

PHARMION CORP  
Form 10-K  
March 16, 2005

**Table of Contents**

**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, 2004.**

**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**

*(State or other jurisdiction of  
incorporation or organization)*

**84-1521333**

*(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  No

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.

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

The aggregate market value of the Registrant's voting and non-voting common equity held by non-affiliates as of June 30, 2004, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately \$830,839,767.

As of March 11, 2005, there were 31,819,131 shares of the Registrant's Common Stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant's definitive Proxy Statement for its 2005 Annual Meeting of Stockholders are incorporated by reference into Part III of this report on Form 10-K to the extent stated therein.

---

**TABLE OF CONTENTS**

	<b>Page</b>
<b><u>PART I</u></b>	
<u>Item 1.</u>	1
<u>Item 2.</u>	24
<u>Item 3.</u>	25
<u>Item 4.</u>	25
<b><u>PART II</u></b>	
<u>Item 5.</u>	26
<u>Item 6.</u>	27
<u>Item 7.</u>	29
<u>Item 7A.</u>	45
<u>Item 8.</u>	45
<u>Item 9.</u>	46
<u>Item 9A.</u>	46
<u>Item 9B.</u>	48
<b><u>PART III</u></b>	
<u>Item 10.</u>	48
<u>Item 11.</u>	48
<u>Item 12.</u>	48
<u>Item 13.</u>	48
<u>Item 14.</u>	48
<b><u>PART IV</u></b>	
<u>Item 15.</u>	48
<u>Amendment to Amended/Restated Distribution and License Agreement</u>	
<u>Letter Agreement</u>	
<u>Letter Agreement</u>	
<u>Lease</u>	
<u>Counterpart Guarantee</u>	
<u>Consent of Independent Registered Public Accounting Firm</u>	
<u>Certification for President and CEO Pursuant to Section 302</u>	
<u>Certification for CFO Pursuant to Section 302</u>	
<u>Certification for President, CEO and CFO Pursuant to Section 906</u>	

---

**Table of Contents****PART I**

*Unless the context requires otherwise, references in this report to Pharmion, the Company, we, us, and our to Pharmion Corporation.*

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 other 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 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 cover the hematology and oncology markets in 22 additional countries throughout Europe, the Middle East and Asia. To date, we have acquired the rights to four products. Thalidomide Pharmion 50mg<sup>tm</sup> is being sold by us on a compassionate use or named patient basis in Europe and other international markets while we pursue marketing authorization from the European Agency for the Evaluation of Medicinal Products, or EMEA. In May 2004, Vidaza® was approved for marketing in the U.S. and we commenced sales of the product in July 2004. We have filed for approval to market Vidaza in Europe and Australia and these submissions are under review by the respective regulatory authorities. In addition, we sell Innohep® in the U.S. and Refludan® in Europe and other international markets. 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. We had total sales of \$130.2 million in 2004, \$25.5 million in 2003 and \$4.7 million in 2002.

Our current product portfolio consists of the following four products:

*Vidaza (azacitidine for injectable suspension)* On May 19, 2004, we received full approval from the U.S. Food and Drug Administration, or FDA, to market Vidaza for the treatment of Myelodysplastic Syndromes, or MDS, a bone marrow disorder characterized by the production of abnormally functioning immature blood cells. Vidaza is the first and only drug currently approved for the treatment of MDS and is the first of a new class of drugs known as demethylating agents to be approved. The FDA approved Vidaza for the treatment of all MDS sub-types, including both low and high-risk patients. We launched Vidaza for commercial sale in the U.S. in July 2004. In September 2004 the EMEA accepted for review our Marketing Authorization Application for Vidaza for the treatment of MDS. In addition, we filed for approval to market Vidaza in Australia in October 2004 and both submissions are currently under review by the respective regulatory authorities. We obtained worldwide rights to this product from Pharmacia & Upjohn Company, now part of Pfizer, Inc., in June 2001. In 2004, sales of Vidaza were \$47.1 million, which represented approximately 36% of our total revenue for 2004.

*Thalidomide Pharmion 50mg and Thalidomide Laphal (thalidomide)* Thalidomide has become a standard of care for the treatment of relapsed and refractory multiple myeloma, a cancer of the plasma

## **Table of Contents**

cells in the bone marrow. We have licensed the marketing rights to thalidomide from Celgene Corporation and, in a separate agreement, have an exclusive supply agreement for thalidomide with Celgene UK Manufacturing II Limited (formerly known as 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. Thalidomide Pharmion 50mg has been approved as a treatment for relapsed and refractory multiple myeloma in Australia, New Zealand, Turkey and Israel. Although thalidomide has become a standard of care for the treatment of relapsed/refractory multiple myeloma, these regulatory approvals represent the first, and to date only, regulatory approvals for this indication. In 2004, sales of thalidomide were \$65.3 million, which represented approximately 50% of our total revenue for 2004.

*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 re-launched 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 anti-thrombin 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](http://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](http://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 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



**Table of Contents**

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 have developed highly-trained sales forces that target the hematology and oncology communities in conjunction with medical science liaisons focused on advocate development, educational forums, clinical development strategies and clinical data publications. 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 re-importation. With the commercial launch of Vidaza in the U.S. and increased sales of thalidomide in Europe in 2004, we have substantially increased our sales, marketing and payer-relations organizations.

*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 and build our product pipeline. 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.

**Table of Contents****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:

<b>Product</b>	<b>Disease/Indication</b>	<b>Phase of Development</b>	<b>Licensor</b>	<b>Licensed Territory</b>
Vidaza (azacitidine)	Myelodysplastic Syndromes	Approved May 19, 2004 in the U.S.; commercial launch in July 2004. In registration in Europe and Australia. Phase III/IV study ongoing	Pfizer, Inc.	Global rights
Thalidomide Pharmion 50mg and Thalidomide Laphal (thalidomide)	Relapsed and refractory multiple myeloma	Approved in Australia, New Zealand, Turkey and Israel; compassionate use and named patient sales ongoing in Europe; Phase III study ongoing	Celgene Corporation and Celgene UK Manufacturing II Limited	All countries outside North America, Japan and all provinces of China (except Hong Kong)
Innohep (tinzaparin)	Newly-diagnosed multiple myeloma 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

**Vidaza**

On May 19, 2004, we received full approval from the FDA to market Vidaza in the U.S. for the treatment of all subtypes of MDS. Vidaza is the first and only drug currently approved for the treatment of MDS and is the first of a new class of drugs known as demethylating agents to be approved. The subtypes of MDS are: refractory anemia (RA), refractory anemia with ringed sideroblasts (RARS) (if accompanied by neutropenia or thrombocytopenia or requiring transfusions), refractory anemia with excess blasts (RAEB), refractory anemia with excess blasts in transformation (RAEB-T) and chronic myelomonocytic leukemia (CMMoL).

We launched Vidaza for commercial sale in the U.S. in July 2004. In anticipation of the launch, we expanded our U.S. field organization from 31 to 75 employees, including additional sales representatives, medical science liaisons, payer relations and field based management. Since launch, we have further increased our field organization from 75 to 85 employees. In addition, we developed appropriate materials for mailings, educational literature and advertising in medical journals geared to hematologists and oncologists, as well as presentations at key industry conferences in support of the Vidaza launch. Since we believe that securing timely reimbursement will be critical to the commercial success of Vidaza, we assembled a payer-relations team to work with state Medicare carriers, state Medicaid programs and private payers to insure that healthcare providers are promptly paid for Vidaza.

**Table of Contents**

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 market under the trademark Vidaza. Under the agreement with Pfizer, we also obtained an exclusive worldwide license to use Pfizer'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 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. A New Drug Application, or 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 National Cancer Institute, or 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 differentiation 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. More than 80% of 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 30,000 new cases each year. According to the ACS, these numbers appear to be increasing each year. Currently, we estimate there are approximately 40,000 MDS patients throughout the U.S. with similar incidence and prevalence rates in the E.U. 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. Prior to the availability of Vidaza, patients generally received best supportive care, which typically consisted of a combination of transfusions, antibiotics and growth factors, such as erythropoietin and granulocyte colony stimulating factor. In addition, best supportive care treatment options included low-dose chemotherapies, if clinicians felt that their patients could tolerate the side effects and, for patients under 60 years of age, bone marrow transplants.

Vidaza has been granted orphan product designation by the FDA that entitles the drug to seven years of market exclusivity for MDS in the U.S. We submitted the NDA on December 29, 2003 and received full approval from the FDA less than five months later. Vidaza was granted priority review status by the FDA on February 10, 2004.

The NDA submission was based upon a National Cancer Institute-sponsored open-label, controlled Phase III study for the treatment of MDS, conducted by Cancer and Leukemia Group B, or CALGB, and two supportive Phase II studies conducted by CALGB, which were also sponsored by the National Cancer

**Table of Contents**

Institute. The results of this Phase III study were published in the May 2002 Journal of Clinical Oncology. For the purposes of the FDA submission, we re-collected and reanalyzed the CALGB data.

The Phase III study examined the safety and efficacy of Vidaza plus supportive care or supportive care alone in 191 patients with all five subtypes of MDS classified according to the French-American-British system. Patients with acute myelogenous leukemia were not intended to be included. Vidaza was administered subcutaneously at a dose of 75 mg/m<sup>2</sup> daily for seven days every four weeks. Dosage adjustments were allowed based on response or adverse events. Patients in the observation arm were allowed by protocol to cross over to Vidaza if they met pre-determined criteria indicating worsening of their condition. The primary endpoint of the study was response rate.

Our recollected and reanalyzed CALGB data, including an independent review showed that, of the 191 patients included in the study, 19 had the diagnosis of AML at baseline. These patients were excluded from the primary analysis of response rate, although they were included in the intent-to-treat analysis of all patients randomized. The overall response rate, which includes both complete and partial responses, was 15.7% in Vidaza-treated patients without AML (16.2% for all Vidaza randomized patients including AML), compared to zero percent in the observation group (p<0.0001). Responses occurred in all five subtypes of MDS as well as in patients determined to have a baseline diagnosis of AML.

Patients responding to Vidaza had a decrease in bone marrow blasts percentage or an increase in platelets, hemoglobin or white blood cells. Greater than 90 percent of the responders initially demonstrated these changes by the fifth treatment cycle. All patients who had been transfusion dependent became transfusion independent during complete or partial response. The mean and median duration of clinical response for patients experiencing complete or partial response was estimated at 512 and 330 days, respectively. Seventy-five percent of the responding patients were still in partial response or better at the completion of treatment. Approximately 55% of the observation patients crossed over to receive Vidaza treatment, and of that crossover group, 12.8% demonstrated complete or partial response.

The Phase II studies consisted of two multi-center, open-label, single-arm studies. A study of 72 patients with RAEB, RAEB-T, CMMoL or AML who were treated with subcutaneous Vidaza demonstrated an overall response rate of 13.9%. A study of 48 patients with RAEB, RAEB-T or AML who were treated with intravenous Vidaza demonstrated an overall response rate of 18.8%. Response occurred in all MDS subtypes as well as in patients with adjudicated baseline diagnosis of AML in both of these studies.

Benefit was also seen in patients who did not meet the criteria for partial response or better, but were considered improved. About 24% of patients treated with Vidaza were considered improved and about two-thirds of those became transfusion independent. In the observation group, five of 83 patients met the criteria for improvement; none became transfusion independent. In all three studies, about 19% of patients met the criteria for improvement with a median duration of 195 days. All three studies used similar dosing regimens and response criteria. Response rates were similar regardless of age or gender.

The recommended starting dose is 75 mg/m<sup>2</sup> delivered subcutaneously, daily for seven consecutive days, every four weeks. It is recommended that patients be treated for a minimum of four cycles; however, complete or partial response may require more than four cycles. Treatment may be continued as long as the patient continues to benefit. Patients should be monitored for hematologic response and renal toxicities, and dosage delay or reduction may be necessary.

We have initiated a comparative Phase III/IV clinical trial that will examine survival and other secondary end points, using a multi-center, randomized, open-label, parallel group study design. 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. Because this study is global in nature and MDS treatment practices vary among countries, there are three comparative conventional care treatments in the comparator arm of the study: best supportive care only; low dose cytarabine plus best supportive care; and 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



**Table of Contents**

enrollment. The study will recruit over 350 patients and will be one of the largest studies to date in this disease. We expect to complete enrollment of this study by the end of 2005.

The primary objective of this Phase III/ IV study is to look at survival in these MDS patients. This study will also assess several 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.

We have also initiated an additional clinical study that will investigate use of Vidaza with alternative dosing schedules and we continue our Vidaza formulation development activities. The alternative dosing study consists of two arms of fifty patients each. One arm examines 75 mg/m<sup>2</sup> of Vidaza in a schedule of five days on, two days off, two days on. The other arm examines 50 mg/m<sup>2</sup> of Vidaza in a schedule of five days on, two days off, five days on. Our formulation development efforts are focused on improving administration and manufacturing efficiencies, and, as a result of these activities, potentially enhancing our intellectual property. We have also initiated exploratory work to identify the feasibility of developing an oral formulation of Vidaza.

In addition, a number of investigator-initiated trials investigating the use of Vidaza in a variety of settings are planned for 2005. Investigator-initiated clinical development efforts are focused on MDS, AML and other hematological malignancies as well as solid tumors. We do not control these studies and the investigator is responsible for submitting and maintaining an Investigational New Drug Application, or IND, covering the clinical investigation as required by the FDA or the equivalent regulatory applications required by foreign regulatory authorities. Generally, we have the right to review and use for our own business purposes clinical data generated by these trials, however, the investigators own the study data and may publish study data subject to our right to review any publications prior to submission.

We expect to devote significant resources to continue the clinical development of Vidaza in MDS as well as other potential hematological and oncological disorders believed to be associated with hypermethylation.

In September 2004 the EMEA accepted for review our Marketing Authorization Application, or MAA, for Vidaza for the treatment of MDS. We also filed for approval to market Vidaza in Australia in October 2004. We are working with the EMEA to respond promptly to inquiries on our MAA submission. However, the timelines for product approval in Europe are often longer than the corresponding approval timelines in the U.S. and, in contrast with the U.S. regulatory process, the EMEA does not provide applicants with a deadline on when it will render a decision on an MAA. Furthermore, we cannot be certain that the EMEA will approve Vidaza for marketing in Europe based on the same data accepted by the FDA. If the EMEA requires additional clinical data to approve Vidaza for marketing in Europe, we believe our ongoing Phase III/ IV, if the results are positive, could provide the required data.

The EMEA granted Vidaza Orphan Product Designation, which, if the MAA is approved, and the criteria for orphan drug designation continue to be met, entitles the drug to ten years of market exclusivity from the date of the MAA's approval for the MDS indication in the European Union. During this period the EMEA would be prohibited, except in very limited circumstances, from approving another formulation of Vidaza for the treatment of MDS.

***Thalidomide***

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.<sup>™</sup> program, and its current and future thalidomide-related dossiers, including clinical and pharmaceutical formulation data. In October 2004, Penn T Limited was acquired by Celgene and was renamed Celgene UK Manufacturing II Limited, or CUK. In December 2004, we amended our agreements with Celgene and CUK. Under the modified agreements we made a one-time payment of \$77 million in return for a substantial

**Table of Contents**

reduction in our product supply price and royalty obligations to Celgene and CUK. In addition, for an additional one-time payment to Celgene of \$3 million, we added Hong Kong, Korea and Taiwan to our sales territories and eliminated a right held by Celgene to terminate our license to market the product if regulatory approval of thalidomide in Europe had not occurred by November 2006. Furthermore, under our agreements with Celgene, to further the clinical development of thalidomide, particularly in multiple myeloma, we have also agreed to fund up to \$10 million incurred by Celgene for the conduct of thalidomide clinical trials during 2005, 2006 and 2007.

In the second quarter of 2003, we began selling thalidomide on a compassionate use and named patient basis in Europe while we actively seek marketing authorizations for this drug in Europe and several additional countries. Thalidomide Pharmion 50mg has been approved as a treatment for relapsed and refractory multiple myeloma and ENL in Australia, New Zealand, Turkey and Israel. These approvals are the only regulatory approvals of thalidomide for multiple myeloma in the world.

Since acquiring thalidomide rights from Celgene, 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 EMEA and the Therapeutic Goods Administration, or the TGA, in Australia and to regulatory authorities in New Zealand, South Africa, Saudi Arabia, Turkey, Israel, Thailand and the Philippines. We are seeking approval for thalidomide as a treatment for relapsed and refractory multiple myeloma and for erythema nodosum leprosum, or ENL. Thalidomide Pharmion 50mg has been approved in Australia, New Zealand, Turkey and Israel for these indications. In May 2004, we withdrew our multiple myeloma applications with the EMEA, but intend to resubmit our application with additional clinical data from ongoing studies in relapsed/ refractory multiple myeloma patients. This action was based on the EMEA's stated view that additional clinical data would be required before it can reach an opinion on whether or not Thalidomide Pharmion 50mg should be approved as a treatment for multiple myeloma. There are at least two studies underway that we believe will provide the clinical data required by the EMEA. We completed enrollment in the first of these studies in October 2004 and we expect that enrollment of the second study will be completed in the second quarter of 2005. We will continue to sell thalidomide on a named patient or compassionate use basis in Europe while we pursue a marketing authorization for the drug.

*Acquired Laphal Développement, S.A or Laphal.* 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 CUK's compassionate use and named patient sales in the U.K., Ireland and Denmark* Under our initial license agreement with CUK, CUK was 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, CUK 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.

*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 CUK. 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 or PRMP* 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.

**Table of Contents**

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 over 20 languages for use by physicians, pharmacists and patients throughout Europe and our other markets. We implemented the PRMP in June 2003 in connection with the commencement of our compassionate use and named patient sales.

*Appointed Lipomed our Swiss and Austrian distributor and settled patent litigation we initiated against Lipomed*  
In May 2004, we appointed Lipomed AG, a Swiss pharmaceutical company, on customary terms, as our exclusive distributor of Thalidomide Pharmion 50mg in Switzerland and Austria. In addition, both parties agreed to terminate ongoing patent infringement litigation that we had initiated against Lipomed in the fall of 2003. Under the terms of the agreements, Lipomed exclusively distributes Thalidomide Pharmion 50mg in Switzerland and Austria and has stopped selling its own formulation of thalidomide in other European markets. Lipomed also utilizes the PRMP to control the use and distribution of thalidomide.

Thalidomide was developed in the late 1950s 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 has 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 four 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 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.



**Table of Contents**

*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%) achieved a greater than 50% reduction in M-protein, and an additional 14 patients (28%) 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 patient group, 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 colorectal cancer, non-small cell lung cancer, prostate cancer, glioblastoma and metastatic melanoma.

Despite the lack of any formal regulatory approval for thalidomide in Europe, 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. Through mid-2003, substantially all drug product used in Europe was distributed by four 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 three suppliers: CUK (then known as Penn T Limited); Laphal, the French pharmaceutical company that we acquired in March 2003; and Lipomed, which subsequently agreed to exclusively distribute Thalidomide Pharmion 50mg in Switzerland and Austria and to stop selling its own formulation of thalidomide in other European markets. CUK, Laphal and Lipomed supplied thalidomide pursuant to the regulatory provisions allowing for sale of unlicensed drugs on a compassionate use or named patient basis. While the thalidomide supplied by CUK, Laphal and Lipomed was not given free of charge, it was sold at a significant discount to the price charged by Celgene in the U.S.



**Table of Contents**

We recognized that Grünenthal's decision to discontinue distributing thalidomide would create a large void in the supply of thalidomide for the thousands of 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. Accordingly, 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 50mg in Australia, New Zealand, Turkey and Israel, we have been actively marketing the product in each of those countries.

In March 2002, working with the data packages that we had obtained from Celgene and CUK, 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 May 2004, we withdrew our relapsed and refractory multiple myeloma applications from the EMEA with the intent of resubmitting one or more applications with additional clinical data for relapsed/ refractory or newly diagnosed multiple myeloma patients, or both. We made this decision following a series of discussions with the EMEA during which it indicated that it would require additional clinical data for thalidomide before it can reach an opinion on whether or not the drug should be approved as a treatment for multiple myeloma. We intend to provide a dossier to the EMEA incorporating newly generated clinical data on thalidomide that will reflect current practices in the use of the drug to treat multiple myeloma.

We are focused on completing several ongoing studies with thalidomide in patients with multiple myeloma, at least two of which we believe could provide the significant new clinical data required by the EMEA. The first is a study comparing survival and additional clinical endpoints for two doses of thalidomide in patients with relapsed/refractory multiple myeloma. Enrollment of this 400 patient study was completed in October 2004. The second study, currently being conducted by Celgene in collaboration with us and with our financial support, compares time to progression and additional clinical endpoints, including survival, in newly diagnosed patients taking thalidomide plus dexamethasone versus patients taking dexamethasone alone. We expect that enrollment of this 435 patient study will be completed in the second quarter of 2005.

We will continue to sell thalidomide in Europe on a named patient or compassionate use basis while these studies are completed and we pursue marketing authorization.

In addition to these EMEA regulatory approval activities, the regulatory authorities in Australia, New Zealand, Turkey and Israel have approved the use of Thalidomide Pharmion 50mg for treatment of relapsed and refractory multiple myeloma and ENL. Although thalidomide has become a standard of care for the treatment of relapsed/refractory multiple myeloma, these regulatory approvals represent the first, and to date only, regulatory approvals for this indication. We have also submitted regulatory approval applications for Thalidomide Pharmion 50mg in Saudi Arabia, South Africa, Thailand and the Philippines.

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



**Table of Contents**

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. 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.

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. We did, however, withdraw Laphal's relapsed and refractory multiple myeloma and ENL applications from the EMEA at the same time as we withdrew the Pharmion applications for those indications. 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 believe that an integral component of our applications was and will continue to be 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 intend to work closely with the EMEA to better determine a path to approval for thalidomide in the relapsed/refractory multiple myeloma indication. We remain committed to gaining an approval for thalidomide in Europe, and we believe an approval in Europe would significantly enhance our revenue opportunity in those markets.

***Innohep***

Innohep, the trade name 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 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, although the product has achieved significant 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.

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

## **Table of Contents**

and training of our U.S. sales force and re-launched 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 since we began selling the product 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 this feature, combined with the convenience of its once per day dosing, makes Innohep an attractive treatment choice for a cancer patient with DVT.

### ***Refludan***

Refludan, the trade name for lepirudin, is an anti-thrombin agent for patients with heparin-induced thrombocytopenia type II, or HIT type II. 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. Schering AG continues to market the product in the U.S. and Canada through its subsidiary, Berlex Laboratories, Inc. We are currently marketing Refludan principally in Europe and Australia.

HIT is an allergic, adverse immune response to heparin. Generally this response occurs after two to four 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. Given the relatively low incidence rate for HIT, we do not expect Refludan sales to grow significantly above the current level.

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 22 additional countries throughout Europe, the Middle East and Asia.

### **Sales, Marketing and Distribution**

We have established sales and marketing organizations in the U.S., Europe and Australia.

In the U.S., as of March 9, 2005, we have increased our field based organization to 85 professionals consisting of fifty-nine clinical account specialists, eight medical science liaisons, five reimbursement specialists, one sales director, three strategic account managers, three national accounts managers and six field based managers. Each member of our field based staff has significant experience in pharmaceutical and oncology products sales and marketing. They target hematologists and oncologists who prescribe high volumes of cancer therapies. The concentration of high volume prescribers will allow us to promote Vidaza and Innohep with a relatively small, dedicated sales and marketing organization. The field based organization is also supported by a medical education team that focuses on the development, presentation and distribution of scientific and clinical information regarding our products and the diseases they treat.

In Europe, we employ a general manager in each of the U.K., France, Germany, Spain and Italy, and a general manager for the Nordic countries. 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,

**Table of Contents**

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 the notes to our consolidated financial statements included elsewhere in this report.

In addition to our own sales organizations, we have access to the hematology and oncology markets in 22 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**

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

\* In Switzerland, we sell Recludan directly to customers and we sell Thalidomide Pharmion 50mg through our Swiss distributor, Lipomed AG.

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 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 physicians, 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 our largest three wholesale customers in the U.S. totaled approximately 35% of our total net sales for the year ended December 31, 2004.



**Table of Contents****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 or, if necessary and appropriate, through company acquisition, and move our future product pipeline candidates, as identified, forward through the approval process.

**Collaborations and License Agreements*****Celgene and CUK Agreements***

In 2001, we licensed rights relating to the use of thalidomide from Celgene and separately entered into an exclusive supply agreement for thalidomide with CUK. Under the agreements, as amended, we obtained the right to market thalidomide in all countries other than the United States, Canada, Mexico, Japan and all provinces of China (except Hong Kong). More specifically, under agreements with Celgene, as amended, we obtained the rights in these territories to Celgene's formulation of thalidomide, Thalomid, exclusive licenses or sublicenses for the 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 and proprietary S.T.E.P.S. program as our PRMP in connection with the distribution of thalidomide in these territories. Under agreements with CUK, as amended, CUK is our exclusive supplier of thalidomide formulations that we sell in certain territories licensed to us by Celgene. We pay (i) Celgene a royalty/license fee of 8% on our net sales of thalidomide under the terms of the license agreements, and (ii) CUK product supply payments equal to 15.5% of our net sales of thalidomide under the terms of the product supply agreement. 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 certain amounts incurred by Celgene for the conduct of thalidomide clinical trials. Through December 31, 2004, we have funded \$6 million of these costs and have agreed to fund an additional \$10 million of Celgene's costs for these studies incurred between January 1, 2005 and December 31, 2007, payable in quarterly installments through the end of 2007. The agreements with Celgene and CUK each have a ten-year term running from the date of receipt of our first regulatory approval for thalidomide in the United Kingdom. In October 2004, Celgene acquired CUK.

***Pfizer Agreement***

We licensed worldwide exclusive 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 Pfizer a royalty of 20% on net sales of Vidaza. The license from Pfizer 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.

***LEO Pharma Agreement***

In July 2002, we obtained an exclusive ten year licensing agreement 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. Furthermore, the agreement contains a minimum net sales clause that is effective for two consecutive two-

**Table of Contents**

year periods. If we do not achieve these minimum sales levels for two consecutive years, we have the right to pay LEO Pharma additional royalties up to the amount LEO Pharma would have received had we achieved these net sales levels. If we opt not to make the additional royalty payment, LEO Pharma has the right to terminate the license agreement. The second of the two-year terms will conclude on December 31, 2006.

***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 \$9.0 million and are obligated to make an aggregate of \$4.0 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 we 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%.

**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 CUK, 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 our agreement with CUK we purchase from CUK all of our requirements of the product. Pricing is subject to an annual audit and, if appropriate, an 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 provide twelve months advance notice and pay 300,000 (approximately \$409,000 as of December 31, 2004). If our notice to discontinue ordering Thalidomide Laphal is not timely, the fee may increase to as much as 500,000 (approximately \$680,000 as of December 31, 2004). 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 in which we sell or expect to sell the product. To date, we have obtained our commercial quantities of Vidaza from Ash Stevens and Ben Venue under standard purchase order commitments, and we are in active negotiations with both of these suppliers to finalize long-term commercial supply agreements. We

## **Table of Contents**

are actively seeking back-up manufacturers for Vidaza and also working with a number of partners in our reformulation efforts.

*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.

### ***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 and 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 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,

**Table of Contents**

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 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 Medicinal Products for Human Use, or the CHMP, on behalf of the EMEA. The EMEA will, based upon the review of the CHMP, 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



**Table of Contents**

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 labeling 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, 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.



**Table of Contents**

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.

Holders of an approved NDA are required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain requirements concerning advertising and promotional labeling for their products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. We continue to rely upon third-party manufacturers to produce our products. We cannot be sure that those manufacturers will remain in compliance with applicable regulations or that future FDA inspections will not identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct.

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 payers (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

**Table of Contents**

minimum 15.1% of the average manufacturer price, or AMP, of that product, or if it is greater, the difference 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.

In addition, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 together with rulemaking by the Centers for Medicare and Medicaid Services, or CMS, changed the methodology for Medicare reimbursement of pharmaceutical products administered in physician offices and hospital outpatient facilities, including Vidaza and Innohep. Under the new regulations, reimbursements will now be the average selling price, or ASP, of a product plus 6%, rather than a specified discount from the average wholesale price, or AWP, as was the case under prior regulations. The new ASP-based reimbursement regime generally will reduce the reimbursement physicians will receive under Medicare for most for most office-administered injectable drugs, including Vidaza and Innohep. Although the actual impact of these reimbursement changes is not currently well known, there is a risk that the new reimbursement policies will adversely affect product use by physicians.

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 that 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.

## **Table of Contents**

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.

### ***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 payers 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. Composition of matter patent protection for each of our existing products has expired. We have exclusive rights to one issued patent and two pending European patent applications that relate to uses of thalidomide. Patent protection for uses of thalidomide expire in February 2014. We own, or co-own with Ash Stevens, Inc., three patent families and have exclusive rights to one additional patent family relating to the production or formulation of Vidaza. We have exclusive rights to a family of patents and patent applications relating to the production of Refludan with protection until November 2016. In addition, we intend to seek patent protection whenever available for any products or product candidates, in particular in conjunction with our formulation and manufacturing process development activities, and related technology we acquire in the future.

**Table of Contents**

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.

In the absence of or to supplement 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 MDS indication, in the E.U. for Vidaza for the MDS indication and for Thalidomide Pharmion 50mg for the indications multiple myeloma and ENL and in Australia for Vidaza for the MDS indication 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

**Table of Contents**

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 potentially Revlimid™ from Celgene, a small molecule compound that affects multiple cellular pathways and is currently being evaluated for a wide range of hematological cancers, including relapsed and refractory multiple myeloma and MDS.

*Vidaza.* We believe that the primary potential future competition for Vidaza will be Dacogen™ from Supergen Inc., with marketing rights held by MGI Pharma, Inc., which like Vidaza, is a demethylating agent, and Thalomid® and Revlimid, each from Celgene. Both Dacogen and Revlimid are currently in development and/or under review for regulatory approval by the FDA and EMEA. In addition to these products, there are additional products in clinical development for the treatment of MDS and the enrollment of patients in clinical trials for these products may reduce the number of patients that will receive Vidaza treatment. We also face competition for Vidaza from traditional therapies for the treatment of MDS, including the use of blood transfusions and growth factors.

*Innohep.* We believe that the primary competition for Innohep are two low molecular weight heparins, Lovenox® from Sanofi-Aventis, the top-selling low molecular weight heparin worldwide, and Fragmin® from Pfizer, Inc., as well as Arixtra® from GlaxoSmithKline plc, 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, an anticoagulant indicated for both the prevention and treatment of HIT.

**Clinical, Development and Regulatory Expense**

In the years ended December 31, 2004, 2003 and 2002, we incurred clinical, development and regulatory expense of \$28.4 million, \$24.6 million and \$15.0 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 March 9, 2005, we had 289 employees, consisting of 81 in regulatory affairs and clinical development, 141 in sales and marketing and 67 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. In December 2004, we entered into an agreement to lease approximately 26,000 square feet of office space in Windsor in the United Kingdom. We expect to occupy that space by June 2005. The lease expires in 2010 and has a renewal option for an additional five years. 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

**Table of Contents**

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.

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

No matters were submitted to a vote of our security holders through solicitation of proxies or otherwise during the fourth quarter of the year ended December 31, 2004.

**Table of Contents****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:

	High	Low
<b>Year Ended December 31, 2003</b>		
Fourth Quarter	\$ 15.70	\$ 11.00
<b>Year Ended December 31, 2004</b>		
First Quarter	\$ 24.70	\$ 14.72
Second Quarter	\$ 49.79	\$ 20.60
Third Quarter	\$ 58.49	\$ 40.37
Fourth Quarter	\$ 53.35	\$ 41.48

On March 11, 2005, the last reported sale price of our common stock on the NASDAQ National Market was \$32.22 per share.

American Stock Transfer and Trust Company is the transfer agent and registrar for our common stock. As of the close of business on March 11, 2005, we had approximately 81 holders of record 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, 2004

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)	2,400,684	\$ 18.47	1,282,316

- (1) As of December 31, 2004, 3,258,000 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, 2004, 425,000 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

**Table of Contents**

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.

**Recent Sales of Unregistered Securities**

In June 2004, Penn Pharmaceuticals Holdings Limited, or Penn Holdings, exercised a stock purchase warrant previously issued by us to Penn Holdings, resulting in the issuance to Penn Holdings of 44,026 shares of our common stock. Penn Holdings utilized the cashless exercise option pursuant to the warrant agreement and surrendered 16,580 shares to us as consideration for this exercise. The issuance of these shares of common stock were not registered under the Securities Act in reliance upon Section 3(a)(9) under the Securities Act.

In September 2004, Celgene exercised two additional stock purchase warrants previously issued by us to Celgene, which resulted in the issuance to Celgene of 789,087 shares of our common stock. We received approximately \$7.6 million in total exercise proceeds upon Celgene's exercise of these warrants. The issuance of these shares of common stock were not registered under the Securities Act in reliance upon Section 3(a)(9) under the Securities Act

**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) was declared effective by the SEC on November 5, 2003. 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, 2004, we have used all of the net proceeds from the offering to fund operations, the commercial launch and clinical development of Vidaza, ongoing thalidomide clinical development, payments to Celgene and CUK pursuant to our amended agreements relating to Thalidomide Pharmion 50mg, capital expenditures, working capital needs and other general corporate purposes.

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 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, 2004, 2003, 2002, 2001 and 2000. 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

**Table of Contents**

share data do not include the effect of any options or warrants outstanding as they would be anti-dilutive. For further discussion of earnings per share, please see note 2 to our consolidated financial statements.

	2004	2003(1)	2002	2001	2000
<b>(In thousands, except share and per share data)</b>					
<b>Consolidated Statement of Income Data:</b>					
<b>Statement of Income</b>					
Net Sales	\$ 130,171	\$ 25,539	\$ 4,735	\$	\$
Operating expenses:					
Cost of sales, including royalties	43,635	11,462	1,575		
Clinical regulatory and development	28,392	24,616	15,049	6,009	972
Selling, general and development	66,848	36,109	23,437	8,322	3,664
Product rights amortization	3,395	1,972	375		
Total operating expenses	142,270	74,159	40,436	14,331	4,636
Loss from operations	(12,099)	(48,620)	(35,701)	(14,331)	(4,636)
Other income (expense) net	2,415	(154)	1,109	621	190
Loss before taxes	(9,684)	(48,774)	(34,592)	(13,710)	(4,446)
Income tax expense	7,853	1,285	105		
Net loss	(17,537)	(50,059)	(34,697)	(13,710)	(4,446)
Accretion to redemption value of redeemable convertible preferred stock		(10,091)	(8,576)	(2,458)	(409)
Net loss attributable to common stockholders	\$ (17,537)	\$ (60,150)	\$ (43,273)	\$ (16,168)	\$ (4,855)
Net loss attributable to common stockholders per common share, basic and diluted	(0.63)	(14.70)	(57.58)	(23.99)	(7.28)
Shares used in computing net loss attributable to common stockholders per common share, basic and diluted	27,933,202	4,093,067	751,525	673,822	667,000
Pro forma net loss attributable to common stockholders per common share, assuming conversion of preferred stock, basic and diluted (unaudited)		(2.66)	(2.47)	(2.26)	

Shares used in computing  
pro forma net loss  
attributable to common  
stockholders per common  
share, assuming conversion  
of preferred stock basic and  
diluted

18,791,015

14,072,707

6,060,284

28

---

**Table of Contents**

	2004	2003(1)	2002	2001	2000
<b>Consolidated Balance Sheet:</b>					
Cash, cash equivalents and short-term investments	\$ 245,543	\$ 88,542	\$ 62,604	\$ 68,444	\$ 5,317
Working capital	233,366	86,539	60,891	66,568	4,966
Total assets	411,230	145,473	80,847	70,278	6,055
Convertible notes		13,374			
Other long-term liabilities	3,824	8,144	190		
Redeemable convertible preferred stock			135,987	87,790	10,312
Accumulated deficit	(138,096)	(120,559)	(62,950)	(19,697)	(4,590)
Total stockholders' equity (deficit)	351,953	104,914	(62,216)	(19,783)	(4,709)

- (1) We acquired Laphal Development 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, which resulted in \$76.2 million of net proceeds through the issuance of 6,000,000 shares of common stock. Concurrent with effective date of the initial public offering, 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**

The following discussion should be read in conjunction with the financial statements and the related notes that appear elsewhere in this document.

**Overview**

We are 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 cover the hematology and oncology markets in 22 additional countries throughout Europe, the Middle East and Asia. To date, we have acquired the rights to four products. Thalidomide Pharmion 50mg<sup>tm</sup> is being sold by us on a compassionate use or named patient basis in Europe and other international markets while we pursue marketing authorization from the European Agency for the Evaluation of Medicinal Products, or EMEA. In May 2004, Vidaza® was approved for marketing in the U.S. and we commenced sales of the product in July 2004. We have filed for approval to market Vidaza in Europe and Australia and these submissions are under review by the respective regulatory authorities. In addition, we sell Innohep® in the U.S. and Refludan® in Europe and other international markets. 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. We had total sales of \$130.2 million in 2004, \$25.5 million in 2003 and \$4.7 million in 2002.

**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.

**Table of Contents**

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 our 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 our 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. For the years ended December 31, 2004 and 2003, we reduced the estimated net realizable value of obsolete and short-dated inventory by \$1.4 million and \$1.8 million, respectively.

***Long-Lived Assets***

Our long-lived assets consist primarily of product rights and property and equipment. In accordance with Statement of Financial Accounting Standards No. 144 ( SFAS No. 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. The process of calculating the expected future cash flows involves estimating future events and trends such as sales, cost of sales, operating expenses and income taxes. The actual results of any of these factors could be materially different than what we estimate. The net value of our product rights and property and equipment was \$112.8 million and \$35.7 million at December 31, 2004 and 2003, respectively.

***Goodwill***

We completed a business acquisition in 2003 that resulted in the creation of goodwill. In accordance with SFAS No. 142, *Goodwill and Other Intangible Assets*, we do not amortize goodwill. SFAS No. 142 requires us to perform an impairment review of goodwill at least annually. If it is determined that the value of goodwill is impaired, we will record the impairment charge in the statement of operations in the period it is discovered. The process of reviewing for impairment of goodwill is similar to that of long-lived assets in that expected future cash flows are calculated using estimated future events and trends such as sales, cost of sales, operating expenses and income taxes. The actual results of any of these factors could be materially different than what we estimate. The net value of our goodwill was \$9.4 million and \$3.7 million at December 31, 2004 and 2003, respectively.

**Recently Issued Accounting Standards*****Accounting for Stock-Based Compensation***

On December 16, 2004, the Financial Accounting Standards Board issued SFAS No. 123 (revised 2004), *Share-Based Payment*, which is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation*. SFAS No. 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends

**Table of Contents**

SFAS No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However, SFAS No. 123(R) *requires* all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. See Note 2, *Summary of Significant Accounting Policies Accounting for Stock-Based Compensation*, of Notes to Consolidated Financial Statements for our presentation of net income and earnings per share assuming we had applied the fair value recognition provisions of the earlier version of SFAS No. 123 to our stock-based employee compensation.

SFAS No. 123(R) must be adopted no later than July 1, 2005. Early adoption will be permitted in periods in which financial statements have not yet been issued. We expect to adopt SFAS No. 123(R) on July 1, 2005.

SFAS No. 123(R) permits public companies to adopt its requirements using one of two methods:

A modified prospective method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS No. 123(R) for all share-based payments granted after the effective date and (b) based on the requirements of SFAS No. 123 for all rewards granted to employees prior to the effective date of SFAS No. 123(R) that remain unvested on the effective date; or

A modified retrospective method which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under SFAS 123 for purposes of pro forma disclosures either (a) all prior periods or (b) prior interim periods of the year of adoption. We are still evaluating which method we will adopt on July 1, 2005.

**Results of Operations****Comparison of Years Ended December 31, 2004, 2003 and 2002**

*Net Sales.* Net sales for the years ended December 31, 2004, 2003 and 2002 were as follows.

	2004	2003	2002
	<b>(In thousands)</b>		
Net Sales U.S.	\$ 55,642	\$ 3,751	\$ 2,100
Net Sales Europe and other countries	\$ 74,529	\$ 21,788	\$ 2,635
Total Net Sales	\$ 130,171	\$ 25,539	\$ 4,735
Increase from prior year	\$ 104,632	\$ 20,804	n/a
% Change from prior year	409.7%	439.4%	n/a

The increase in sales for the year ended December 31, 2004 as compared to 2003 is due primarily to the launch of Vidaza in the U.S. on July 1, 2004 as well as growth in compassionate use and named patient sales of thalidomide in Europe and other international markets. Vidaza sales for 2004 totaled \$47.1 million. Thalidomide sales totaled \$65.3 million in 2004, compared to \$15.6 million in 2003. We began selling thalidomide on a compassionate use or named patient basis in France and Belgium in April 2003 following our acquisition of Gophar S.A.S., the parent company of Laphal. In July 2003, we began selling thalidomide in additional countries in Europe and other international markets. The growth in thalidomide sales experienced in 2004 is due both to increased volume of product sold as well as an increase in the average selling price of thalidomide in certain markets. The increase in net sales for the year ended December 31, 2003 as compared to 2002 is largely due to the initiation of thalidomide sales. In addition, sales of Innohep and Refludan in 2003 increased by \$4.7 million as those products were sold only for a partial year in 2002.

Net sales in 2002 were generated by Innohep and Refludan, both of which we began selling in the second half of the year. The combined sales of these products and other orphan products acquired as part of our 2003 acquisition of Laphal totaled \$9.9 million in 2003 and \$17.8 million in 2004.



**Table of Contents**

*Cost of Sales.* Cost of sales includes the cost of product sold, royalties due on the sales of our products and the distribution and logistics costs related to selling our products. Cost of sales for the years ended December 31, 2004, 2003 and 2002 were as follows.

	2004	2003	2002
	<b>(In thousands)</b>		
Cost of Sales	\$ 43,635	\$ 11,462	\$ 1,575
Increase from prior year	\$ 32,173	\$ 9,887	\$ n/a
% Change from prior year	280.7%	627.7%	n/a
As a % of net sales	33.5%	44.9%	33.3%

The increase in cost of sales in 2004 and 2003 over the predecessor year is attributable to the increase in sales for those years. The decrease in cost of sales as a percentage of net sales experienced in 2004 as compared to 2003 is largely due to charges totaling \$2.1 million recorded in 2003 relating to Refludan product inventory. These charges increased cost of sales as a percentage of net sales by approximately 8 percentage points. The launch of Vidaza in 2004 also improved the overall gross margin as compared to 2003, reducing 2004 cost of sales as a percentage of net sales by approximately 4 percentage points as the Vidaza gross margin is higher than that of our other products on a combined basis.

*Clinical, development and regulatory expenses.* Clinical, development and regulatory expenses generally consist of regulatory, clinical and manufacturing development, and medical and safety monitoring costs for both products in development as well as products being sold. Clinical, development and regulatory expenses for the years ended December 31, 2004, 2003 and 2002 were as follows.

	2004	2003	2002
	<b>(In thousands)</b>		
Clinical, development and regulatory expenses	\$ 28,392	\$ 24,616	\$ 15,049
Increase from prior year	\$ 3,776	\$ 9,567	n/a
% Change from prior year	15.3%	63.6%	n/a

Clinical, development and regulatory expenses for the year ended December 31, 2004 increased by \$3.8 million over 2003. This increase was due primarily to a \$3.0 million increase in medical safety and monitoring costs associated with the selling of our products, including expanded staffing to support the growth in sales of thalidomide as well as the U.S. launch of Vidaza. Clinical and regulatory expenses increased by \$2.1 million in 2004 as compared to 2003. This increase was primarily related to a \$2.3 million increase in personnel related costs as we expanded staffing to support the regulatory and clinical development activities of thalidomide and Vidaza, including the pursuit of European marketing authorization approvals for those products. In addition we incurred a net cost of \$1.1 million in 2004 for the settlement of a patent infringement suit filed by us against Lipomed, AG. These increases in clinical and regulatory expenses were partially offset by \$1.3 million decline in clinical development expenses for Vidaza and thalidomide in 2004, due primarily to the completion of clinical data analysis in 2003 to support the submission of the Vidaza new drug approval application filed with the FDA in the fourth quarter of 2003. Finally, manufacturing development expenses declined by \$1.3 million in 2004 due to the completion in 2003 of Vidaza manufacturing development activities required for the submission of the New Drug Application for Vidaza.

Clinical, development and regulatory expenses increased by \$9.6 million during the year ended December 31, 2003 as compared to 2002. In 2003 we spent approximately \$16.8 million on Vidaza 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. The remainder of the \$9.6 million increase was due to increased salaries and benefits expenses and other non-product specific costs.

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

**Table of Contents**

may not be favorable. Further, data from clinical trials is subject to varying interpretation, and may be deemed 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 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 personnel related costs for corporate staff, outside legal, tax and auditing services, and corporate facility and insurance costs. Selling, general and administrative expenses for the years ended December 31, 2004, 2003 and 2002 were as follows.

	2004	2003	2002
	(In thousands)		
Selling, general and administrative expenses	\$ 66,848	\$ 36,108	\$ 23,436
Increase from prior year	\$ 30,740	\$ 12,672	n/a
% Change from prior year	85.1%	54.1%	n/a

Selling, general and administrative expenses have increased significantly over the three years ended December 31, 2004 as we established our commercial organizations in the U.S., Europe, Australia and Thailand to support the selling of our products in these markets. Our general and administrative functions also expanded over this period to support the growth of our business and the additional requirements of becoming a publicly held company.

Sales and marketing expenses totaled \$46.8 million for the year ended December 31, 2004, an increase of \$26.0 million over 2003. Generally, this increase is due to expansion of our commercial organization and sales and marketing activities in the U.S. and our European and other international markets to support the U.S. launch of Vidaza and the significant growth in thalidomide sales. Field sales and sales management expenses in the U.S. increased by \$10.7 million in 2004 due to the expansion of our sales organization to support the launch of Vidaza. We increased our U.S. field-based organization from approximately 30 employees to 75 employees during 2004. Other U.S. selling expenses also increased in connection with the Vidaza launch. European and international field sales and sales management expenses increased by \$5.7 million in 2004. We began selling thalidomide in Europe on a compassionate use or named patient basis in mid-2003. The sales expense growth in 2004 reflects having these costs for a full year in 2004 as well as increased selling activities to support the sales growth of thalidomide. Marketing expenses increased by \$9.6 million in 2004, due primarily to the U.S. launch of Vidaza and increased activities to support the sales growth of thalidomide. Product marketing costs increased by \$7.5 million while non-product specific costs, such as personnel costs and travel, increased by \$2.1 million.

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 product specific marketing costs in 2003.

General and administrative expenses totaled \$20.0 million for the year ended December 31, 2004, an increase of \$4.7 million over the prior year. This increase is primarily due to increased costs associated with becoming a public company with the completion of our initial public offering in November 2003. Professional fees, including legal, accounting, tax and Sarbanes-Oxley implementation consulting, increased by \$2.5 million during 2004. Directors and officers liability insurance premiums increased by \$.6 million in 2004 and the establishment of our investor relations function increased 2004 expenses by \$.4 million. In addition, business development costs increased by \$.8 million in 2004 as we significantly increased our activities associated with identifying potential product licensing and acquisition candidates.



**Table of Contents**

General and administrative expenses totaled \$15.3 million for the year ended December 31, 2003, an increase of \$3.0 million over 2002. This increase 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 insurance costs, partially offset by a decrease of \$.4 million in other corporate expenses.

*Product rights amortization.* Product rights amortization expense for the years ended December 31, 2004, 2003 and 2002 was as follows.

	2004	2003	2002
	(In thousands)		
Product rights amortization	\$ 3,396	\$ 1,972	\$ 375
Increase from prior year	\$ 1,424	\$ 1,597	n/a
% Change from prior year	72.2%	425.9%	n/a

The increase in amortization expense in 2004 as compared to 2003 is due primarily to having a full year of amortization of product rights acquired through the purchase of Laphal Developement in April 2003. In addition, the August 2003 renegotiation of the financial terms of the Refludan product rights resulted in an increase to the value of the capitalized product rights and increased the related amortization expense for all of 2004 compared to only 5 months of 2003. The increase in 2003 is due primarily to the amortization of product rights acquired through the 2003 acquisition of Laphal and the renegotiation of the financial terms of the Refludan rights in August 2003.

*Interest and other income (expense), net.* Interest and other income (expense), net, totaled \$2.4 million for the year ended December 31, 2004, an increase of \$2.6 million over 2003. This increase is due primarily to increased interest income from higher balances of cash, cash equivalents and short-term investments resulting from the equity offerings completed in November 2003 and July 2004. In addition, in March 2004 \$14 million of 6% convertible notes, originally issued in April 2003, were converted into shares of our common stock, thereby eliminating the interest expense associated with those notes. Interest and other income (expense), net totaled \$(.2) for the year ended December 31, 2003, a decrease of \$1.3 million as compared to the year ended December 31, 2002. This net decrease is primarily due to higher interest expense in 2003 related to the \$14 million 6% convertible notes issued in April 2003.

*Income tax expense.* Income tax expense totaled \$7.9 million for the year ended December 31, 2004 as compared to \$1.3 million for the year ended December 31, 2003 and \$.1 million for the year ended December 31, 2002. Although we have incurred pre-tax losses on a consolidated basis, certain of our foreign subsidiaries generate taxable income, and therefore incur income tax expense. The increase in income tax expense for 2004 as compared to 2003 is due primarily to an increase in taxable income in certain foreign countries. The \$1.2 million increase in income tax expense for 2003 as compared to 2002 is due to similar factors, largely driven by the acquisition of Laphal Developement in April 2003.

**Liquidity and Capital Resources**

Since our inception, we have incurred significant losses and as of December 31, 2004, we had an accumulated deficit of \$138.1 million. We achieved profitability on a quarterly basis for the first time in the fourth quarter of 2004, but have not yet achieved profitability on a full year basis. We expect that our clinical, development and regulatory and selling, general and administrative expenses will continue to grow and, as a result, we will need to generate significant sales to maintain 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 stock in two public offerings. Net proceeds from our preferred stock sales totaled \$125.0 million, the issuance of convertible notes generated \$14.0 million, and our public offerings of common stock completed in November 2003 and July 2004 resulted in combined net proceeds of \$314.1 million. We began generating revenue from product sales in July 2002.



**Table of Contents**

Cash and cash equivalents and short-term investments increased from \$88.5 million at December 31, 2003 to \$245.5 million at December 31, 2004. This increase is primarily due to the receipt of the net proceeds from a public offering of our common stock completed in July 2004 of \$237.9 million plus \$8.4 million of proceeds from the exercise of common stock options and warrants, partially offset by cash used to fund operations of \$6.1 million, purchases of property and equipment of \$1.2 million, \$4.0 million to repay debt obligations, and net cash of \$80.0 million paid to Celgene to reduce our thalidomide product supply cost, add three countries to our thalidomide licensed territory and to eliminate Celgene's right to terminate the thalidomide license agreement in the event thalidomide has not received a marketing approval by November 2006.

We expect that our cash on hand at December 31, 2004, along with cash generated from expected product sales, will be adequate to fund our operations for at least the next twelve months. However, we reexamine our cash requirements periodically in light of changes in our business. For example, in the event that we make additional product acquisitions, we may need to raise additional funds. 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.

Accounts receivable, net increased to \$35.2 million at December 31, 2004 from \$8.0 million at December 31, 2003. This increase is due to the growth in sales in 2004, primarily from the launch of Vidaza in the U.S. and increased thalidomide sales in Europe and other international markets. Our customer payment practices vary significantly between countries. Increased sales in countries in which payments tend to be slower, often as a result of the pace at which governmental entities reimburse our customers, may increase the financial risk of certain of our customers in those countries. Accounts receivable in countries in which customer payments are typically slow, namely Spain and Portugal, totaled \$6.9 million at December 31, 2004. To date, we have experienced minimal losses with respect to the collection of our accounts receivable and we believe that the accounts receivable for Spain and Portugal are collectible. We continually seek improvement in our collection process to maximize cash flow from product sales in a timely manner.

**Contractual Obligations**

Our contractual obligations as of December 31, 2004 were as follows:

Contractual Obligations	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
(In millions)					
Operating leases	\$ 11.8	\$ 3.1	\$ 7.3	\$ 1.4	
Clinical development funding	10.0	4.7	5.3		
Product and company acquisition payments	9.4	9.4			
Product royalty payments	7.3	3.3	4.0		
Inventory purchase commitments	7.1	7.1			
Long-term debt obligations	0.6	0.4	0.2		
<b>Total fixed contractual obligations</b>	<b>\$ 46.2</b>	<b>\$ 28.0</b>	<b>\$ 16.8</b>	<b>\$ 1.4</b>	

*Operating leases.* Our commitment for operating leases relates primarily to our corporate and sales offices located in the U.S., Europe, Thailand and Australia. These lease commitments expire on various dates through 2009.

*Clinical development funding.* We have entered into two agreements with Celgene to provide funding to support clinical development studies sponsored by Celgene studying thalidomide as a treatment for various types of cancers.

Under these agreements, we will pay Celgene \$4.7 million in 2005 and \$2.65 million in each of 2006 and 2007.

*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

**Table of Contents**

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 for our license of Refludan and a royalty of 14% of our net sales of Refludan commencing in January 2004 and up to \$7.5 million of contingent payments described below. In the fourth quarter of 2004, we achieved a cumulative sales milestone related to our acquisition of Laphal. Accordingly, we paid in the first quarter of 2005 a total of \$4.0 million (approximately \$5.4 million) to the former shareholders of the parent company of Laphal.

*Product royalty payments.* Pursuant to our thalidomide product license agreements with Celgene, 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. In addition, our Innohep license agreement with LEO Pharma requires annual minimum royalty payments through 2006.

*Inventory purchase commitments.* The contractual summary above includes contractual obligations related to our product 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.

*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 a second payment of \$4 million, or an aggregate of approximately \$5.4 million based on foreign currency exchange rates as of December 31, 2004, if Laphal's products achieve future revenue milestones.

**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.

**Risks Related to Our Business*****We have a history of net losses, and may not maintain profitability in the future.***

We have incurred annual net losses since our inception, including a net loss of \$17.5 million on an annual basis for the fiscal year ended December 31, 2004. As of December 31, 2004, we had an accumulated deficit of \$138.1 million. In February 2005, we announced that the fourth quarter of 2004 was our first profitable quarter. 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. Furthermore, our expenditures could increase significantly if we acquire additional products or product candidates. Accordingly, we will need to generate significantly greater revenues to maintain profitability. If we fail to achieve profitability on a continuous basis within the time frame expected by investors or securities analysts, the market price of our common stock may decline.

***Our business is largely dependent on the commercial success of Vidaza. If we are unable to successfully commercialize Vidaza we may be unable to continue our operations as planned.***

The success of our business is largely dependent on the commercial success of Vidaza. Although initial sales of Vidaza since we launched the product last year are encouraging, Vidaza is new to the market and we do not have substantial data on the use of the product by physicians and patients. As a consequence, we cannot assure you that Vidaza will gain widespread acceptance from members of the medical community or that the

**Table of Contents**

initial acceptance of Vidaza we have observed thus far will be maintained. Acceptance will be a function of its continued acceptance by regulators, physicians, patients and other key decision-makers as a safe, superior therapeutic as compared to currently existing or future treatments for MDS. Moreover, the FDA is currently considering for approval new therapeutics for treating MDS that have been under development by our competitors. Even if Vidaza does achieve market acceptance, we may not be able to maintain that market acceptance over time if these new products are introduced and are more favorably received than Vidaza or render Vidaza obsolete.

Regulatory authorities in our markets subject approved products and manufacturers of approved products to continual regulatory review. Previously unknown problems, such as unacceptable toxicities or side effects, may only be discovered after a product has been approved and used in an increasing number of patients. If this occurs, regulatory authorities may impose labeling restrictions on the product that could affect its commercial viability or could require withdrawal of the product from the market. Because Vidaza has only recently been approved for commercial sale, there is a risk that we will discover such previously unknown problems associated with the use of Vidaza in patients, which could limit sales growth or cause sales of Vidaza to decline.

***We may not receive regulatory approvals for Thalidomide Pharmion 50mg or, outside of the U.S., for 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, and our ability to commercialize Vidaza outside the U.S. is subject to regulatory approval by governmental authorities in Europe and elsewhere. In May 2004, we withdrew our multiple myeloma applications with the EMEA for Thalidomide Pharmion 50mg, based on the EMEA's stated view that additional clinical data would be required before it can reach an opinion on whether or not Thalidomide Pharmion 50mg should be approved as a treatment for multiple myeloma. We intend to resubmit our application with additional clinical data from ongoing studies in both relapsed/ refractory and newly-diagnosed multiple myeloma patients. In September 2004 the EMEA accepted for review our Marketing Authorization Application for Vidaza for the treatment of MDS based on data from the same clinical studies accepted by the FDA for approval of Vidaza in the U.S. We cannot assure you that the results of our ongoing clinical trials for Thalidomide Pharmion 50mg and the data submitted to the EMEA for approval of Vidaza will support our applications for these regulatory approvals. 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 a 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 delay or prevent regulatory approval in Europe or 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.

**Table of Contents**

***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 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.

Regulatory authorities in our markets require that drugs be manufactured, packaged and labeled in conformity with cGMP regulations and guidelines. In addition, before any product batch produced by our manufacturers can be shipped, it must conform to release specifications pre-approved by regulators for the content of the pharmaceutical product. The manufacturing process for Vidaza is very complex, and we have limited experience with manufacturing commercial batches of Vidaza. There is a risk that our manufacturers will not comply with all applicable regulatory standards, and may not be able to manufacture Vidaza on a commercial scale that conforms on a consistent basis to our release specifications approved by the FDA.

To date, we have relied on sole sources for the manufacture of our products and 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 fail to deliver the required commercial quantities of bulk drug substance or finished product on a timely basis and at commercially reasonable prices, and we are 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. Moreover, failure of our third party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of Vidaza and our other products.

***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 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.

**Table of Contents**

***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 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. 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.

***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.

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.

**Table of Contents**

The primary competition and potential competition for our products currently are:

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

*Vidaza:* Thalomid® and Revlimid™, each from Celgene, and Dacogen™, from Supergen Inc., with marketing rights held by MGI Pharma, Inc., which like Vidaza, is a demethylating agent;

*Innohep:* Lovenox®, from Sanofi-Aventis, Fragmin®, from Pfizer, Inc. and Arixtra, from GlaxoSmithKline plc; and

*Refludan:* Argatroban, from GlaxoSmithKline.

Both Dacogen and Revlimid are currently in development and/or under review for regulatory approval by the FDA and EMEA. In addition to these products, there are additional products in clinical development for the treatment of MDS and the enrollment of patients in clinical trials for these products may reduce the number of patients that will receive Vidaza treatment. We also face competition for Vidaza from traditional therapies for the treatment of MDS, including the use of blood transfusions and growth factors.

***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.

***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. 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.

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, 2004 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. Each of Mr. Mahaffy and Dr. Hemberger has entered into an employment agreement with us for a term that runs until the agreement is otherwise terminated by us or them. Their employment agreements provide that they cannot compete with us for a period of one year after their employment with us is terminated. If we lose

**Table of Contents**

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.

***We have 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, Thalidomide Pharmion 50mg and Refludan currently have patent protection under issued patents. As a result, we must rely in large part on orphan drug exclusivity, trade secrets, 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, competitors could overcome the competitive advantage gained by orphan drug exclusivity by introducing other products in the same indication. 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 and we must rely on our use patent protection to prevent competitors from selling thalidomide in our markets.

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 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.

***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, if we acquire additional businesses or products we will incur significant acquisition costs and operating expenses, which could harm our financial condition and operating results. In addition, 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.

## **Table of Contents**

### ***Changes to financial accounting standards may affect our results of operations and cause us to change our business practices.***

We prepare our financial statements to conform with generally accepted accounting principles, or GAAP, in the United States. These accounting principles are subject to interpretation by the American Institute of Certified Public Accountants, the Financial Accounting Standards Board, or FASB, the SEC and various bodies formed to promulgate and interpret appropriate accounting policies. A change in those accounting principles or interpretations could have a significant effect on our reported financial results and may affect our reporting of transactions completed before a change is announced or adopted. Changes to those rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business. For example, accounting policies affecting certain aspects of our business, including rules relating to employee stock option grants, have recently been revised. In December 2004, the FASB issued a revision of SFAS No. 123, Accounting for Stock-Based Compensation, which amends SFAS No. 123 to require the recognition of employee stock options as compensation based on their fair value at the time of grant (with limited exceptions). These new rules, which are effective on the commencement of the first interim period starting after June 15, 2005, will require us to change our accounting policy and record an expense for our stock-based compensation plans using the fair value method, and will result in additional accounting charges as described in *Management's Discussion and Analysis of Financial Condition and Results of Operations - Recently Issued Accounting Standards*.

### ***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;

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. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 together with rulemaking by the Centers for Medicare and Medicaid Services, or CMS, changed the methodology for Medicare reimbursement of pharmaceutical products administered in

physician offices and hospital outpatient facilities, including

42

---

**Table of Contents**

Vidaza and Innohep. Under the new regulations, reimbursements will now be the average selling price, or ASP, of a product plus 6%, rather than a specified discount from the average wholesale price, or AWP, as was the case under prior regulations. The new ASP-based reimbursement regime generally will reduce the reimbursement physicians will receive under Medicare for most office-administered injectable drugs, including Vidaza and Innohep. Although the actual impact of these reimbursement changes is not currently well known, there is a risk that the new reimbursement policies will adversely affect product use by physicians, thereby reducing our sales for these products.

In other countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals and the level of reimbursement are subject to governmental control. 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., including the U.S., 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 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

**Table of Contents**

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, labeling, 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.

**Risks Related to Our Common Stock**

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

Our amended and restated certificate of incorporation, bylaws, Delaware law and our employment agreements with members of senior management 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.

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

## **Table of Contents**

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.

The employment agreements with members of our senior management provide that certain benefits will be payable to the executives in the event we undergo a change in control and the termination of the executive's employment within two years after such change in control for any reason other than for cause, disability, death, normal retirement or early retirement.

***Our stock price has been and may continue to be volatile and your investment in our common stock could suffer a decline in value.***

We completed our initial public offering in November 2003. Since our initial public offering, the price of our common stock as reported by the NASDAQ National Market has ranged from a low of \$11.00 to a high of \$58.49.

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.

### **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.

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.

**Table of Contents**

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

None.

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

**Evaluation of Disclosure 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, or the Exchange Act, 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.

**Management's Report on Internal Control Over Financial Reporting**

The management of the company is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15(d)-15(f) of the Exchange Act. Our internal control system was designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Our management assessed the effectiveness of the company's internal control over financial reporting as of December 31, 2004. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework. Based on our assessment we believe that, as of December 31, 2004, our internal control over financial reporting is effective based on those criteria.

**Table of Contents**

Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004, has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included in this Item 9A immediately below.

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of Pharmion Corporation:

We have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting, that Pharmion Corporation maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Pharmion Corporation's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Pharmion Corporation maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Pharmion Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Pharmion Corporation as of December 31, 2004 and 2003, 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, 2004 of Pharmion Corporation and our report dated March 11, 2005 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Denver, Colorado  
March 11, 2005

**Table of Contents**

**Item 9B. *Other Information***

None.

**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 2005 Annual Meeting of Stockholders to be filed with the Commission within 120 days after the end of our fiscal year ended December 31, 2004 (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 incorporated by reference from the information set forth in the section of the Proxy Statement entitled "Code of Ethics." The information required by this Item concerning our equity compensation plan is set forth under Item 5 of this Annual Report on Form 10-K.

**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 and Financial Statement Schedules***

(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.

**Table of Contents***(2) Consolidated Financial Statement Schedules*

The following consolidated financial statement schedule of the Company for each of the years ended December 31, 2004, 2003 and 2002, 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.

	<b>Page Number</b>
Schedule II Valuation and Qualifying Accounts	S-1

*(3) Exhibits*

<b>Exhibit Number</b>	<b>Description of Document</b>
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.

**Table of Contents**

<b>Exhibit Number</b>	<b>Description of Document</b>
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.
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(3)*	Employment Agreement, dated as of February 23, 2004, by and between the Registrant and Patrick J. Mahaffy.
10.18(3)*	Amended and Restated Employment Agreement, dated as of March 1, 2004, 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(3)*	Amended and Restated Employment Agreement, dated as of March 1, 2004, by and between the Registrant and Erle Mast.
10.22(3)*	Amended and Restated Employment Agreement, dated as of March 1, 2004, 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.
10.25(2)*	Addendum to Employment Agreement, dated June 15, 2004, by and between the Registrant and Michael Cosgrave.
10.26	Amendment No. 2, dated December 3, 2004, to Amended and Restated Distribution and License Agreement, dated November 16, 2001, between Pharmion GmbH and Celgene UK Manufacturing II Limited (formerly Penn T Limited).
10.27	Letter Agreement, dated December 3, 2004, among the Registrant, Pharmion GmbH and Celgene Corporation amending the Letter Agreement regarding clinical funding, dated April 2, 2003, between Registrant, Pharmion GmbH and Celgene.
10.28	Letter Agreement, dated December 3, 2004, between the Registrant, Pharmion GmbH and Celgene Corporation amending the License Agreement, dated November 16, 2001, among Registrant, Pharmion GmbH and Celgene.

10.29

Lease, dated December 21, 2004, by and between Pharmion Limited and Alecta Pensionsförsäkring Ömsesidigit.

50

---

**Table of Contents**

<b>Exhibit Number</b>	<b>Description of Document</b>
10.30	Counterpart Guarantee, dated December 21, 2004, by and between Registrant and Alecta Pensionsförsäkring Ömsesidigit.
21.1(2)	Subsidiaries of the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney. (reference is made to page 52)
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.
(2)	Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-116252) and amendments thereto, declared effective June 30, 2004.
(3)	Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2004 (File No. 000-50447)
*	Management Contract or Compensatory Plan or Arrangement

**Table of Contents****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 15, 2005

**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 and in the capacities and on the dates indicated.

Name	Title	Date
/s/ Patrick J. Mahaffy Patrick J. Mahaffy	President, Chief Executive Officer and Director (Principal Executive Officer)	March 15, 2005
/s/ Erle T. Mast Erle T. Mast	Chief Financial Officer (Principal Financial and Accounting Officer)	March 15, 2005
/s/ Judith A. Hemberger Judith A. Hemberger	Executive Vice President, Chief Operating Officer and Director	March 15, 2005
/s/ Edward J. McKinley Edward J. McKinley	Director	March 15, 2005
/s/ Brian G. Atwood Brian G. Atwood	Director	March 15, 2005
/s/ Thorlef Spickschen Thorlef Spickschen	Director	March 15, 2005



**Table of Contents**

<b>Name</b>	<b>Title</b>	<b>Date</b>
/s/ M. James Barrett M. James Barrett	Director	March 15, 2005
/s/ James Blair James Blair	Director	March 15, 2005
/s/ Cam Garner Cam Garner	Director	March 15, 2005

**Table of Contents**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

Pharmion Corporation Consolidated Financial Statements:

<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets</u>	F-3
<u>Consolidated Statements of Operations</u>	F-4
<u>Consolidated Statements of Stockholders' Equity</u>	F-5
<u>Consolidated Statements of Cash Flows</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-7
<u>Schedule II Valuation and Qualifying Accounts</u>	S-1

F-1

---

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders of Pharmion Corporation

We have audited the accompanying consolidated balance sheets of Pharmion Corporation as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2004. 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 the standards of the Public Company Accounting Oversight Board (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, 2004 and 2003, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles. 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.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Pharmion Corporation's internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 11, 2005 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Denver, Colorado  
March 11, 2005

F-2

---

**Table of Contents**

**PHARMION CORPORATION  
CONSOLIDATED BALANCE SHEETS**

	December 31,	
	2004	2003
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 119,657,986	\$ 88,541,793
Short-term investments	125,884,838	
Accounts receivable, net of allowances of \$2,209,842 and \$818,516, respectively	35,193,222	7,992,177
Inventories, net	3,687,496	4,923,161
Prepaid royalties		1,342,987
Other current assets	4,396,282	2,779,203
<b>Total current assets</b>	<b>288,819,824</b>	<b>105,579,321</b>
Product rights, net	108,478,367	30,650,819
Goodwill	9,425,524	3,651,804
Property and equipment, net	4,283,763	5,049,420
Other assets	222,994	541,223
<b>Total assets</b>	<b>\$ 411,230,472</b>	<b>\$ 145,472,587</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 9,891,391	\$ 4,241,075
Accrued and other current liabilities	45,562,831	14,799,437
<b>Total current liabilities</b>	<b>55,454,222</b>	<b>19,040,512</b>
Long term liabilities:		
Convertible notes		13,374,455
Deferred tax liability	3,605,721	3,664,618
Other long-term liabilities	217,828	4,479,267
<b>Total long term liabilities</b>	<b>3,823,549</b>	<b>21,518,340</b>
<b>Total liabilities</b>	<b>59,277,771</b>	<b>40,558,852</b>
Stockholders' equity (deficit)		
Common stock: par value \$0.001, 100,000,000 shares authorized, 31,780,715 and 23,948,636 shares issued and outstanding, respectively	31,781	23,949
Preferred stock: par value \$0.001, 10,000,000 shares authorized, no shares issued and outstanding		
Additional paid-in capital	482,660,589	222,217,779
Deferred compensation	(679,572)	(1,155,169)

Edgar Filing: PHARMION CORP - Form 10-K

Accumulated other comprehensive income	8,036,088	4,386,182
Accumulated deficit	(138,096,185)	(120,559,006)
Total stockholders equity	351,952,701	104,913,735
Total liabilities and stockholders equity	\$ 411,230,472	\$ 145,472,587

See accompanying notes.

F-3

---

**Table of Contents**

**PHARMION CORPORATION**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

**Years Ended December 31,**

	<b>2004</b>	<b>2003</b>	<b>2002</b>
Net sales	\$ 130,170,640	\$ 25,539,248	\$ 4,735,354
Operating expenses:			
Cost of sales, including royalties	43,634,611	11,461,994	1,575,105
Clinical, development and regulatory	28,391,812	24,615,968	15,049,487
Selling, general and administrative	66,847,663	36,108,728	23,436,614
Product rights amortization	3,395,504	1,971,597	375,439
Total operating expenses	142,269,590	74,158,287	40,436,645
Loss from operations	(12,098,950)	(48,619,039)	(35,701,291)
Interest and other income (expense), net	2,414,838	(154,390)	1,109,690
Loss before taxes	(9,684,112)	(48,773,429)	(34,591,601)
Income tax expense	7,853,067	1,285,473	105,255
Net loss	(17,537,179)	(50,058,902)	(34,696,856)
Less accretion of redeemable convertible preferred stock to redemption value		(10,090,971)	(8,575,644)
Net loss attributable to common stockholders	\$ (17,537,179)	\$ (60,149,873)	\$ (43,272,500)
Net loss attributable to common stockholders per common share, basic and diluted	\$ (.63)	\$ (14.70)	\$ (57.58)
Shares used in computing net loss attributable to common stockholders per common share, basic and diluted	27,933,202	4,093,067	751,525
Unaudited pro forma net loss attributable to common stockholders per common share assuming conversion of preferred stock, basic and diluted (Note 2)	N/A	\$ (2.66)	\$ (2.47)
Shares used in computing unaudited pro forma net loss attributable to common stockholders per common share assuming conversion of preferred stock, basic and diluted (Note 2)	N/A	18,791,015	14,072,707

See accompanying notes.

F-4

Table of Contents

**PHARMION CORPORATION**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**

	Common Stock		Treasury Stock		Additional Paid-In Capital	Deferred Compensation	Other Comprehensive Income	Accumulated (Deficit)	Total Stockholder Equity (Deficit)
	Shares	Amount	Shares	Amount					
<b>Balance at January 1, 2002</b>	849,500	850	(22,500)	(13,500)		(88,309)	14,313	(19,696,600)	(19,783,243)
Comprehensive loss:								(34,696,856)	(34,696,856)
Foreign currency translation adjustment							762,625		762,625
Comprehensive loss									(33,934,231)
Exercise of stock options	42,177	42			32,629				32,671
Cancellation of vested shares common stock	(22,500)	(23)	22,500	13,500	(13,477)				
Amortization of deferred compensation						44,160			44,160
Accretion of deferred stock redemption value					(19,152)			(8,556,492)	(8,575,644)
<b>Balance at December 31, 2002</b>	869,177	869				(44,149)	776,938	(62,949,948)	(62,216,290)
Comprehensive loss:								(50,058,902)	(50,058,902)
Foreign currency translation adjustment							3,609,244		3,609,244
Comprehensive loss									(46,449,658)
Exercise of stock options	53,190	53			73,595				73,648
	(4,687)	(4)			(1,871)				(1,875)

purchase of vested shares common stock								
ferred compensation associated with stock option plans			1,740,879	(1,740,879)				
amortization of ferred compensation quance of arrants associated with convertible notes			729,697			629,859		629,859
cretion of ferred stock redemption ue			(2,540,815)				(7,550,156)	(10,090,971)
conversion of ferred stock common stock	17,030,956	17,031	146,060,825					146,077,856
quance of nnon stock, of issuance plans	6,000,000	6,000	76,155,469					76,161,469
<b>Balance at December 31, 2013</b>	23,948,636	\$ 23,949	\$ 222,217,779	\$ (1,155,169)	\$ 4,386,182	\$ (120,559,006)	\$ 104,913,730	
Comprehensive loss:								
Net loss							(17,537,179)	(17,537,179)
Foreign currency translation adjustment						3,923,764		3,923,764
Net unrealized gains on available-for-sale investments						(273,858)		(273,858)
Comprehensive loss								(13,887,273)
Exercise of stock options and arrants	1,206,551	1,207	8,384,438					8,385,646
purchase of vested shares common stock	(6,642)	(7)	(3,979)					(3,986)
conversion of not and accrued	1,342,170	1,342	14,160,149					14,161,491

Interest to equity									
Amortization of									
Preferred									
Compensation				475,597					475,597
Balance of									
Common stock,									
Cost of issuance	5,290,000	5,290		237,902,202					237,907,492
Costs									
<b>Balance at</b>									
<b>December 31,</b>									
<b>2014</b>	31,780,715	\$ 31,781	\$	\$ 482,660,589	\$ (679,572)	\$ 8,036,088	\$ (138,096,185)	\$ 351,952,700	

See accompanying notes.

F-5

**Table of Contents**

**PHARMION CORPORATION**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**Years Ended December 31,**

	<b>2004</b>	<b>2003</b>	<b>2002</b>
<b>Operating activities</b>			
Net loss	\$ (17,537,179)	\$ (50,058,902)	\$ (34,696,856)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	5,609,395	3,516,450	1,044,453
Compensation expense related to stock option issuance	475,597	629,859	
Other	(539,165)	201,675	62,834
Changes in operating assets and liabilities:			
Accounts receivable, net	(25,432,117)	(5,610,818)	(433,065)
Inventories	1,682,708	(1,733,357)	(1,351,257)
Other current assets	(39,688)	(232,363)	(2,544,209)
Other long-term assets	324,875	1,033,649	(1,484,399)
Accounts payable	5,215,896	(1,081,441)	2,709,344
Accrued and other current liabilities	24,176,512	5,632,587	1,612,470
Net cash used in operating activities	(6,063,166)	(47,702,661)	(35,080,685)
<b>Investing activities</b>			
Purchases of property and equipment	(1,164,801)	(2,468,685)	(2,904,669)
Acquisition of business, net of cash acquired	(19,032)	(12,289,524)	
Purchase of product rights	(80,000,000)	(1,000,000)	(8,000,000)
Purchase of available-for-sale investments	(158,593,097)		
Sale and maturity of available-for-sale investments	32,584,820		
Net cash used in investing activities	(207,192,110)	(15,758,209)	(10,904,669)
<b>Financing activities</b>			
Proceeds from sale of preferred and common stock, net of issuance costs	237,907,492	76,161,469	39,621,351
Proceeds from exercise of common stock options and warrants	8,381,659	71,774	32,671
Proceeds from issuance of convertible debt and warrants		14,000,000	
Payment of debt obligations	(3,972,033)	(1,075,924)	(7,856)
Net cash provided in financing activities	242,317,118	89,157,319	39,646,166
Effect of exchange rate changes on cash and cash equivalents	2,054,351	241,025	499,276

Edgar Filing: PHARMION CORP - Form 10-K

Net increase (decrease) in cash and cash equivalents	31,116,193	25,937,474	(5,839,912)
Cash and cash equivalents, beginning of period	88,541,793	62,604,319	68,444,231
Cash and cash equivalents, end of year	\$ 119,657,986	\$ 88,541,793	\$ 62,604,319

Noncash items:

Financed property and equipment acquisitions	57,718		222,705
Financed product rights acquisition		8,208,071	
Conversion of debt and accrued interest to common stock	14,161,491		
Accrual of additional business acquisition consideration	5,457,600		

Supplemental disclosure of cash flow information:

Cash paid for interest	485,787	237,421	3,179
Cash paid for income taxes	1,317,307	237,389	

See accompanying notes.

F-6

**Table of Contents**

**PHARMION CORPORATION  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Business Operations**

Pharmion Corporation (the Company) was incorporated in Delaware on August 26, 1999 and commenced operations in January 2000. The Company is engaged in the acquisition, development and commercialization of pharmaceutical products for the treatment of oncology and hematology patients. The Company's product acquisition and licensing efforts are focused on both late-stage development products as well as those approved for marketing. In exchange for distribution and marketing rights, the Company generally grants the seller royalties on future sales and, in some cases, up-front cash payments. To date, the Company has acquired the distribution and marketing rights to four products, three of which are approved for marketing and with the fourth being sold on a compassionate use or named patient basis while the Company pursues marketing approval. The Company has established operations in the United States, Europe and Australia. Through a distributor network, the Company can reach the hematology and oncology community in additional countries in the Middle East and Asia.

On September 25, 2003, the Company effected a one for four reverse stock split of its common stock. All share and per share amounts included in these consolidated financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock split.

On November 12, 2003, the Company completed an initial public offering, which resulted in net proceeds of \$76.2 million from the issuance of 6,000,000 shares of common stock. In connection with the initial public offering, all of the outstanding shares of the Company's preferred stock were converted into shares of common stock.

On July 7, 2004, the Company completed a public offering of common stock. A total of 5,290,000 shares of common stock were sold at a price to the public of \$48.00 per share, resulting in net proceeds to the Company of \$237.9 million.

**2. Summary of Significant Accounting Policies**

***Basis of Presentation***

The consolidated financial statements include the accounts of Pharmion Corporation and all subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

***Cash and Cash Equivalents***

Cash and cash equivalents consist of money market accounts and overnight deposits. The Company considers all highly liquid investments purchased with a maturity of three months or less to be cash equivalents. Interest income resulting from cash and cash equivalent holdings was \$2,559,956, \$494,595, and \$990,842 for the years ended December 31, 2004, 2003 and 2002, respectively.

During 2004, the Company entered into an international standby letter of credit to guarantee both current and future commitments of a new foreign office lease agreement. The aggregate amount outstanding under the letter of credit was approximately \$1.6 million at December 31, 2004 and is secured by restricted cash held in U.S. cash accounts.

***Short-term Investments***

Short-term investments consist of investment grade government agency and corporate debt securities due within one year. Investments with maturities beyond one year are classified as short-term based on their highly liquid nature and because such investments represent the investment of cash that is available for current operations. All investments are classified as available-for-sale and are recorded at market value. Unrealized gains and losses are reflected in other comprehensive income.

**Table of Contents**

**PHARMION CORPORATION  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Inventories***

Inventories consist of Vidaza, Innohep, Refludan and thalidomide. Vidaza and Innohep are drugs that are sold exclusively in the U.S. market, while Refludan and thalidomide are sold in the international markets. All of the products are manufactured by third-party manufacturers and delivered to the Company as finished goods. Inventories are stated at the lower of cost or market, cost being determined under the first-in, first-out method. The Company periodically reviews inventories and items considered outdated or obsolete are reduced to their estimated net realizable value. For the years ended December 31, 2004 and 2003, the Company reduced the estimated net realizable value of obsolete and short-dated inventory by \$1.4 million and \$1.8 million, respectively.

Inventories consisted of \$351,263 and \$0 of raw material and \$3,336,233 and \$4,923,161 of finished goods, respectively, at December 31, 2004 and 2003.

At December 31, 2004, the Company had firm inventory purchase commitments, due within one year, of approximately \$7.1 million.

***Revenue Recognition***

The Company sells its 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 the customer, the sales price is fixed and determinable, and collectibility is reasonably assured. Within the United States and certain foreign countries, revenue is recognized upon shipment (freight on board shipping point) as title has transferred to the customer along with the risk 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.

Revenue is reported net of allowances for chargebacks from distributors, product returns, rebates, and 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 the estimates, the Company will adjust the allowances at the time such differences become 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. As such, the Company must estimate the likelihood that products sold to wholesale distributors will ultimately be subject to a rebate or price discount. This estimate is based on historical trends and industry data on the utilization of the Company's products.

***Cost of Sales***

Cost of sales includes the cost of product sold, royalties due on the sales of the products and the distribution and logistics costs related to selling the products.

***Risks and Uncertainties***

The Company is subject to risks common to companies in the pharmaceutical industry including, but not limited to, uncertainties related to regulatory approvals, dependence on key products, dependence on key customers and suppliers, and protection of proprietary rights.

**Table of Contents**

**PHARMION CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Advertising Costs***

The Company expenses all advertising, promotional and publication costs as incurred. Total advertising costs were approximately \$5,606,000, \$2,218,000 and \$1,914,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

***Translation of Foreign Currencies***

The functional currencies of the Company's foreign subsidiaries are the local currencies, primarily the British Pound Sterling, Euro and Swiss Franc. In accordance with Statement of Financial Accounting Standards (SFAS) No. 52, *Foreign Currency Translation*, assets and liabilities are translated using the current exchange rate as of the balance sheet date. Income and expenses are translated using a weighted average exchange rate over the period ending on the balance sheet date. Adjustments resulting from the translation of the financial statements of the Company's foreign subsidiaries into U.S. dollars are excluded from the determination of net loss and are accumulated in a separate component of stockholders' equity. Foreign exchange transaction gains and losses which, to date have not been significant, are included in the results of operations.

***Comprehensive Income***

The Company reports comprehensive income in accordance with the provisions of SFAS No. 130, *Reporting Comprehensive Income*. Comprehensive income includes all changes in equity for cumulative translation adjustments resulting from the consolidation of foreign subsidiaries and unrealized losses on available for sale securities.

***Product Rights***

The cost of acquiring the distribution and marketing rights of the Company's products were capitalized and are being amortized on a straight-line basis over the estimated benefit period of 10-15 years.

***Goodwill***

The Company completed a business acquisition in 2003, which resulted in the creation of goodwill. In accordance with SFAS No. 142, *Goodwill and Other Intangible Assets*, the Company does not amortize goodwill. SFAS No. 142 requires the Company to perform an impairment review of goodwill at least annually. If it is determined that the value of goodwill is impaired, the Company will record the impairment charge to the statement of operations in the period it is discovered. During the year ended December 31, 2004, the Company recorded an increase of \$5,457,600 to goodwill to reflect additional consideration due the seller of the business acquired in 2003 (see Note 4).

***Property and Equipment***

Property and equipment are stated at cost. Repairs and maintenance are charged to operations as incurred, and significant expenditures for additions and improvements are capitalized. Leasehold improvements are amortized over the economic life of the asset or the lease term, whichever is shorter. Depreciation

**Table of Contents****PHARMION CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

and amortization of property and equipment are computed using the straight-line method based on the following estimated useful lives:

	<b>Estimated Useful Life</b>
Computer hardware and software	3 years
Leasehold improvements	3-5 years
Equipment	7 years
Furniture and fixtures	10 years

***Long-Lived Assets***

Long-lived assets, other than goodwill, consist primarily of product rights, and property and equipment. In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, the recoverability of the carrying value of long-lived assets to be held and used is evaluated if changes in the business environment or other facts and circumstances that suggest they may be impaired. If this evaluation indicates the carrying value will not be recoverable, based on the undiscounted expected future cash flows generated by these assets, the Company reduces the carrying amount to the estimated fair value.

***Concentration of Credit Risk***

Financial instruments which potentially subject the Company to concentrations of credit risk are primarily cash and cash equivalents, short-term investments and accounts receivable. The Company maintains its cash and investment balances in the form of money market accounts, debt and equity securities and overnight deposits with financial institutions that management believes are creditworthy. The Company has no financial instruments with off-balance-sheet risk of accounting loss.

The Company's products are sold both to wholesale distributors and directly to hospitals and clinics. Ongoing credit evaluations of customers are performed and collateral is generally not required. Many of the international hospitals and clinics are government supported and may take a significant amount of time to collect. Accounts receivable, net of allowances, for the U.S. were \$12.9 million and \$0, respectively at December 31, 2004 and 2003. International accounts receivable net of allowances, were \$22.3 million and \$8.0 million, respectively, at December 31, 2004 and 2003. The Company maintains a reserve for potential credit losses based on the financial condition of customers and the aging of accounts. Losses have been within management's expectations.

In 2004, 2003 and 2002, revenues generated from three customers in the United States totaled approximately 35%, 13% and 37%, respectively, of consolidated net revenues. Revenues generated from international customers were individually less than 5% of consolidated net revenues.

***Clinical, Development and Regulatory Costs***

Clinical, development, and regulatory costs include salaries, benefits and other personnel related expenses as well as fees paid to third parties for clinical development and regulatory services. Such costs are expensed as incurred.

***Fair Value of Financial Instruments***

Financial instruments consist of cash and cash equivalents, short-term investments, accounts receivable, accounts payable and accrued liabilities. The carrying values of these instruments approximate fair value due to their short-term nature.

**Table of Contents**

**PHARMION CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Use of Estimates***

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

***Accounting for Stock-Based Compensation***

The Company has elected to account for its stock compensation arrangements to employees under the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ( APB No. 25 ), and its related interpretations. Under the provisions of APB No. 25, the company utilizes the intrinsic value method of accounting. Under this method, compensation expense is recognized on the date of grant if the current market price of the underlying stock exceeds the exercise price. The difference in value between the current market price and the exercise price is recorded as deferred compensation and is amortized to expense over the vesting period of the option on a straight-line basis. Pro forma information regarding net loss is required by SFAS No. 123, *Accounting for Stock-Based Compensation*, and has been determined as if the Company had accounted for its employee stock options under the fair value method of that statement. The fair value for options granted was estimated at the date of grant using the Black-Scholes valuation model. Under this model, the following weighted average assumptions were used:

	2004	2003	2002
Expected dividend yield	0%	0%	0%
Expected stock price volatility	76%	86%	85%
Risk free interest rate	2.9%	2.8%	2.9%
Expected life of options	4.6 years	5 years	5 years

The expected stock price volatility was estimated using percentages reported by similar public companies within the pharmaceutical industry as well as trading history of the Company's common stock. The weighted-average fair value per share was \$20.67, \$8.98, and \$1.33 for the options granted in 2004, 2003, and 2002, respectively. The difference between the actual expense recorded and pro forma expense for all periods presented is provided in the table below:

**Years Ended December 31,**

	2004	2003	2002
Net loss attributable to common stockholders as reported	\$ (17,537,179)	\$ (60,149,873)	\$ (43,272,500)
Add stock based compensation expense included in net loss	475,597	585,710	
Deduct total stock based compensation expense determined using the fair value method for all rewards	(3,821,369)	(931,910)	(315,318)
Pro forma net loss	\$ (20,882,951)	\$ (60,496,073)	\$ (43,587,818)
Net loss per common share basic and diluted			
As reported	\$ (.63)	\$ (14.70)	\$ (57.58)

Pro forma	(.75)	(14.78)	(58.00)
-----------	-------	---------	---------

Option valuation models such as the Black-Scholes value method described above require the input of highly subjective assumptions. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can

F-11

---

**Table of Contents****PHARMION CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

materially affect the fair value estimate, in the opinion of the Company's management, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

The Company accounts for options issued to consultants using the provisions of SFAS No. 123 and Emerging Issues Task Force (EITF) 96-18, *Accounting for Equity Instruments that are Issued to other than Employees for Acquiring or in Conjunction with Selling Goods or Services*.

***Net Loss Per Share***

Basic net loss per share is computed by dividing net loss for the period by the weighted average number of shares of common stock outstanding during the period reduced, where applicable, for outstanding, yet unvested, shares. Diluted net loss per share is computed by dividing the net loss for the period by the weighted average number of common and potential incremental common shares outstanding during the period, if their effect is dilutive. Potential incremental common shares include shares of common stock issuable upon the exercise of stock options and warrants and upon the conversion of convertible notes and redeemable convertible preferred stock outstanding during the period. The potential shares of common stock have not been included in the diluted net loss per share calculation because to do so would be anti-dilutive. Such shares totaled 1,599,076, 3,625,180, and 5,800,304 for the years ended December 31, 2004, 2003 and 2002, respectively.

***Pro Forma Net Loss Per Share***

Immediately prior to the effective date of the Company's initial public offering (November 12, 2003), all redeemable convertible preferred stock shares outstanding converted into an aggregate of 17,030,956 shares of common stock. The pro forma net loss per share was calculated on the consolidated statement of operations for fiscal years 2003 and 2002 to show the effects of this conversion on earnings per share. It is computed by dividing net loss before accretion of redeemable convertible preferred stock by the weighted average number of common shares outstanding, including the pro forma effects of conversion of all outstanding redeemable convertible preferred stock into shares of the Company's common stock.

***Recently Issued Accounting Standards***

On December 16, 2004, the Financial Accounting Standards Board issued SFAS No. 123 (revised 2004), *Share-Based Payment*, which is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation*. SFAS No. 123(R) supersedes APB No. 25, and amends SFAS No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However, SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative.

SFAS No. 123(R) must be adopted no later than July 1, 2005. Early adoption will be permitted in periods in which financial statements have not yet been issued. The Company expects to adopt SFAS No. 123(R) on July 1, 2005.

SFAS No. 123(R) permits public companies to adopt its requirements using one of two methods:

A modified prospective method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS No. 123(R) for all share-based payments granted after the effective date and (b) based on the requirements of SFAS No. 123 for all rewards granted to employees prior to the effective date of SFAS No. 123(R) that remain unvested on the effective date; or

**Table of Contents**

**PHARMION CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

A modified retrospective method which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under SFAS 123 for purposes of pro forma disclosures either (a) all prior periods or (b) prior interim periods of the year of adoption. The Company is still evaluating which method it will adopt on July 1, 2005.

**3. Geographic Information**

Foreign and domestic financial information (in thousands):

	Year	United States	Foreign Entities	Total
Net Sales	2004	\$ 55,642	\$ 74,529	\$ 130,171
	2003	3,751	21,788	25,539
	2002	2,100	2,635	4,735
Operating income (loss)	2004	\$ (16,472)	\$ 4,373	\$ (12,099)
	2003	(32,899)	(15,720)	(48,619)
	2002	(26,114)	(9,587)	(35,701)
Total Assets	2004	\$ 235,958	\$ 175,272	\$ 411,230
	2003	90,295	55,178	145,473

**4. Acquisition of Laphal Développement**

On March 25, 2003, a subsidiary of the Company acquired 100% of the outstanding stock of Gophar S.A.S. and its wholly owned subsidiary, Laphal Développement S.A. (collectively, Laphal). Laphal is a French pharmaceutical company focused on the sale of orphan drugs primarily in France and Belgium. Under the terms of the related Stock Purchase Agreement (SPA), the Company paid 12 million at closing, less the amount of Laphal's net financial debt (as defined in the SPA). The actual amount of cash paid for Laphal, net of cash received in the acquisition and including transaction costs incurred was approximately \$12.3 million. Two additional payments of 4 million each will be paid if certain aggregate sales targets are achieved. The first of their sales targets was achieved in the fourth quarter of 2004, and as such, the 4 million (approximately \$5.4 million) payment due the former shareholders of Gophar is accrued in the accompanying financial statements as of December 31, 2004. As a result of this purchase, the Company acquired the rights to the Laphal thalidomide formulation and access to certain European markets.

F-13

**Table of Contents**

**PHARMION CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following assets and liabilities were acquired in the acquisition of Laphal.

		As of March 25, 2003
<b>Current assets:</b>		
Cash and cash equivalents	\$	1,551,479
Accounts receivable		1,096,486
Inventories		413,707
Other current assets		496,447
<b>Total current assets</b>		<b>3,558,119</b>
Product rights		13,723,231
Goodwill		3,651,804
Property and equipment, net		8,743
<b>Total assets acquired</b>		<b>20,941,897</b>
<b>Current liabilities:</b>		
Accounts payable	\$	1,353,288
Accrued and other current liabilities		1,206,851
Long-term debt, due within one year		277,006
<b>Total current liabilities</b>		<b>2,837,145</b>
Deferred tax liability		3,651,804
Long-term debt		576,100
<b>Total liabilities assumed</b>	\$	<b>7,065,049</b>
<b>Net assets acquired</b>	\$	<b>13,876,848</b>

The operating results of Laphal have been included in the results of the Company from the date of the acquisition. Product rights relate to thalidomide and are being amortized over the 15 year period in which the Company expects to generate significant revenues from this product.

The following pro forma combined financial information for the years ended December 31, 2003 and 2002 is derived from the historical financial statements of the Company and of Laphal for the periods then ended, adjusted to give effect to their consolidation using the purchase method of accounting and to reflect interest costs on the convertible notes issued by the Company to fund the acquisition. This pro forma financial information assumes the acquisition of Laphal occurred as of the beginning of the periods shown. It is provided for illustrative purposes only and is not indicative of the operating results that would have been achieved had the acquisition been consummated at the dates indicated, nor is it necessarily indicative of future operating results:

<b>Year Ended December 31, 2003</b>	<b>Year Ended December 31, 2002</b>
---	---

Edgar Filing: PHARMION CORP - Form 10-K

Net sales	\$	27,326,566	\$	10,283,058
Net loss	\$	(50,426,996)	\$	(36,374,903)
Net loss attributable to common stockholders per common share, basic and diluted	\$	(14.79)	\$	(59.81)

F-14

---

**Table of Contents**

**PHARMION CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**5. Short-term Investments**

The amortized cost, gross unrealized gains, gross unrealized losses and fair value of available-for-sale investments by security classification at December 31, 2004, was as follows:

December 31, 2004	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Asset backed securities	\$ 17,500,097	\$	\$ (66,550)	\$ 17,433,547
Corporate debt securities	28,688,241		(48,763)	28,639,478
Government agencies	77,194,609		(158,545)	77,036,064
Other debt securities	2,775,749			2,775,749
<b>Total securities</b>	<b>\$ 126,158,696</b>	<b>\$</b>	<b>\$ (273,858)</b>	<b>\$ 125,884,838</b>

During the year ended December 31, 2004, the gross realized gains on sales of available-for-sale securities totaled \$342,809 and the gross realized losses totaled \$(181,333). The gains and losses on available-for-sale securities are based on the specific identification method.

The fair value of available-for-sale securities with unrealized losses at December 31, 2004 was as follows:

December 31, 2004	Amortized Cost	Gross Unrealized Loss
Asset backed securities	\$ 17,500,097	\$ (66,550)
Corporate debt securities	28,688,241	(48,763)
Government agencies	77,194,609	(158,545)
<b>Total securities</b>	<b>\$ 123,382,947</b>	<b>\$ (273,858)</b>

Unrealized losses were due to changes to interest rates associated with securities with short maturity lives and are deemed to be temporary. The duration in which the securities have been in an unrealized loss position was less than 12 months.

The amortized cost and estimated fair value of the available-for-sale securities at December 31, 2004, by maturity, was as follows:

Maturity	Amortized Cost	Estimated Fair Value
Due within one year	\$ 122,904,838	\$ 122,639,250
Due after one year through three years	3,245,588	3,245,588
<b>Total securities</b>	<b>\$ 126,158,696</b>	<b>\$ 125,884,838</b>



Table of Contents

**PHARMION CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**6. License Agreements**

The cost value and accumulated amortization associated with the Company's product rights is as follows:

	As of December 31, 2004		As of December 31, 2003	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Amortized product rights:				
Thalidomide	\$ 97,242,280	\$ (2,509,252)	\$ 15,849,130	\$ (791,337)
Refludan	12,208,071	(2,212,732)	12,208,071	(865,045)
Innohep	5,000,000	(1,250,000)	5,000,000	(750,000)
<b>Total product rights</b>	<b>\$ 114,450,351</b>	<b>\$ (5,971,984)</b>	<b>\$ 33,057,201</b>	<b>\$ (2,406,382)</b>

Amortization expense of \$3,395,504, \$1,971,620, and \$375,439 was recorded for the years ended December 31, 2004, 2003 and 2002, respectively. The estimated amortization expense for the next five years is approximately \$9 million per year.

***Thalidomide***

In 2001, the Company licensed rights relating to the development and commercial use of thalidomide from Celgene and separately entered into an exclusive supply agreement for thalidomide with Celgene UK Manufacturing II Limited (formerly known as Penn T Limited), or CUK. Under the agreements, as amended in December 2004, the territory licensed from Celgene is for all countries other than the United States, Canada, Mexico, Japan and all provinces of China (except Hong Kong). The Company pays (i) Celgene a royalty/license fee of 8% on the Company's net sales of thalidomide under the terms of the license agreements, and (ii) CUK product supply payments equal to 15.5% of the Company's net sales of thalidomide under the terms of the product supply agreement. The agreements with Celgene and CUK each have a ten-year term running from the date of receipt of the Company's first regulatory approval for thalidomide in the United Kingdom. In October of 2004, Celgene acquired CUK.

In December 2004, the Company amended its thalidomide agreements with Celgene and CUK to reduce the thalidomide product supply payment, expand the Company's licensed territory, and eliminate certain license termination rights held by Celgene. The Company paid Celgene a one-time payment of \$80 million in exchange for (i) the reduction in the cost of product supply from 28.0% of net sales to 15.5% of net sales, (ii) the addition of Korea, Hong Kong, and Taiwan to the Company's licensed territory and, (iii) elimination of Celgene's right to terminate the license agreement in the event the Company has not obtained a marketing authorization approval for thalidomide in the United Kingdom by November 2006. The \$80 million payment was capitalized as part of the thalidomide product rights and is being amortized over the remaining period the Company expects to generate significant thalidomide sales, approximately 13 years from December 31, 2004.

The Company has also committed to provide funding to support further clinical development studies of thalidomide sponsored by Celgene. Under these agreements, the Company will pay Celgene \$4.7 million in 2005 and \$2.65 million in each of 2006 and 2007.

In connection with the 2003 acquisition of Laphal (see Note 4), the Company acquired rights to Laphal's formulation of thalidomide. The portion of the purchase price allocated to thalidomide has been included in product rights, net on the accompanying balance sheet.



**Table of Contents**

**PHARMION CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Vidaza***

In 2001, the Company licensed worldwide rights to Vidaza (azacitidine) from Pharmacia & Upjohn Company, now part of Pfizer, Inc. Under terms of the license agreement, the Company is responsible for all costs to develop and market Vidaza and the Company pays Pfizer a royalty equal to 20% of Vidaza net sales. No up-front or milestone payments have or will be made to Pfizer. The license has a term extending for the longer of the last to expire of valid patent claims in any given country or ten years from the first commercial sale of the product in a particular country.

***Refludan***

In May 2002, the Company entered into agreements to acquire the exclusive right to market and distribute Refludan in all countries outside the U.S. and Canada. These agreements, as amended in August 2003, transferred all marketing authorizations and product registrations for Refludan in the individual countries within the Company's territories. The Company has paid Schering an aggregate of \$9 million to date and is obligated to make four additional fixed payments to Schering, payable in quarterly installments of \$1 million through the end of 2005. The value of the total cash payments made and the present value of future payments is \$12.2 million, which was capitalized to product rights and is being amortized over the 10 year period during which the Company expects to generate revenue. Additional payments of up to \$7.5 million will be due Schering upon achievement of certain milestones. Because such payments are contingent upon future events, they are not reflected in the accompanying financial statements. In addition, the Company paid Schering an 8% royalty on net sales of Refludan through December 31, 2003 and will pay a royalty of 14% of net sales of Refludan thereafter until the aggregate royalty payments total \$12.0 million measured from January 2004. At that time, the royalty rate will be reduced to 6%.

***Innohep***

In June 2002, the Company entered into a 10 year agreement with LEO Pharma A/ S for the license of the low molecular weight heparin, Innohep. Under the terms of the agreement, the Company acquired an exclusive right and license to market and distribute Innohep in the United States. On the closing date the Company paid \$5 million for the license, which is capitalized as product rights and is being amortized over a 10 year period in which the Company expects to generate significant revenues. On the closing date, the Company paid an additional \$2.5 million, which is creditable against royalty payments otherwise due during the period ending March 1, 2005. In addition, the Company is obligated to pay LEO Pharma royalties at the rate of 30% of net sales on annual net sales of up to \$20 million and at the rate of 35% of net sales on annual net sales exceeding \$20 million, less in each case the Company's purchase price from LEO Pharma of the units of product sold. Furthermore, the agreement contains a minimum net sales clause that is effective for two consecutive two-year periods. If the company does not achieve these minimum sales levels for two consecutive years, it has the right to pay LEO Pharma additional royalties up to the amount LEO Pharma would have received had the company achieved these net sales levels. If the company opts not to make the additional royalty payment, LEO Pharma has the right to terminate the license agreement. The second of the two-year terms will conclude on December 31, 2006.

**Table of Contents**

**PHARMION CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**7. Property and Equipment**

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
<b>Property and equipment:</b>		
Computer hardware and software	\$ 5,171,173	\$ 4,251,895
Furniture and fixtures	1,497,455	1,311,303
Equipment	1,142,592	827,681
Leasehold improvements	1,288,820	1,213,363
	9,100,040	7,604,242
Less accumulated depreciation	(4,816,277)	(2,554,822)
<b>Total property and equipment, net</b>	<b>\$ 4,283,763</b>	<b>\$ 5,049,420</b>

Depreciation expense was \$2,213,891, \$1,544,830, and \$669,014 for the years ended December 31, 2004, 2003 and 2002, respectively.

**8. Accrued and Other Current Liabilities**

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
<b>Accrued and other current liabilities</b>		
Royalties payable	\$ 10,695,532	\$ 2,040,588
Income taxes payable	7,319,821	1,035,652
Product rights and notes payable	4,332,811	3,988,456
Accrued salaries and benefits	11,107,500	3,180,228
Accrued operating expenses	12,107,167	4,554,513
	\$ 45,562,831	\$ 14,799,437

**9. Other Long-term Liabilities**

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
Product rights payable	\$ 3,831,399	\$ 7,398,544
Notes payable	719,240	1,069,179
	4,550,639	8,467,723

Edgar Filing: PHARMION CORP - Form 10-K

Current portion of product rights and notes payable	(4,332,811)	(3,988,456)
Other long term liabilities	\$ 217,828	\$ 4,479,267

F-18

---

**Table of Contents****PHARMION CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In August 2003, the Company restructured the purchase of Refludan product rights with Schering AG and agreed to make a \$1 million payment upon execution of the agreement and nine future quarterly payments of \$1 million commencing in December 2003. The future payments were discounted at 7% per annum, to determine the present value of the product rights payable balance. Maturities of other long-term liabilities are as follows:

2005	\$	4,332,811
2006		147,234
2007		67,772
2008		2,822
	\$	4,550,639

**10. Convertible Notes Payable**

In April 2003, the Company issued \$14 million of 6% convertible notes with interest payable annually. Holders of the notes also received warrants to purchase an aggregate of 424,242 shares of the Company's common stock at a price of \$11.00 per share. The value of the warrants was reflected as an additional debt discount to be amortized over the term of the debt or 5 years. Effective March 1, 2004, the \$14 million of convertible notes plus accrued interest were converted into 1,342,170 shares of common stock. The remaining unamortized debt discount was recorded as a decrease to equity.

**11. Leases and Other Commitments**

The Company leases office space and equipment under various noncancelable operating lease agreements. One of these agreements has a renewal term which allows the Company to extend this lease up to six years, or through 2013. Rental expense was \$2,874,934, \$1,561,425, and \$943,635 for the years ended December 31, 2004, 2003 and 2002, respectively.

As of December 31, 2004, future minimum rental commitments, by fiscal year and in the aggregate, for the Company's operating leases are as follows:

2005	\$	3,074,579
2006		3,108,750
2007		2,531,770
2008		1,645,935
2009		1,435,646
Total minimum lease payments	\$	11,796,680

**12. Income Taxes**

The Company accounts for income taxes in accordance with SFAS No. 109, *Accounting for Income Taxes*. Under the provisions of SFAS No. 109, a deferred tax liability or asset (net of a valuation allowance) is provided in the financial statements by applying the provisions of applicable tax laws to measure the deferred tax consequences of temporary differences that will result in net taxable or deductible amounts in future years as a result of events recognized in the financial statements in the current or preceding years.

At December 31, 2004, the Company has federal, state, and foreign net operating loss carryforwards for income tax purposes of approximately \$111.8 million, which will expire in the years 2019 through 2024 if not utilized.

**Table of Contents****PHARMION CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The Tax Reform Act of 1986 contains provisions that limit the utilization of net operating loss and tax credit carryforwards if there has been a change of ownership as described in Section 382 of the Internal Revenue Code. Such a change of ownership may limit the Company's utilization of its net operating loss and tax credit carryforwards, and could be triggered by subsequent sales of securities by the Company or its stockholders.

The components of the Company's deferred tax assets and liabilities are as follows:

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
<b>Deferred tax assets:</b>		
Net operating loss	\$ 28,550,438	\$ 18,822,182
Credit carryforwards	6,513,802	4,195,219
Organization costs	3,406,902	4,769,663
Allowance on accounts receivable	815,237	301,476
Depreciation	140,025	(143,883)
Other	511,395	400,133
<b>Total gross deferred tax assets</b>	<b>39,937,799</b>	<b>28,344,790</b>
Valuation allowance	(39,205,040)	(28,282,751)
<b>Deferred tax assets, net of valuation allowance</b>	<b>732,759</b>	<b>62,039</b>
<b>Deferred tax liabilities:</b>		
Amortization of product rights	(3,437,962)	(3,559,476)
Prepaid expenses	(730,964)	(154,366)
Other	(169,554)	(12,815)
<b>Total gross deferred tax liabilities</b>	<b>(4,338,480)</b>	<b>(3,726,657)</b>
<b>Net deferred tax liability</b>	<b>\$ (3,605,721)</b>	<b>\$ (3,664,618)</b>

A valuation allowance was recorded in 2004 and 2003 due to the Company's inability to determine if it is more likely than not that the deferred tax asset will be realized in future periods.

The Company's effective tax rate differs from the federal income tax rate for the following reasons:

	<b>Years Ended December 31,</b>	
	<b>2004</b>	<b>2003</b>
Expected federal income tax benefit (expense) at statutory rate	34.0%	34.0%
Effect of permanent differences	(10.4)%	(4.4)%
State income tax, net of federal benefit	(6.4)%	1.2%
Effect of tax credits	23.9%	5.3%
Effect of foreign operations	(50.2)%	(5.0)%

Valuation allowance	(72.0)%	(33.7)%
	(81.1)%	(2.6)%

F-20

---

**Table of Contents****PHARMION CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The provision (benefit) for income taxes is comprised of the following:

	<b>Years Ended December 31,</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
<b>Current provision:</b>			
Federal	\$		\$
State	618,802	194,496	
Foreign	7,647,744	1,090,977	105,255
<b>Total</b>	<b>8,266,546</b>	<b>1,285,473</b>	<b>105,255</b>
<b>Deferred provision:</b>			
Federal	(8,283,747)	(7,067,508)	
State	(714,122)	(609,273)	
Foreign	(2,236,232)	(3,986,714)	
<b>Total</b>	<b>(11,234,101)</b>	<b>(11,663,495)</b>	
Valuation allowance	10,820,622	11,663,495	
<b>Total</b>	<b>\$ 7,853,067</b>	<b>\$ 1,285,473</b>	<b>\$ 105,255</b>

The Company reported net income (loss) before tax from operations within the U.S. of \$(14,027,515), \$(32,145,779) and \$(18,406,402) and from foreign operations of \$4,343,403, \$(16,627,650) and \$(16,185,199), respectively, for the years ended December 31, 2004, 2003 and 2002.

**13. Stock Option Plans**

In 2000, the Company's Board of Directors approved the 2000 Stock Incentive Plan (the 2000 Plan) and, as of December 31, 2004, has authorized 3,258,000 shares of stock to be reserved under the plan. The 2000 Plan provides for awards of both nonstatutory stock options and incentive stock options within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended, and stock purchase rights to purchase shares of the Company's common stock. A total of 481,093 shares of common stock are available for future stock option issuance to eligible employees, consultants, and directors of the Company as of December 31, 2004.

In 2001, the Company's Board of Directors approved the 2001 Non-Employee Director Stock Option Plan (the 2001 Plan) and, as of December 31, 2004, has authorized 425,000 shares of stock to be reserved under the plan. The 2001 Plan provides for awards of nonstatutory stock options only. A total of 193,750 shares of common stock are available for future stock option issuance to directors of the Company as of December 31, 2004.

The 2000 Plan and the 2001 Plan are administered by the compensation committee of the Board of Directors, which has the authority to select the individuals to whom awards will be granted and to determine whether and to what extent stock options and stock purchase rights are to be granted, the number of shares of common stock to be covered by each award, the vesting schedule of stock options, generally over a period of four years, and all other terms and conditions of each award. The grants expire seven and ten years from the date of grant for the 2000 and 2001 Plans, respectively.

In September 2003, the Board of Directors amended both the 2000 and 2001 plans to allow for automatic evergreen annual additions to the stock options available for grant not to exceed 500,000 shares and 50,000 shares, respectively.



**Table of Contents**

**PHARMION CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

A summary of the Plans activity is as follows:

	Number of Options	Weighted Average Exercise Price
Balance, January 1, 2002	237,379	\$ 0.68
Granted	1,142,738	1.96
Exercised	(42,177)	0.76
Terminated or expired	(15,948)	0.56
Balance, December 31, 2002	1,321,992	1.76
Granted	610,219	9.21
Exercised	(53,190)	1.38
Terminated or expired	(60,809)	1.91
Balance, December 31, 2003	1,818,212	4.28
Granted	1,110,303	34.87
Exercised	(373,436)	2.22
Terminated or expired	(154,395)	8.52
Balance, December 31, 2004	2,400,684	\$ 18.47

A summary of options outstanding as of December 31, 2004, is as follows:

Range of Exercise Prices	Outstanding Options			Exercisable Options	
	Shares Under Option	Weighted- Average Remaining Contractual Life	Weighted- Average Exercise Price	Shares Currently Vested and Exercisable	Weighted- Average Exercise Price
\$0.40 to 1.60	497,668	4.5	\$ 1.52	465,807	\$ 1.52
\$1.61 to 2.40	481,876	5.4	\$ 2.40	430,772	\$ 2.40
\$2.41 to 20.00	388,688	5.9	\$ 13.96	71,336	\$ 13.59
\$20.01 to 30.00	372,377	6.3	\$ 21.95		\$
\$30.01 to 40.00	140,850	7.0	\$ 39.31	25,000	\$ 39.98
\$40.01 to 50.00	427,725	7.0	\$ 43.68	25,000	\$ 48.26
\$50.01 to 52.27	91,500	6.8	\$ 50.43		\$
Total	2,400,684	5.9	\$ 18.47	1,017,915	\$ 4.83

During the period January 1, 2003 through November 5, 2003, options were granted to employees and directors at exercise prices that were less than the estimated fair value of the underlying shares of common stock as of the grant

date. In accordance with APB No. 25, deferred compensation expense is being recognized for the excess of the estimated fair value of the Company's common stock as of the grant date over the exercise price of the options and amortized to expense on a straight-line basis over the vesting periods of the related options, which is generally four years. The Company recorded compensation expense totaling \$475,597 and \$585,710 for the years ended December 31, 2004 and 2003 respectively. As of December 31, 2004 and 2003, the unamortized compensation expense recorded as deferred compensation within the statement of stockholders' equity was \$679,572 and \$1,155,169, respectively.

F-22

---

Table of Contents

**PHARMION CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**14. Common and Redeemable Convertible Preferred Stock***Common Stock*

On January 4, 2000, the Company issued 667,000 shares of its common stock to founders for \$2,000. On January 5, 2000, the Company executed a restricted stock agreement pertaining to the issuance of these shares to its founders. Under this agreement, 33.33% of these shares vested immediately while the remaining shares vest over a term of forty-eight months. As a result, the Company's 2004, 2003 and 2002 statements of operations reflect \$0, \$44,149, and \$44,160, respectively, of stock compensation related to this arrangement.

*Redeemable Convertible Preferred Stock*

In January 2000, the Company issued 5,069,792 shares of redeemable convertible preferred stock ( Series A Preferred ), in a first closing, to a group of private investors at a purchase price of \$1.00 per share. In December 2000 and January 2001, the Company issued 3,237,500 and 9,605,973 shares, respectively, of Series A Preferred, in a second closing, to the same group of investors at a purchase price of \$1.50 per share. In November 2001, the Company issued 31,071,769 shares of redeemable convertible preferred stock ( Series B Preferred ) to a group of investors at a purchase price of \$2.09 per share. In October 2002, the Company issued 19,138,756 shares of redeemable convertible preferred stock ( Series C Preferred ) at a purchase price of \$2.09 per share.

All of the preferred shares had preferences before common stock in liquidation equal to the initial preferred purchase price, plus any accrued but unpaid noncumulative dividends. In addition, the Series B and Series C Preferred shares had preferences before the Series A Preferred shares and were entitled to share on a pro rata, as if converted, basis in the remaining assets with the common shares after preferential liquidation payments were made to preferred shareholders.

In connection with the completion of the Company's initial public offering in November 2003, all of the outstanding shares of redeemable convertible preferred stock were automatically converted into 17,030,956 shares of the Company's common stock.

*Warrants*

In November 2001, the Company issued a warrant to purchase 1,701,805 shares of Series B Preferred stock at \$2.09 per share to a business partner which was exercisable one year after the date of grant and expired seven years from the date of grant. Based on the estimated fair value of the warrant, development expense in the amount of \$884,939 was recorded in connection with the issuance of this warrant in 2001. Upon conversion of the Company's preferred shares to common stock in November 2003, the number of shares available under the warrant was automatically modified to 425,451 shares of common stock at \$8.36 per share.

In April 2003, the Company issued two warrants in conjunction with the convertible debt issued in 2003. The warrants had a life of five years and could be exercised immediately. A total of 424,242 shares of common stock could be purchased at a price of \$11.00 per share under these warrants. The \$729,697 fair value of the warrant has been classified as additional paid-in capital with a corresponding amount treated as a debt discount which is being amortized using the interest method.

In June 2004, a stock purchase warrant was exercised by one of the business partners, resulting in the issuance of 44,026 shares of common stock. The option holder utilized the cashless exercise option allowed under the warrant agreement and surrendered 16,580 shares to the Company as consideration for this exercise.

In September 2004, the second business partner exercised two stock purchase warrants which resulted in the issuance of 789,087 shares of common stock. Total exercise proceeds received by the Company were \$7.6 million.

Table of Contents

**PHARMION CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**15. Employee Savings Plans**

Through 2002, the Company's employees located in the U.S., were leased from ADP Total Source II, the employer of record, and worked exclusively for the Company. These employees participated in a 401(k) plan sponsored by ADP Total Source II that allowed participants to contribute up to 15% of their salary, subject to eligibility requirements and annual limits. Effective January 1, 2003, the employee leasing arrangement with ADP Total Source II was terminated and the administration of the 401(k) plan for U.S. employees was transitioned to the Company. Under the ADP and Company sponsored plans, the Company matches 100% of the participant's contribution up to a limit of 3% of the participant's annual salary. Matching contributions totaled \$276,952, \$204,561, and \$112,910 in 2004, 2003 and 2002, respectively. The Company's international employees are eligible to participate in retirement plans, subject to the local laws that are in effect for each country. The Company matched \$477,695, \$321,695, and \$144,355 of the contributions made by these employees in 2004, 2003 and 2002, respectively.

**16. Related Parties**

As part of the relocation assistance provided to three officers, during 2002, the Company made loans totaling \$400,000 to these individuals. At December 31, 2004 the balance outstanding for these loans is \$125,000. The loans do not bear interest and are secured by a second deed of trust on the principal residences of each of the officers. The notes are repayable over terms ranging from two to four years. The Company has agreed, for as long as these officers remain employed by the Company, to make annual bonus payments to these officers in amounts sufficient the pay to loan amounts then due.

**17. Quarterly Information (Dollars in thousands, except per share data) (Unaudited)**

	<b>March 31, 2004</b>	<b>June 30, 2004</b>	<b>September 30, 2004</b>	<b>December 31, 2004</b>
Net sales	\$ 15,721	\$ 20,396	\$ 42,576	\$ 51,478
Cost of sales, including royalties	6,309	7,453	14,169	15,704
Loss from operations	(8,814)	(8,221)	(1,712)	3,224
Net loss	(9,809)	(9,983)	(355)	2,609
Net loss applicable to common shareholders per share - basic	(.40)	(.39)	(.01)	.08
Net loss applicable to common shareholders per share - diluted	\$ (.40)	\$ (.39)	\$ (.01)	\$ .08

	<b>March 31, 2003</b>	<b>June 30, 2003</b>	<b>September 30, 2003</b>	<b>December 31, 2003</b>
Net sales	\$ 1,658	\$ 4,429	\$ 7,673	\$ 11,779
Cost of sales, including royalties	779	3,681	2,681	4,321
Loss from operations	(14,020)	(14,071)	(8,924)	(11,604)
Net loss	(13,893)	(13,994)	(9,254)	(12,918)
Net loss applicable to common shareholders	(16,718)	(16,819)	(12,079)	(14,534)
Net loss applicable to common shareholders per share - basic and diluted	\$ (21.29)	\$ (20.72)	\$ (14.35)	\$ (1.05)
	\$ (0.78)	\$ (0.78)	\$ (0.52)	\$ (0.60)

Proforma net loss applicable to  
common shareholders per share basic  
and diluted (Note 2)

F-24

---

**Table of Contents**

**SCHEDULE II**  
**Valuation and Qualifying Accounts**

Years Ended December 31,	Balance at Beginning of Period	Additions Charged to Expense or Sales	Deductions	Balance at End of Period
<b>(In thousands)</b>				
<b>2004</b>				
Allowances for chargebacks, cash discounts and doubtful accounts	\$ 819	\$ 7,419	\$ (6,028)	\$ 2,210
Inventory reserve	1,387	1,366	(2,393)	360
<b>2003</b>				
Allowances for chargebacks, cash discounts and doubtful accounts	\$ 734	\$ 2,486	\$ (2,401)	\$ 819
Inventory reserve		1,761	(374)	1,387
<b>2002</b>				
Allowances for chargebacks, cash discounts and doubtful accounts	\$	\$ 1,156	\$ (422)	\$ 734
Inventory reserve				

S-1

**Table of Contents****EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description of Document</b>
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)	

Edgar Filing: PHARMION CORP - Form 10-K

- 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.
- 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.
-

**Table of Contents**

<b>Exhibit Number</b>	<b>Description of Document</b>
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(3)*	Employment Agreement, dated as of February 23, 2004, by and between the Registrant and Patrick J. Mahaffy.
10.18(3)*	Amended and Restated Employment Agreement, dated as of March 1, 2004, 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(3)*	Amended and Restated Employment Agreement, dated as of March 1, 2004, by and between the Registrant and Erle Mast.
10.22(3)*	Amended and Restated Employment Agreement, dated as of March 1, 2004, 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.
10.25(2)*	Addendum to Employment Agreement, dated June 15, 2004, by and between the Registrant and Michael Cosgrave.
10.26	Amendment No. 2, dated December 3, 2004, to Amended and Restated Distribution and License Agreement, dated November 16, 2001, between Pharmion GmbH and Celgene UK Manufacturing II Limited (formerly Penn T Limited).
10.27	Letter Agreement, dated December 3, 2004, among the Registrant, Pharmion GmbH and Celgene Corporation amending the Letter Agreement regarding clinical funding, dated April 2, 2003, between Registrant, Pharmion GmbH and Celgene.
10.28	Letter Agreement, dated December 3, 2004, between the Registrant, Pharmion GmbH and Celgene Corporation amending the License Agreement, dated November 16, 2001, among Registrant, Pharmion GmbH and Celgene.
10.29	Lease, dated December 21, 2004, by and between Pharmion Limited and Alecta Pensionsförsäkring Ömsesidigit.
10.30	Counterpart Guarantee, dated December 21, 2004, by and between Registrant and Alecta Pensionsförsäkring Ömsesidigit.
21.1(2)	Subsidiaries of the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney. (reference is made to page 52)
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.

Edgar Filing: PHARMION CORP - Form 10-K

- (1) Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-108122) and amendments thereto, declared effective November 5, 2003.
- (2) Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-116252) and amendments thereto, declared effective June 30, 2004.
- (3) Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2004 (File No. 000-50447)
  - \* Management Contract or Compensatory Plan or Arrangement