commercial infrastructure.

We expect selling, general and administrative expenses to continue to increase in future years as we expand our U.S. and European sales forces to support the launch of products currently in development. While the dollar amount of selling, general and administrative expenses will increase, we expect these expenses as a percentage of net sales to decline as our sales volume increases.

Product rights amortization. Product rights amortization totaled $2.0 million for the year ended December 31, 2003, an increase of $1.6 million over 2002. The increase in 2003 is due primarily to the amortization of product rights acquired through the March 2003 acquisition of Laphal and the renegotiation of the financial terms of the Refludan rights acquired from Schering in August 2003. Product rights amortization totaled $.4 million in 2002, which related to the acquisition of product licenses during 2002. We did not have any product rights amortization for 2001 since we did not acquire our first product until 2002.

Interest and other income (expense), net. Interest and other income (expense), net, totaled ($.2) million for the year ended December 31, 2003, a decrease of $1.3 million from 2002. This decrease is primarily due to an increase in interest expense related to the $14 million 6% convertible notes issued in April 2003. Interest and other income (expense), net increased by $.5 million in 2002 over 2001 reflecting an increase in interest income on higher cash balances due to the sale of preferred stock in the fourth quarters of both 2001 and 2002.

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Income tax expense. Income tax expense totaled $1.3 million for the year ended December 31, 2003, an increase of $1.2 million over 2002. This increase in income tax expense is due primarily to additional capital-based taxes in certain jurisdictions, taxable income generated by Laphal acquired in March 2003, and an increase in the taxable income in the United Kingdom due to intercompany management fees earned for services provided to other foreign subsidiaries. We did not incur any income tax expense during 2001.

Liquidity and Capital Resources

Since our inception, we have incurred significant losses and as of December 31, 2003, we had an accumulated deficit of $120.6 million. We have not yet achieved profitability, and anticipate that we will continue to incur net losses for the foreseeable future. We expect that our regulatory and development and selling, general and administrative expenses will continue to grow and, as a result, we will need to generate significant net sales to achieve profitability. To date, our operations have been funded with proceeds from the sale of preferred stock, the issuance of convertible notes, and the sale of common shares in our initial public offering. Net proceeds from our preferred stock sales totaled $125.0 million, the issuance of convertible notes generated $14.0 million, and our initial public offering in November 2003 resulted in net proceeds of $76.2 million. We began generating revenue from product sales in July 2002.

Cash and cash equivalents increased from $62.6 million at December 31, 2002 to $88.5 million at December 31, 2003. This increase in cash is primarily due to the receipt of the net proceeds from our initial public offering of $76.2 million plus $14.0 million of proceeds from the issuance of convertible notes offset by cash used to fund operations of $47.7 million, purchases of property and equipment of $2.5 million, and net cash of $12.3 million used to acquire Laphal. Cash and cash equivalents decreased $5.8 million from December 31, 2001 to December 31, 2002. This net decrease was due to cash used to fund our 2002 operations of $35.1 million, capital expenditures of $2.9 million , and product acquisition payments totaling $8.0 million. These uses of cash were largely offset by $39.7 million in net proceeds from the sale of preferred stock in the fourth quarter of 2002.

We expect that our cash on hand at December 31, 2003, along with cash generated from expected product sales, will be adequate to fund our operations for at least the next twelve months. In the event that we make additional product acquisitions, we expect that we will need to raise additional funds. Further, until we can generate sufficient cash from product sales, we expect to finance our operations through cash on hand plus proceeds from the sale of equity or debt securities. Adequate funds, either from the financial markets or other sources may not be available when needed or on terms acceptable to us. Insufficient funds may cause us to delay, reduce the scope of, or eliminate one or more of our planned development, commercialization or expansion activities. Our future capital needs and the adequacy of our available funds will depend on many factors, including the effectiveness of our sales and marketing activities, the cost of clinical studies and other actions needed to obtain regulatory approval of our products in development, and the timing and cost of any product acquisitions.

Contractual Obligations

Our contractual obligations as of December 31, 2003 were as follows:

Contractual Obligations	Total	Less Than 1 Year	1-3 Years	4-5 Years	More Than 5 Years
			(In millions)		
Convertible notes	$14.0	$	$	$14.0	$
Product and company acquisition payments	8.0	4.0	4.0		
Product royalty payments	19.4	7.3	12.1		
Long-term debt obligations	0.7	0.3	0.4		
Clinical development funding	5.0	3.0	2.0		
Operating leases	7.1	2.2	3.4	1.5	
Inventory purchase commitments	1.8	1.8			
Total fixed contractual obligations	$56.0	$18.6	$21.9	$15.5	$

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Convertible notes. In April 2003, we issued $14 million of 6% convertible notes due April 2008. On March 1, 2004, holders of the notes elected in accordance with the terms of the notes, to convert all $14 million of convertible notes plus accrued interest thereon into 1,342,170 shares of the Company s common stock.

Product and company acquisition payments. We have future payment obligations associated with our acquisition of Laphal and our licensing of Refludan®. Certain of these payments are fixed and determinable while the timing and amount of others are contingent upon future events such as achieving revenue milestones. Under the terms of our agreements with Schering, we agreed to make an aggregate of $10.0 million of fixed payments to Schering, payable in quarterly installments of $1.0 million through the end of 2005 and a royalty of 14% of our net sales commencing in January 2004 and up to $7.5 million of contingent payments described below.

Product royalty payments. Pursuant to our thalidomide product license agreements with Celgene and Penn T Limited, we are required to make additional quarterly payments to the extent that the royalty and license payments due under those agreements do not meet certain minimums. These minimum royalty and license payment obligations expire the earlier of 2006 or the date we obtain regulatory approval to market thalidomide in the E.U. The amounts reflected in the summary above represent the minimum amounts due under these agreements.

Clinical development funding. We have entered into an agreement with Celgene to provide funding to support clinical development studies sponsored by Celgene studying thalidomide as a treatment for various types of cancers. Under our agreement, we will pay Celgene $3.0 million in 2004 and $2.0 million in 2005.

Operating leases. Our commitment for operating leases relates to our corporate and sales offices located in the U.S., Europe, Thailand and Australia. These leases expire on various dates through 2011.

Contingent product and company acquisition payments. The contractual summary above reflects only payment obligations for product and company acquisitions that are fixed and determinable. We also have contractual payment obligations, the amount and timing of which are contingent upon future events. In accordance with generally accepted accounting principles, contingent payment obligations are not recorded on our balance sheet until the amount due can be reasonably determined. Under the agreements with Schering, in addition to the $10.0 million of fixed payments required, payments totaling up to $7.5 million are due if milestones relating to revenue and gross margin targets for Refludan® are achieved. The terms of our Laphal acquisition require two additional payments of 4 million each, or an aggregate of $10.0 million based on foreign currency exchange rates as of December 31, 2003, if Laphal s products achieve future revenue milestones.

Inventory purchase commitments. The contractual summary above includes contractual obligations related to our supply contracts. Under these contracts, we provide our suppliers with rolling 12-24 month supply forecasts, with the initial 3-6 month periods representing binding purchase commitments.

Factors Affecting Our Business Conditions

In addition to the other information included in this report, the following factors should be considered in evaluating our business and future prospects:

We have a history of net losses, and may not achieve or maintain profitability.

We have incurred net losses since our inception, including a net loss of $50.1 million for the year ended December 31, 2003. As of December 31, 2003, we had an accumulated deficit of $120.6 million. We expect to make substantial expenditures to further develop and commercialize our products, including costs and expenses associated with completing clinical trials, seeking regulatory approvals and marketing of our products. We will need to generate significantly greater revenues to achieve and then maintain profitability. As a result, we are unsure when we will become profitable, if at all. If we fail to achieve profitability within the time frame expected by investors or securities analysts, the market price of our common stock may decline.

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We have a limited operating history.

We have a limited operating history. Accordingly, you must consider our prospects in light of the risks and difficulties encountered by companies in the early stage of development. As an early-stage company, we have yet to fully prove our business plan. We have not yet achieved full regulatory approval for Thalidomide Pharmion 50mg or Vidaza, and our revenues to date from sales of our products have not been significant.

We may not receive regulatory approvals for Thalidomide Pharmion 50mg or Vidaza or approvals may be delayed.

Our ability to fully commercialize Thalidomide Pharmion 50mg is subject to regulatory approval by governmental authorities in Europe and our other markets, while our ability to commercialize Vidaza is subject to regulatory approval by governmental authorities in the U.S., Europe and elsewhere. We cannot assure you that the results of the clinical trials conducted, we intend to conduct or we are required to conduct for Thalidomide Pharmion 50mg and Vidaza will support our applications for regulatory approval. The timing of our submissions, the outcome of reviews by the applicable regulatory authorities in each relevant market, and the initiation and completion of clinical trials are subject to uncertainty, change and unforeseen delays. Moreover, favorable results in later stage clinical trials do not ensure regulatory approval to commercialize a product. Some companies that have believed their products performed satisfactorily in clinical trials have nonetheless failed to obtain regulatory approval of their products. We will not be able to market Thalidomide Pharmion 50mg or Vidaza in any country where the drug is not approved, and if Thalidomide Pharmion 50mg or Vidaza is not approved for sale in any market where we have acquired rights to the product, we will only be able to sell it in such market, if at all, on a compassionate use or named patient basis, which may limit sales and revenues.

Thalidomide s history of causing birth defects may prevent it from becoming commercially successful.

At the time thalidomide first came on the market in the late 1950 s and into the early 1960 s, it was not known that the drug could cause birth defects in babies born to women who had taken the drug while pregnant. Although no proper census was ever taken, it has been estimated that there were between 10,000 and 20,000 babies born with birth defects as a result of thalidomide. The majority of these births were in the U.K. and Germany, two of our largest target markets for sales of Thalidomide Pharmion 50mg. As a result, thalidomide s historical reputation in our target markets may present a substantial barrier to its market acceptance. Thalidomide s potential for causing severe birth defects and its negative historical reputation may limit the extent of its market acceptance among both doctors and patients, despite the efficacy that it has been proven to have in patients afflicted with a number of different diseases. In addition, any report of a birth defect attributed to the current use of thalidomide could result in a material decrease in our sales of thalidomide, and may result in the forced withdrawal of thalidomide from the market.

We may not be able to obtain sufficient product liability insurance on commercially reasonable terms or with adequate coverage for Thalidomide Pharmion 50mg.

Historically, the vast majority of product liability insurers have been unwilling to write any product liability coverage for thalidomide. Although we currently have product liability coverage for Thalidomide Pharmion 50mg that we believe is appropriate, if our sales of this product grow in the future, our current coverage may be insufficient. We may be unable to obtain additional coverage on commercially reasonable terms if required, or our coverage may be inadequate to protect us in the event claims are asserted against us. In addition, we might be unable to renew our existing level of coverage if there were a report of a birth defect attributable to the current use of thalidomide, whether or not sold by us.

If we breach any of the agreements under which we license commercialization rights to products or technology from others, we could lose license rights that are important to our business.

We license commercialization rights to products and technology that are important to our business, and we expect to enter into similar licenses in the future. For instance, we acquired our first four products through

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exclusive licensing arrangements. Under these licenses we are subject to commercialization and development, sublicensing, royalty, insurance and other obligations. If we fail to comply with any of these requirements, or otherwise breach these license agreements, the licensor may have the right to terminate the license in whole or to terminate the exclusive nature of the license. In particular, if we fail to obtain the required regulatory approvals to market and sell thalidomide in the U.K. by November 2006, Celgene Corporation has the right to terminate their license agreement with us on thirty days notice. Loss of any of these licenses or the exclusivity rights provided therein could harm our financial condition and operating results.

Our failure to successfully acquire, develop and market additional product candidates or approved products would impair our ability to grow.

As part of our growth strategy, we intend to acquire, develop and market additional products and product candidates. Because we neither have, nor currently intend to establish, internal research capabilities, we are dependent upon pharmaceutical and biotechnology companies and other researchers to sell or license products to us. The success of this strategy depends upon our ability to identify, select and acquire the right pharmaceutical product candidates and products. To date, we have in-licensed rights to four products, and our only product acquisitions have been those associated with our acquisition of Laphal.

Any product candidate we license or acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA, and applicable foreign regulatory authorities. All product candidates are prone to the risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure you that any products that we develop or acquire that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace.

Proposing, negotiating and implementing an economically viable acquisition is a lengthy and complex process. Other companies, including those with substantially greater financial, marketing and sales resources, may compete with us for the acquisition of product candidates and approved products. We may not be able to acquire the rights to additional product candidates and approved products on terms that we find acceptable, or at all.

Even if U.S. and European regulatory authorities approve Vidaza for the treatment of the diseases we are targeting, Vidaza may not be commercially successful.

Even if Vidaza receives regulatory approval, patients and physicians may not readily accept it, which would limit its sales. Acceptance will be a function of Vidaza being clinically useful and demonstrating superior therapeutic effect with an acceptable side effect profile as compared to currently existing or future treatments. In addition, even if Vidaza does achieve market acceptance, we may not be able to maintain that market acceptance over time if new products are introduced that are more favorably received than Vidaza or render Vidaza obsolete.

We face substantial competition, which may result in others commercializing competing products before or more successfully than we do.

Our industry is highly competitive. Our success will depend on our ability to acquire, develop and commercialize products and our ability to establish and maintain markets for our products. Potential competitors in North America, Europe and elsewhere include major pharmaceutical companies, specialized pharmaceutical companies and biotechnology firms, universities and other research institutions. Many of our competitors have substantially greater research and development capabilities and experience, and greater manufacturing, marketing and financial resources, than we do. Accordingly, our competitors may develop or license products or other novel technologies that are more effective, safer or less costly than our existing products or products that are being developed by us, or may obtain regulatory approval for products before we do. Clinical development by others may render our products or product candidates noncompetitive.

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Other pharmaceutical companies may develop generic versions of our products that are not subject to patent protection or otherwise subject to orphan drug exclusivity or other proprietary rights. Governmental and other pressures to reduce pharmaceutical costs may result in physicians writing prescriptions for these generic products. Increased competition from the sale of competing generic pharmaceutical products could cause a material decrease in revenue from our products.

The primary competition for our products currently are:

Thalidomide Pharmion 50mg: Velcade™, from Millenium Pharmaceuticals Inc., and Revlimid™, from Celgene Corporation;

Vidaza: Thalomid® and Revlimid™, each from Celgene, and Decitabine, from Supergen Inc.;

Innohep®: Lovenox®, from Aventis, and Fragmin®, from Pharmacia Corporation; and

Refludan®: Argatroban, from GlaxoSmithKline plc.

If the third party manufacturers upon whom we rely fail to produce our products in the volumes that we require on a timely basis, or to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the commercialization of, or be unable to meet demand for, our products and may lose potential revenues.

We do not manufacture any of our products or product candidates and we do not plan to develop any capacity to do so. We have contracted with third-party manufacturers to manufacture each of our four products. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, especially in scaling up initial production. These problems include difficulties with production costs and yields, quality control and assurance and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Our third-party manufacturers may not perform as agreed or may terminate their agreements with us.

We do not have alternate manufacturing plans in place at this time. The number of third-party manufacturers with the expertise, required regulatory approvals and facilities to manufacture bulk drug substance on a commercial scale is extremely limited, and it would take a significant amount of time to arrange for alternative manufacturers. If we need to change to other commercial manufacturers, the FDA and comparable foreign regulators must approve these manufacturers facilities and processes prior to our use, which would require new testing and compliance inspections, and the new manufacturers would have to be educated in or independently develop the processes necessary for the production of our products.

Any of these factors could cause us to delay or suspend clinical trials, regulatory submissions, required approvals or commercialization of our products or product candidates, entail higher costs and result in our being unable to effectively commercialize our products. Furthermore, if our third-party manufacturers failed to deliver the required commercial quantities of bulk drug substance or finished product on a timely basis and at commercially reasonable prices, and we were unable to promptly find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volume and on a timely basis, we would likely be unable to meet demand for our products and we would lose potential revenues.

Our failure to raise additional funds in the future may affect the development and sale of our products.

Our operations to date have generated substantial and increasing needs for cash. Our negative cash flows from operations are expected to continue for at least the next 24 months. The development and approval of our product candidates and the acquisition and development of additional products or product candidates by us, as well as the expansion of our sales, marketing and regulatory organizations, will require a commitment of substantial funds. Our future capital requirements are dependent upon many factors and may be significantly greater than we expect.

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We believe, based on our current operating plan, including anticipated sales of our products, that our cash, cash equivalents and marketable securities as of December 31, 2003 will be sufficient to fund our operations for at least the next twelve months. If our existing resources are insufficient to satisfy our liquidity requirements due to slower than anticipated sales of our products or otherwise, or if we acquire additional products or product candidates, we may need to sell additional equity or debt securities. If we are unable to obtain this additional financing, we may be required to delay, reduce the scope of, or eliminate one or more of our planned development, commercialization or expansion activities, which could harm our financial condition and operating results.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on our senior management, especially Patrick J. Mahaffy, our President and Chief Executive Officer, and Judith A. Hemberger, our Executive Vice President and Chief Operating Officer, whose services are critical to the successful implementation of our product acquisition, development and regulatory strategies. If we lose their services or the services of one or more of the other members of our senior management or other key employees, our ability to successfully implement our business strategy could be seriously harmed. We are not aware of any present intention of any of these individuals to leave our company. We do not maintain key person life insurance on any of the members of our senior management. Replacing key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel.

Our sales of Refludan® may be limited as a result of concerns about its safety.

In September 2002, following guidance from the EMEA, Schering AG, from whom we license Refludan®, issued a warning letter to doctors in Germany regarding the incidence of anaphylaxis, a severe allergic reaction, in approximately a dozen patients treated with Refludan® in both the U.S. and Europe, five of which cases resulted in fatalities. Although the possibility of anaphylaxis from Refludan® is a known possible reaction and is indicated in the product s label, the occurrences referenced in the warning letter appeared to be at a higher frequency than had previously been reported. We believe that the growth potential for sales of Refludan® was negatively impacted by the issuance of the warning letter, and that as a result sales may not increase above their current levels.

We have only limited patent protection for our current products, and we may not be able to obtain, maintain and protect proprietary rights necessary for the development and commercialization of our products or product candidates.

Our commercial success will depend in part on obtaining and maintaining a strong proprietary position for our products both in the U.S., Europe and elsewhere. Of our four current products, only Thalidomide Pharmion 50mg and Refludan® currently have any patent protection under issued patents. As a result, we must rely in large part on orphan drug exclusivity, trade secrets, process patents, know-how and continuing technological innovations to protect our intellectual property and to enhance our competitive position. Even if we are granted orphan drug exclusivity, competitors are not prohibited from developing or marketing different drugs for an indication. As a result, the competitive advantage gained by orphan drug exclusivity can be overcome by other products. Until we are granted a marketing authorization, while we are selling Thalidomide Pharmion 50mg on a compassionate use and named patient basis, we do not have orphan drug exclusivity, which means competitors may sell thalidomide in our markets. In particular, we are aware of a company based in Switzerland that is seeking to sell thalidomide in certain of our markets without a risk management program.

We also rely on protection derived from trade secrets, process patents, know-how and technological innovation. To maintain the confidentiality of trade secrets and proprietary information, we generally seek to

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enter into confidentiality agreements with our employees, consultants and collaborators upon the commencement of a relationship with us. However, we may not obtain these agreements in all circumstances. In addition, adequate remedies may not exist in the event of unauthorized use or disclosure of this information. The loss or exposure of our trade secrets, know-how and other proprietary information could harm our operating results, financial condition and future growth prospects. Furthermore, others may have developed, or may develop in the future, substantially similar or superior know-how and technology.

We intend to seek patent protection whenever it is available for any products or product candidates we acquire in the future. However, any patent applications for future products may not issue as patents, and any patent issued on such products may be challenged, invalidated, held unenforceable or circumvented. Furthermore, the claims in patents which have been issued on products we may acquire in the future may not be sufficiently broad to prevent third parties from commercializing competing products. In addition, the laws of various foreign countries in which we compete may not protect the intellectual property on which we may rely to the same extent as do the laws of the U.S. If we fail to obtain adequate patent protection for our products, our ability to compete could be impaired.

Fluctuations in our operating results could affect the price of our common stock.

Our operating results may vary significantly from period to period due to many factors, including the amount and timing of sales of our products, the availability and timely delivery of a sufficient supply of our products, the timing and expenses of preclinical and clinical trials, announcements regarding clinical trial results and product introductions by us or our competitors, the availability and timing of third-party reimbursement and the timing of regulatory submissions and approvals. If our operating results do not match the expectations of securities analysts and investors as a result of these and other factors, the trading price of our common stock will likely decrease.

We may undertake acquisitions in the future and any difficulties from integrating such acquisitions could damage our ability to attain or maintain profitability.

We may acquire additional businesses, products or product candidates that complement or augment our existing business. To date, our only experience in acquiring and integrating a business involved our acquisition of Laphal in March 2003. Integrating any newly acquired business or product could be expensive and time-consuming. We may not be able to integrate any acquired business or product successfully or operate any acquired business profitably. Moreover, we may need to raise additional funds through public or private debt or equity financing to make acquisitions, which may result in dilution for stockholders and the incurrence of indebtedness.

Our business is subject to economic, political, regulatory and other risks associated with international sales and operations.

Since we sell our products in Europe, Australia and many additional countries, our business is subject to risks associated with conducting business internationally. We anticipate that revenue from international operations will continue to represent a substantial portion of our total revenue. In addition, a number of our suppliers are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

difficulties in compliance with foreign laws and regulations;

changes in foreign regulations and customs;

changes in foreign currency exchange rates and currency controls;

changes in a specific country s or region s political or economic environment;

trade protection measures, import or export licensing requirements or other restrictive actions by the U.S. or foreign governments;

negative consequences from changes in tax laws;

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difficulties associated with staffing and managing foreign operations;

longer accounts receivable cycles in some countries; and

differing labor regulations.

Risks Related to Our Industry

Our ability to generate revenue from our products will depend on reimbursement and drug pricing policies and regulations.

Our ability to achieve acceptable levels of reimbursement for drug treatments by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize, and attract collaborative partners to invest in the development of, product candidates. We cannot be sure that reimbursement in the U.S., Europe or elsewhere will be available for any products we may develop or, if already available, will not be decreased or eliminated in the future. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products, and may not be able to obtain a satisfactory financial return on our products.

Third-party payers increasingly are challenging prices charged for medical products and services. Also, the trend toward managed health care in the U.S. and the changes in health insurance programs, as well as legislative proposals to reform health care or reduce government insurance programs, may result in lower prices for pharmaceutical products, including any products that may be offered by us. Cost-cutting measures that health care providers are instituting, and the effect of any health care reform, could harm our ability to sell any products that are successfully developed by us and approved by regulators. Moreover, we are unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect this legislation or regulation would have on our business. In the event that governmental authorities enact legislation or adopt regulations which affect third-party coverage and reimbursement, demand for our products may be reduced thereby harming our sales and profitability.

If product liability lawsuits are brought against us, we may incur substantial liabilities.

The clinical testing and commercialization of pharmaceutical products involves significant exposure to product liability claims. If losses from such claims exceed our liability insurance coverage, we may incur substantial liabilities. Whether or not we were ultimately successful in product liability litigation, such litigation could consume substantial amounts of our financial and managerial resources, and might result in adverse publicity, all of which would impair our business. We may not be able to maintain our clinical trial insurance or product liability insurance at an acceptable cost, if at all, and this insurance may not provide adequate coverage against potential claims or losses. If we are required to pay a product liability claim, we may not have sufficient financial resources to complete development or commercialization of any of our product candidates and our business and results of operations will be harmed.

If our promotional activities fail to comply with the regulations and guidelines of the various relevant regulatory agencies, we may be subject to warnings or enforcement action that could harm our business.

Physicians may prescribe drugs for uses that are not described in the product s labeling for uses that differ from those tested in clinical studies and approved by the FDA or similar regulatory authorities in other countries. These off-label uses are common across medical specialties and may constitute the best treatment for many patients in varied circumstances. Regulatory authorities generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications on the subject of off-label use. Companies cannot actively promote approved drugs for off-label uses, but in some countries outside of the E.U. they may disseminate to physicians articles published in peer-reviewed journals, like *The New England Journal of Medicine* and *The Lancet*, that discuss off-label uses of approved products. To the extent allowed, we may disseminate peer-reviewed articles on our products to our physician customers. We believe our promotional activities are currently in compliance with the regulations and guidelines of the

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various regulatory authorities. If, however, our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. Furthermore, if the discussion of off-label use in peer-reviewed journals, or the dissemination of these articles, is prohibited, it may harm demand for our products.

We are subject to numerous complex regulatory requirements and failure to comply with these regulations, or the cost of compliance with these regulations, may harm our business.

The testing, development and manufacturing of our products are subject to regulation by numerous governmental authorities in the U.S., Europe and elsewhere. These regulations govern or affect the testing, manufacture, safety, labelling, storage, record-keeping, approval, advertising and promotion of our products and product candidates, as well as safe working conditions and the experimental use of animals. Noncompliance with any applicable regulatory requirements can result in refusal of the government to approve products for marketing, criminal prosecution and fines, recall or seizure of products, total or partial suspension of production, prohibitions or limitations on the commercial sale of products or refusal to allow us to enter into supply contracts. Regulatory authorities typically have the authority to withdraw approvals that have been previously granted.

The regulatory requirements relating to the manufacturing, testing, and marketing of our products may change from time to time. For example, at present, member states in the E.U. are in the process of incorporating into their domestic laws the provisions contained in the E.U. Directive on the implementation of good clinical practice in the conduct of clinical trials. The Directive imposes more onerous requirements in relation to certain aspects of the conduct of clinical trials than are currently in place in many member states. This may impact our ability to conduct clinical trials and the ability of independent investigators to conduct their own research with support from us. In addition, the E.U. rules concerning the authorization of medicinal products are in the process of being amended. We do not expect the new rules to apply until 2005. The final rules are not yet available and as such the impact on our business cannot be known at this time.

Risks Related to Our Common Stock

If a significant number of shares of our common stock are sold into the market, the market price of our common stock could significantly decline, even if our business is doing well.

Our employees, officers and directors may elect to sell their shares of our common stock or exercise their stock options in order to sell the stock underlying their options in the market. Sales of a substantial number of shares of our common stock in the public market could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities. Officers, directors and stockholders owning an aggregate of approximately 17.9 million shares, have agreed, subject to exceptions, that they will not, without the prior written consent of the underwriters, directly or indirectly sell any of these shares, or exercise any of their options and warrants prior to May 4, 2004, which is 180 days after the effective date of our initial public offering, but these agreements can be waived by the underwriters in their sole discretion

Our certificate of incorporation, our bylaws and Delaware law contain provisions that could discourage, delay or prevent a change in control or management of Pharmion.

Our amended and restated certificate of incorporation and bylaws contain provisions which could delay or prevent a third party from acquiring shares of our common stock or replacing members of our board of directors, each of which certificate of incorporation provisions can only be amended or repealed upon the consent of 80% of our outstanding shares. Our amended and restated certificate of incorporation allows our board of directors to issue up to 10,000,000 shares of preferred stock. The board can determine the price, rights, preferences and privileges of those shares without any further vote or action by the stockholders. As a result, our board of directors could make it difficult for a third party to acquire a majority of our outstanding voting stock, for example by adopting a stockholders rights plan.

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Our amended and restated certificate of incorporation also provides that the members of the board are divided into three classes. Each year the terms of approximately one-third of the directors will expire. Our bylaws do not permit our stockholders to call a special meeting of stockholders. Under the bylaws, only our Chief Executive Officer, Chairman of the Board or a majority of the board of directors are able to call special meetings. The staggering of directors terms of office and the limitation on the ability of stockholders to call a special meeting may make it difficult for stockholders to remove or replace the board of directors should they desire to do so. Since management is appointed by the board of directors, any inability to effect a change in the board may result in the entrenchment of management. The bylaws also require that stockholders give advance notice to our Secretary of any nominations for director or other business to be brought by stockholders at any stockholders meeting. These provisions may delay or prevent changes of control or management, either by third parties or by stockholders seeking to change control or management.

We are also subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law. Under these provisions, if anyone becomes an interested stockholder, we may not enter into a business combination with that person for three years without special approval, which could discourage a third party from making a takeover offer and could delay or prevent a change of control. For purposes of Section 203, interested stockholder means, generally, someone owning 15% or more of our outstanding voting stock or an affiliate of ours that owned 15% or more of our outstanding voting stock during the past three years, subject to certain exceptions as described in Section 203.

Our stock price may be volatile and your investment in our common stock could suffer a decline in value.

We only recently completed our initial public offering. Prior to this offering, you could not buy or sell our common stock publicly. An active trading market for our common stock may not continue to develop or be sustained.

Some specific factors that may have a significant effect on our common stock market price include:

actual or anticipated fluctuations in our operating results;

our announcements or our competitors announcements of clinical trial results or new products;

changes in our growth rates or our competitors growth rates;

the timing or results of regulatory submissions or actions with respect to our products;

public concern as to the safety of our products;

changes in health care, drug pricing or reimbursement policies in a country where we sell our products;

our inability to raise additional capital;

conditions of the pharmaceutical industry or in the financial markets or economic conditions in general; and

changes in stock market analyst recommendations regarding our common stock, other comparable

companies or the pharmaceutical industry generally.

If our officers, directors and largest stockholders choose to act together, they may be able to control our management and operations, acting in their best interests and not necessarily those of other stockholders.

Our directors, executive officers and principal stockholders and their affiliates beneficially own approximately 68.7% of our common stock. Accordingly, they collectively have the ability to determine the election of all of our directors and to determine the outcome of most corporate actions requiring stockholder approval. They may exercise this ability in a manner that advances their best interests and not necessarily those of other stockholders.

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Item 7A. ***Quantitative and Qualitative Disclosures on Market Risk***

We currently invest our excess cash balances in short-term investment grade securities including money market accounts that are subject to interest rate risk. The amount of interest income we earn on these funds will decline with a decline in interest rates. However, due to the short-term nature of short-term investment grade securities and money market accounts, an immediate decline in interest rates would not have a material impact on our financial position, results of operations or cash flows.

The interest rate on our convertible notes is fixed and, as such, our interest expense is not impacted by changes in interest rates.

We are exposed to movements in foreign exchange rates against the U.S. dollar for inter-company trading transactions and the translation of net assets and earnings of non-U.S. subsidiaries. Our primary operating currencies are the U.S. dollar, U.K. pound sterling, the euro, and Swiss francs. We have not undertaken any foreign currency hedges through the use of forward foreign exchange contracts or options. Foreign currency exposures have been managed solely through managing the currency denomination of our cash balances.

Item 8. ***Financial Statements and Supplementary Data***

The financial statements required pursuant to this item are included in Item 15 of this report and are presented beginning on page F-1.

Item 9. ***Changes in and Disagreements with Accountants on Accounting Financial Disclosure***

None**.**

Item 9A. ***Controls and Procedures.***

We carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer, or CEO, and Chief Financial Officer, or CFO, of the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15(d)-15(e) of the Securities Exchange Act of 1934, as amended, as of the end of the period covered by this report. Based on that evaluation, the CEO and CFO have concluded that our disclosure controls and procedures are effective to provide reasonable assurance that information required to be disclosed by us in our periodic reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure. It should be noted that the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and can therefore only provide reasonable, not absolute assurance that the design will succeed in achieving its stated goals.

In addition, we reviewed our internal controls, and there have been no changes in our internal controls over financial reporting during the quarter ended December 31, 2003 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART III

Item 10. ***Directors and Executive Officers of the Registrant***

The information required by this Item concerning our directors is incorporated by reference from the information set forth in the section entitled Section 16(a) Beneficial Ownership Reporting Compliance in the Company s definitive Proxy Statement for the 2004 Annual Meeting of Stockholders to be filed with the Commission within 120 days after the end of our fiscal year ended December 31, 2003 (the Proxy Statement). The information required by this Item concerning our executive officers is incorporated by reference from the information set forth in the section of the Proxy Statement entitled Executive Officers, Directors and Key Employees. The information required by this Item concerning our code of ethics is

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incorporated by reference from the information set forth in the section of the Proxy Statement entitled Code of Ethics.

Item 11. ***Executive Compensation***

The information required by this Item regarding executive compensation is incorporated by reference from the information set forth in the section of the Proxy Statement entitled Executive Compensation.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

The information required by this Item regarding security ownership of certain beneficial owners and management is incorporated by reference from the information set forth in the section of the Proxy Statement entitled Security Ownership of Certain Beneficial Owners and Management. The information required by this Item regarding our equity compensations plans is incorporated by reference from the information set forth in the section of the Proxy Statement entitled Equity Compensation Plan Information.

Item 13. ***Certain Relationships and Related Transactions***

The information required by this Item regarding certain relationships and related transactions is incorporated by reference from the information set forth in the section of the Proxy Statement entitled Certain Transactions.

Item 14. ***Principal Accountant Fees and Services.***

The information required by this Item regarding principal accountant fees and services is incorporated by reference from the information set forth in the sections of the Proxy Statement entitled Report of the Audit Committee, Ratification of Selection of Independent Auditors and Fees Paid to Ernst & Young.

PART IV

Item 15. ***Exhibits, Financial Statements, and Schedules and Reports on Form 8-K***

(a) The following documents are being filed as part of this report:

(1) *Consolidated Financial Statements*

Reference is made to the Index to Consolidated Financial Statements of Pharmion Corporation. appearing on page F-1 of this report.

(2) *Consolidated Financial Statement Schedules*

The following consolidated financial statement schedule of the Company for each of the years ended December 31, 2003, 2002 and 2001, is filed as part of this Annual Report on Form 10-K and should be read in conjunction with the Consolidated Financial Statements, and the related notes thereto, of the Company.

	Page Number
Schedule II Valuation and Qualifying Accounts	S-1

(b) *Reports on Form 8-K:*

No reports on Form 8-K were filed by us during the fourth quarter of 2003.

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(c) *Exhibits*

Exhibit Number	Description of Document
2.1(1)	Stock Purchase Agreement, dated March 7, 2003, by and among Pharmion France and the shareholders of Gophar S.A.S.
3.1(1)	Amended and Restated Certificate of Incorporation.
3.2(1)	Amended and Restated Bylaws.
4.1(1)	Specimen Stock Certificate.
4.2(1)	Amended and Restated Investors Rights Agreement, dated as of November 30, 2001, by and among the Registrant, the founders and the holders of the Registrant s Preferred Stock.
4.3(1)	Series C Omnibus Amendment Agreement, dated as of October 11, 2002 to Amended and Restated Investors Rights Agreement, dated as of November 30, 2001, by and among the Registrant, the founders and the holders of the Registrant s Preferred Stock.
4.4(1)	Amendment, dated as of April 8, 2003 to Amended and Restated Investors Rights Agreement, dated as of November 30, 2001, by and among the Registrant, the founders and the holders of the Registrant s Preferred Stock.
4.5(1)	Series B Preferred Stock Purchase Warrant, dated November 30, 2001, issued by the Registrant to Celgene Corporation.
4.6(1)	Senior Convertible Promissory Note, dated April 8, 2003, issued by the Registrant to Celgene Corporation.
4.7(1)	Common Stock Purchase Warrant, dated April 8, 2003, issued by the Registrant to Celgene Corporation.
4.8(1)	Convertible Subordinated Promissory Note, dated April 11, 2003, issued by the Registrant to Penn Pharmaceuticals Holdings Limited.
4.9(1)	Common Stock Purchase Warrant, dated April 11, 2003, issued by the Registrant to Penn Pharmaceuticals Holdings Limited.
10.1(1)*	Amended and Restated 2001 Non-Employee Director Stock Option Plan.
10.2(1)*	Amended and Restated 2000 Stock Incentive Plan.
10.3(1)	Securities Purchase Agreement, dated as of April 8, 2003, by and between the Registrant and Celgene Corporation.
10.4(1)	Securities Purchase Agreement, dated as of April 11, 2003, by and between the Registrant and Penn Pharmaceuticals Holdings Limited.
10.5(1)	Amended and Restated Distribution and License Agreement, dated as of November 16, 2001, by and between Pharmion GmbH and Penn T Limited.
10.6(1)	Amendment No. 1, dated March 4, 2003, to Amended and Restated Distribution and License Agreement, dated as of November 16, 2001, by and between Pharmion GmbH and Penn T Limited.
10.7(1)	Supplementary Agreement, dated June 18, 2003, to Amended and Restated Distribution and License Agreement, dated as of November 16, 2001, by and between Pharmion GmbH and Penn T Limited.
10.8(1)	License Agreement, dated as of November 16, 2001, by and among the Registrant, Pharmion GmbH and Celgene Corporation.
10.9(1)	Amendment No. 1, dated March 3, 2003, to License Agreement, dated as of November 16, 2001, by and among the Registrant, Pharmion GmbH and Celgene Corporation.
10.10(1)	Letter Agreement, dated April 2, 2003, by and among the Registrant, Pharmion GmbH and Celgene Corporation regarding clinical funding.
10.11(1)	Amendment No. 2, dated April 8, 2003, to License Agreement, dated as of November 16, 2001, by and among the Registrant, Pharmion GmbH and Celgene Corporation.
10.12(1)	License and Distribution Agreement, dated as of June 21, 2002, by and between the Registrant and LEO Pharmaceutical Products Ltd. A/S.

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Exhibit Number	Description of Document
10.13(1)	License Agreement, dated as of June 7, 2001, by and between the Registrant, Pharmion GmbH and Pharmacia & Upjohn Company.
10.14(1)	Interim Sales Representation Agreement, dated as of May 29, 2002, by and between Pharmion GmbH and Schering Aktiengesellschaft.
10.15(1)	Distribution and Development Agreement, dated as of May 29, 2002, by and between Pharmion GmbH and Schering Aktiengesellschaft.
10.16(1)	First Amendment Agreement dated August 20, 2003 by and between Pharmion GmbH and Schering Aktiengesellschaft.
10.17(1)*	Non-Competition Agreement, dated as of November 20, 2001, by and between the Registrant and Patrick J. Mahaffy.
10.18(1)*	Non-Competition and Severance Agreement, dated as of November 21, 2001, by and between the Registrant and Judith A. Hemberger.
10.19(1)*	Non-Competition and Severance Agreement, dated as of November 29, 2001, by and between the Registrant and Michael Cosgrave.
10.20(1)*	Employment Agreement, dated as of January 5, 2001, by and between the Registrant and Michael Cosgrave.
10.21(1)*	Employment Agreement, dated as of September 26, 2002, by and between the Registrant and Erle Mast.
10.22(1)*	Employment Agreement, dated as of September 26, 2002, by and between the Registrant and Gillian C. Ivers-Read.
10.23(1)	Office Lease, dated as of April 24, 2002, by and between the Registrant and Centro III, LLC.
10.24(1)	First Amendment to Lease, dated as of January 31, 2003, to Office Lease, dated as of April 24, 2002, by and between the Registrant and Centro III, LLC.
21.1(1)	Subsidiaries of the Registrant.
23.1	Consent of Independent Auditors.
24.1	Power of Attorney. (reference is made to page 44)
31.1	Sarbanes-Oxley Act of 2002, Section 302 Certification for President and Chief Executive Officer.
31.2	Sarbanes-Oxley Act of 2002, Section 302 Certification for Chief Financial Officer.
32.1	Sarbanes-Oxley Act of 2002, Section 906 Certification for President and Chief Executive Officer and Chief Financial Officer.

(1) Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-108122) and amendments thereto, declared effective November 5, 2003.

* Management Contract or Compensatory Plan or Arrangement

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PHARMION CORPORATION

By: /s/ PATRICK J. MAHAFFY

Patrick J. Mahaffy
President and Chief Executive Officer

Date: March 25, 2004

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each individual whose signature appears below constitutes and appoints Patrick J. Mahaffy and Erle T. Mast, and each of them, his true and lawful attorneys-in-fact and agents with full power of substitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Form 10-K, and to file the same, with all exhibits thereto and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Form 10-K has been signed by the following persons on behalf of the Registrant on March 25, 2004, and in the capacities indicated:

Name	Title	Date
/s/ PATRICK J. MAHAFFY Patrick J. Mahaffy	President, Chief Executive Officer and Director (Principal Executive Officer)	March 25, 2004
/s/ ERLE T. MAST Erle T. Mast	Chief Financial Officer (Principal Financial and Accounting Officer)	March 25, 2004
/s/ JUDITH A. HEMBERGER Judith A. Hemberger	Director	March 25, 2004
/s/ JAY MOORIN Jay Moorin	Director	March 25, 2004
/s/ BRIAN G. ATWOOD Brian G. Atwood	Director	March 25, 2004
/s/ THORLEF SPICKSCHEN Thorlef Spickschen	Director	March 25, 2004

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Name	Title	Date
/s/ M. JAMES BARRETT M. James Barrett	Director	March 25, 2004
/s/ JAMES BLAIR James Blair	Director	March 25, 2004
/s/ CAM L. GARNER Cam Garner	Director	March 25, 2004

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REPORT OF INDEPENDENT AUDITORS

The Board of Directors

Pharmion Corporation

We have audited the accompanying consolidated balance sheets of Pharmion Corporation as of December 31, 2003 and 2002, and the related consolidated statements of operations, stockholders equity (deficit) and cash flows for each of the three years in the period ended December 31, 2003. Our audits also include the financial statement schedule listed in the index at Item 15(a)2. These financial statements and schedule are the responsibility of management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Pharmion Corporation at December 31, 2003 and 2002, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

/s/ ERNST & YOUNG LLP

Denver, Colorado
January 30, 2004
Except for Note 9, as to which the date is
March 1, 2004

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PHARMION CORPORATION

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2003	2002
ASSETS		
Current assets:		
Cash and cash equivalents	$ 88,541,793	$ 62,604,319
Accounts receivable, net of allowances of $818,516 and $733,656 at December 31, 2003 and 2002, respectively	7,992,177	519,909
Inventories	4,923,161	1,608,674
Prepaid royalties	1,342,987	1,000,000
Other current assets	2,779,203	2,044,489
Total current assets	105,579,321	67,777,391
Product rights, net	30,650,819	7,624,561
Property and equipment, net	5,049,420	3,877,908
Goodwill	3,651,804	
Other assets	541,223	1,566,775
Total assets	$ 145,472,587	$ 80,846,635
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 4,241,075	$ 3,464,155
Accrued and other current liabilities	14,799,437	3,421,770
Total current liabilities	19,040,512	6,885,925
Long term liabilities:		
Convertible notes	13,374,455	
Deferred tax liability	3,664,618	
Other long-term liabilities	4,479,267	190,115
Total long term liabilities	21,518,340	190,115
Total liabilities	40,558,852	7,076,040
Redeemable convertible preferred stock:		
Preferred stock: par value $0.001, 0 and 71,000,000 shares authorized at December 31, 2003 and 2002, respectively:		
5,100,000 shares designated as Series A-1 redeemable convertible preferred stock (at redemption value, which includes cumulative preferred stock accretion of $0 and $1,226,483 at December 31, 2003 and 2002, respectively); no shares issued and outstanding at December 31, 2003 and 5,069,792 shares issued and outstanding at December 31, 2002		6,273,565
12,900,000 shares designated as Series A-2 redeemable convertible preferred stock (at redemption value, which includes cumulative preferred stock accretion of $0 and $3,087,557 at December 31, 2003 and 2002, respectively); no shares issued and outstanding at December 31, 2003 and 12,843,473 issued and outstanding at December 31, 2002		22,337,180

33,000,000 shares designated as Series B redeemable convertible preferred stock (at redemption value, which includes cumulative preferred stock accretion of $0 and $6,582,884 at December 31, 2003 and 2002, respectively); no shares issued and outstanding at December 31, 2003 and 31,071,769 issued and outstanding at December 31, 2002		67,116,337
20,000,000 shares designated as Series C redeemable convertible preferred stock (at redemption value, which includes cumulative preferred stock accretion of $0 and $544,973 at December 31, 2003 and 2002 respectively); no shares issued and outstanding at December 31, 2003 and 19,138,756 issued and outstanding at December 31, 2002		40,259,803
Total redeemable convertible preferred stock		135,986,885
Stockholders equity (deficit)		
Common stock: par value $0.001, 100,000,000 shares authorized, 23,948,636 and 869,177 shares issued and outstanding at December 31, 2003 and 2002, respectively	23,949	869
Preferred stock: par value $0.001, 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2003 and 2002		
Paid-in capital	222,217,779	
Deferred compensation	(1,155,169)	(44,149)
Accumulated other comprehensive income	4,386,182	776,938
Accumulated deficit	(120,559,006)	(62,949,948)
Total stockholders equity (deficit)	104,913,735	(62,216,290)
Total liabilities and stockholders equity (deficit)	$ 145,472,587	$ 80,846,635

See accompanying notes.

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PHARMION CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS