PHARMION CORP
Form 10-K
March 16, 2005

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SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-K

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

for the fiscal year ended December 31, 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	**84-1521333**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

2525 28th Street, Suite 200
Boulder, Colorado 80301
(720) 564-9100
(Address, including zip code, and telephone number, including area code, of principal executive offices)
Securities registered pursuant to Section 12(b) of the Act:
None
Securities registered pursuant to Section 12(g) of the Act:
Common Stock $.001 Par Value
(Title of Class)

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

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

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

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.

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Amendment to Amended/Restated Distribution and License Agreement
Letter Agreement
Letter Agreement
Lease
Counterpart Guarantee
Consent of Independent Registered Public Accounting Firm
Certification for President and CEO Pursuant to Section 302
Certification for CFO Pursuant to Section 302
Certification for President, CEO and CFO Pursuant to Section 906

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PART I

Unless the context requires otherwise, references in this report to Pharmion, the Company, we, us, and our r 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 oth 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™ 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

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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. The reference to our website does not constitute incorporation by reference of the information contained on our website into this annual report on Form 10-K.

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

Our Strategy

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

Focusing on the hematology and oncology markets. We focus on the hematology and oncology markets for several reasons. The hematology and oncology markets are characterized by a number of disorders with high rates of recurrence and a limited response from current therapies or treatments, many of which include severe side effects. New hematology and oncology product candidates addressing unmet medical needs or providing a superior safety profile are frequently the subject of expedited regulatory reviews and, if 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

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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.

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Our Products

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

Product	Disease/Indication	Phase of Development	Licensor	Licensed Territory
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)
	Newly-diagnosed multiple myeloma	Phase III study ongoing		
Innohep (tinzaparin)	Deep vein thrombosis with or without pulmonary embolisms	Marketed	LEO Pharma A/S	U.S.
Refludan (lepirudin)	Heparin-induced thrombocytopenia type II	Marketed	Schering AG	All countries outside North America

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.

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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

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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^2 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^2 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

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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^2 of Vidaza in a schedule of five days on, two days off, two days on. The other arm examines 50 mg/m^2 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.^{tm} 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

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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.

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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.

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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.

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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

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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

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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,

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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 Refludan 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.

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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-

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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

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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,

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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

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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.

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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

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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.

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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.

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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

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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

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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.

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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
Year Ended December 31, 2003		
Fourth Quarter	$ 15.70	$ 11.00
Year Ended December 31, 2004		
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

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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

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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
		(In thousands, except share and per share data)			
Consolidated Statement of Income Data:					
Statement of Income					
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

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	2004	2003(1)	2002	2001	2000
Consolidated Balance Sheet:					
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 Developement 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™ 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.

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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

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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
			(In thousands)	
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