PHARMION CORP
Form 10-Q
May 10, 2005

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

Form 10-Q

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

For the quarterly period ended March 31, 2005

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, Boulder, Colorado 80304
(Address of principal executive offices)

(720) 564-9100
(Registrant s telephone number)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act 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 whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes þ No o

As of May 4, 2005, there were 31,826,271 shares of the Registrant s Common Stock outstanding.

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PART I
FINANCIAL INFORMATION

Item 1. ***Consolidated Financial Statements***

PHARMION CORPORATION

CONSOLIDATED BALANCE SHEETS
(In thousands, except for share amounts)

	March 31, 2005 (Unaudited)	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 102,026	$ 119,658
Short-term investments	142,447	125,885
Accounts receivable, net of allowances of $2,621 and $2,210, respectively	32,118	35,193
Inventories	4,731	3,688
Other current assets	5,585	4,396
Total current assets	286,907	288,820
Product rights, net	105,432	108,478
Goodwill	14,089	9,426
Property and equipment, net	4,385	4,284
Other assets	223	223
Total assets	$ 411,036	$ 411,231
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 8,735	$ 9,891
Accrued liabilities	44,775	45,563
Total current liabilities	53,510	55,454
Deferred tax liability	3,414	3,606
Other long-term liabilities	149	218
Total liabilities	57,073	59,278
Stockholders equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized and 31,823,082 and 31,780,715 shares issued and outstanding at March 31, 2005 and December 31, 2004, respectively	32	32
Preferred stock, $0.001, 10,000,000 shares authorized, no shares issued and outstanding at March 31, 2005 and December 31, 2004		
Additional paid-in capital	482,650	482,661

Deferred compensation	(453)	(680)
Other comprehensive income	5,560	8,036
Accumulated deficit	(133,826)	(138,096)
Total stockholders equity	353,963	351,953
Total liabilities and stockholders equity	$ 411,036	$ 411,231

The accompanying notes are an integral part of these consolidated financial statements

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PHARMION CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except for share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2005	**2004**
Net sales	$ 51,737	$ 15,721
Operating expenses:		
Cost of sales, including royalties of $10,108 and $4,581 for the three months ended March 31, 2005 and 2004, respectively	13,947	6,309
Clinical, development and regulatory	9,464	6,553
Selling, general and administrative	20,680	10,948
Product rights amortization	2,238	725
Total operating expenses	46,329	24,535
Operating income (loss)	5,408	(8,814)
Interest and other income (expense), net	1,779	(73)
Income (loss) before taxes	7,187	(8,887)
Income tax expense	2,917	922
Net income (loss)	$ 4,270	$ (9,809)
Net income (loss) per common share:		
Basic	$ 0.13	$ (0.40)
Diluted	$ 0.13	$ (0.40)
Weighted average number of common and common equivalent shares used to calculate net income (loss) per common share:		
Basic	31,804,784	24,349,920
Diluted	33,035,855	24,349,920

The accompanying notes are an integral part of these consolidated financial statements

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PHARMION CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2005	**2004**
Operating activities		
Net income (loss)	$ 4,270	$ (9,809)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	2,848	1,210
Compensation expense related to stock option issuance	55	174
Other	273	
Changes in operating assets and liabilities:		
Accounts receivable, net	2,035	(3,349)
Inventories	(1,296)	623
Other current assets	(1,338)	60
Other long-term assets	(4)	247
Accounts payable	(904)	(1,483)
Accrued liabilities	1,547	2,988
Net cash provided by (used in) operating activities	7,486	(9,339)
Investing activities		
Purchases of property and equipment	(818)	(223)
Acquisition of business, net of cash acquired	(5,204)	(19)
Purchase of available-for-sale investments	(65,227)	(33,253)
Sale and maturity of available-for-sale investments	48,335	
Net cash used in investing activities	(22,914)	(33,495)
Financing activities		
Proceeds from exercise of common stock options	161	6
Payment of debt obligations	(1,048)	(967)
Net cash used in financing activities	(887)	(961)
Effect of exchange rate changes on cash and cash equivalents	(1,317)	(420)
Net decrease in cash and cash equivalents	(17,632)	(44,215)
Cash and cash equivalents at beginning of period	119,658	88,542
Cash and cash equivalents at end of period	$ 102,026	$ 44,327
Noncash items		
Accrual of additional business acquisition consideration	5,166	
Conversion of debt and accrued interest to common stock		14,161

The accompanying notes are an integral part of these consolidated financial statements

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PHARMION CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF BUSINESS

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited consolidated financial statements of the Company and its subsidiaries have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and pursuant to the rules and regulations of the SEC pertaining to Form 10-Q. All significant intercompany accounts and transactions have been eliminated in consolidation. Certain disclosures required for complete financial statements are not included herein. These statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company s latest audited annual financial statements, which are included in its 2004 Annual Report on Form 10-K, which has been filed with the SEC.

In the opinion of management, the unaudited interim financial statements reflect all adjustments, which include only normal, recurring adjustments necessary to present fairly the Company s financial position at March 31, 2005 and results of operations and cash flows for the three months ended March 31, 2005 and 2004. The results of operations for the interim periods are not necessarily indicative of the results to be expected for the year ending December 31, 2005 or for any other interim period or for any other future year.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates or assumptions. The significant estimates reflected in these financial statements include estimates of chargebacks from distributors, product returns and rebates, inventory impairment and valuation of stock-based compensation.

Revenue Recognition

The Company sells its products to wholesale distributors and directly to hospitals, clinics and retail pharmacies. Revenue from product sales is recognized when ownership of the product is transferred to the customer, the sales price is fixed and determinable, and collectibility is reasonably assured.

Revenue is reported net of allowances for chargebacks from distributors, product returns, rebates and prompt payment discounts. Significant estimates are required for determining such allowances and are based on historical data, industry information and information from customers. If actual results are different from estimates, the Company will adjust the allowances at the time such differences become apparent.

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

Cash and Cash Equivalents

Cash and cash equivalents consist of money market accounts and overnight deposits. The Company considers all highly liquid investments purchased with a maturity of three months or less to be cash equivalents. Interest income resulting from cash and cash equivalent holdings was $1.9 million and $.2 million for the three months ended March 31, 2005 and 2004, respectively.

The Company has entered into international standby letters of credit to guarantee both current and future commitments of new foreign office lease agreements. The aggregate amount outstanding under the letters of credit was approximately $1.6 million at March 31, 2005 and is secured by restricted cash held in U.S. cash accounts.

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Short-term Investments

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

Inventories

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

Long-Lived Assets

Our long-lived assets consist primarily of product rights and property and equipment. In accordance with Statement of Financial Accounting Standards No. 144 (SFAS 144), Accounting for the Impairment or Disposal of Long-Lived Assets, we evaluate our ability to recover the carrying value of long-lived assets used in our business, considering changes in the business environment or other facts and circumstances that suggest their value may be impaired. If this evaluation indicates the carrying value will not be recoverable, based on the undiscounted expected future cash flows estimated to be generated by these assets, we reduce the carrying amount to the estimated fair value.

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.

In addition to the goodwill that was created as a result of the 2003 business acquisition, the agreement included contingent payments based on cumulative sales milestones. The final cumulative sales milestone was achieved in the first quarter of 2005 which resulted in an additional $5.1 million being added to goodwill.

Concentration of Credit Risk

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

The Company s products are sold both to wholesale distributors and directly to hospitals and clinics. Ongoing credit evaluations of customers are performed and collateral is generally not required. The Company maintains a reserve for potential credit losses, and such losses have been within management s expectations. In the three months ended March 31, 2005 and 2004, revenues generated from the Company s three largest customers in the U.S. totaled approximately 46% and 10%, respectively, of consolidated net revenues. Additionally, the three largest U.S. customers each totaled approximately 15% of consolidated net revenues for the period ended March 31, 2005. Revenues generated from international customers were individually less than 5% of consolidated net revenues.

Accounting for Stock-Based Compensation

At March 31, 2005, the Company had two stock option plans. The Company has elected to account for stock-based compensation arrangements using the intrinsic value method under the provisions of Accounting Principles Board Opinion No. 25 (APB 25), Accounting for Stock Issued to Employees and its related interpretations. Under this method, when the exercise price is less than the market price for the underlying stock on the date of grant, a non-cash charge to compensation expense is recorded ratably over the term of the option vesting period in an amount equal to the difference between the value calculated using the exercise price and the fair value. The Company uses the fair value method to account for nonemployee stock-based compensation.

During 2003, options were granted to employees and directors at exercise prices that were less than the estimated fair value of the underlying shares of common stock as of the grant date. In accordance with APB 25, deferred compensation expense is being recognized for the excess of the estimated fair value of the Company s common stock as of the grant date over the exercise price of the options and amortized to expense on a straight-line basis over the vesting periods of the related options, which is generally 4 years.

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Pro forma information regarding net loss is required by SFAS No. 123, Accounting for Stock-Based Compensation, and has been determined as if the Company had accounted for its employee stock options under the fair value method of that statement. The fair value for these options was estimated at the date of grant using the Black-Scholes valuation model.

The effects of applying the fair value method to the results for the three months ended March 31, 2005 and 2004 are (in thousands):

	Three Months Ended March 31,	
	2005	2004
Net income (loss):		
As reported	$ 4,270	$ (9,809)
Plus: stock based compensation recognized under the intrinsic value method	55	174
Less: stock based compensation under fair value method	(1,984)	(526)
Pro forma net income (loss)	$ 2,341	$ (10,161)
Net income (loss) per common share:		
Basic, as reported	$ 0.13	$ (0.40)
Basic, pro forma	$ 0.07	$ (0.42)
Diluted, as reported	$ 0.13	$ (0.40)
Diluted, pro forma	$ 0.07	$ (0.42)

Option valuation models such as the Black-Scholes value method described above require the input of highly subjective assumptions. Because the Company s employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management s opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

The weighted-average fair value per share was $18.18 and $12.16 for stock options granted in the three months ended March 31, 2005 and 2004, respectively. The assumptions used to develop the estimated fair value of the options granted utilizing the Black-Scholes pricing model are:

	Three Months Ended March 31,	
	2005	2004
Risk-free interest rate	3.8%	2.8%
Expected stock price volatility	61%	85%
Expected option term until exercise (years)	4	5
Expected dividend yield	0%	0%

Recently Issued Accounting Standards

On December 16, 2004, the Financial Accounting Standards Board issued SFAS No. 123 (revised 2004), Share-Based Payment, which is a revision of SFAS No. 123, Accounting for Stock-Based Compensation. SFAS

No. 123(R) supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees, and amends SFAS No. 95, Statement of Cash Flows. Generally, the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However, SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their estimated fair values. Pro forma disclosure is no longer an alternative.

SFAS No. 123(R) must be adopted no later than the beginning of the first fiscal year after June 15, 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 January 1, 2006.

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 January 1, 2006.

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3. NET INCOME (LOSS) PER COMMON SHARE

The Company applies SFAS No. 128, Earnings per Share, which establishes standards for computing and presenting earnings per share. Basic net income (loss) per common share is calculated by dividing net income (loss) applicable to common stockholders by the weighted average number of unrestricted common shares outstanding for the period. Diluted net loss per common share is the same as basic net loss per common share for the three months ended March 31, 2004, since the effects of potentially dilutive securities were antidilutive for that period. Diluted net income per common share is calculated by dividing net income applicable to common stockholders by the weighted average number of common shares outstanding for the period increased to include all additional common shares that would have been outstanding assuming the issuance of potentially dilutive common shares. Potential incremental common shares include shares of common stock issuable upon exercise of stock options, warrants and convertible notes outstanding during the periods presented.

A reconciliation of the weighted average number of shares used to calculate basic and diluted net income (loss) per common share follows:

	Three Months Ended March 31,	
	2005	**2004**
Basic	31,804,784	24,349,920
Effect of dilutive securities:		
Stock options	1,231,071	
Diluted	33,035,855	24,349,920

The total number of potential common shares excluded from diluted earnings per share computation because they were anti-dilutive was 784,967 and 2,035,537 for the three months ended March 31, 2005 and 2004, respectively.

4. LICENSE AGREEMENTS AND PRODUCT RIGHTS

Thalidomide

In 2001, the Company licensed rights relating to the development and commercial use of thalidomide from Celgene Corporation and separately entered into an exclusive supply agreement for thalidomide with Celgene UK Manufacturing II Limited (formerly known as Penn T Limited), or CUK. Under the agreements, as amended in December 2004, the territory licensed from Celgene is for all countries other than the United States, Canada, Mexico, Japan and all provinces of China (except Hong Kong).The Company pays (i) Celgene a royalty/license fee of 8% on the Company s net sales of thalidomide under the terms of the license agreements, and (ii) CUK product supply payments equal to 15.5% of the Company s net sales of thalidomide under the terms of the product supply agreement. The agreements with Celgene and CUK each have a ten-year term running from the date of receipt of the Company s first regulatory approval for thalidomide in the United Kingdom. In October of 2004, Celgene acquired CUK.

In December 2004, the Company amended its thalidomide agreements with Celgene and CUK to reduce the thalidomide product supply payment, expand the Company s licensed territory, and eliminate certain license termination rights held by Celgene. The Company paid Celgene a one-time payment of $80 million in exchange for (i) the reduction in the cost of product supply from 28.0% of net sales to 15.5% of net sales, (ii) the addition of Korea, Hong Kong, and Taiwan to the Company s licensed territory and, (iii) elimination of Celgene s right to terminate the

license agreement in the event the Company has not obtained a marketing authorization approval for thalidomide in the United Kingdom by November 2006. The $80 million payment was capitalized as part of the thalidomide product rights and is being amortized over the remaining period the Company expects to generate significant thalidomide sales, approximately 13 years from December 31, 2004.

The Company has also committed to provide funding to support further clinical development studies of thalidomide sponsored by Celgene. Under these agreements, the Company will pay Celgene $4.7 million for all of 2005 and $2.7 million in each of 2006 and 2007.

Vidaza®

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

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***Refludan*®**

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

***Innohep*®**

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

The cost value and accumulated amortization associated with Thalidomide, Innohep and Refludan are as follows (in thousands):

	As of March 31, 2005		As of December 31, 2004	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Amortized product rights:				
Thalidomide	$ 96,322	$ (4,174)	$ 97,242	$ (2,509)
Refludan	12,208	(2,549)	12,208	(2,213)
Innohep	5,000	(1,375)	5,000	(1,250)
Total product rights	$ 113,530	$ (8,098)	$ 114,450	$ (5,972)

5. INVENTORIES

Inventories at March 31, 2005 and December 31, 2004 consisted of the following (in thousands):

	March 31, 2005	December 31, 2004
Raw materials	$ 1,377	$ 351
Finished goods	3,354	3,337
Total inventories	$ 4,731	$ 3,688

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6. OTHER COMPREHENSIVE INCOME (LOSS)

Total comprehensive income (loss) for the three months ended March 31, 2005 and 2004 was (in thousands):

	Three Months Ended March 31,	
	2005	2004
Net income (loss)	$ 4,270	$ (9,809)
Other comprehensive income (loss):		
Foreign currency translation	(2,427)	(1,023)
Unrealized loss on available for sale securities	(48)	(169)
Comprehensive income (loss)	$ 1,795	$ (11,001)

The foreign currency translation amounts relate to the operating results of our foreign subsidiaries.

7. INCOME TAXES

Income taxes have been provided for using the liability method in accordance with SFAS No. 109, Accounting for Income Taxes. The provision for income taxes reflects management s estimate of the effective tax rate expected to be applicable for the full fiscal year for each country in which we do business. This estimate is re-evaluated by management each quarter based on the Company s estimated tax expense for the year. Income tax expense for the three months ended March 31, 2005 and 2004 resulted primarily from taxable income generated in certain foreign jurisdictions.

8. GEOGRAPHIC INFORMATION

Domestic and foreign financial information for the three months ended March 31, 2005 and 2004 was (in thousands):

		Three Months Ended March 31,	
		2005	2004
United States	Net sales	$ 28,915	$ 1,657
Foreign entities	Net sales	22,822	14,064
Total	Net sales	$ 51,737	$ 15,721
United States	Operating income (loss)	$ 4,688	$ (7,477)
Foreign entities	Operating income (loss)	720	(1,337)
Total	Operating income (loss)	$ 5,408	$ (8,814)

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

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

FORWARD-LOOKING STATEMENTS

All statements, trend analysis and other information contained in this Form 10-Q that are not historical in nature are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, without limitation, discussion relative to markets for our products and trends in revenue, gross margins and anticipated expense levels, as well as other statements including words such as anticipate, believe, plan, estimate, expect and intend and other similar expressions. All statements regarding our expected financial position and operating results, business strategy, financing plans, forecast trends relating to our industry are forward-looking statements. These forward-looking statements are subject to business and economic risks and uncertainties, and our actual results of operations may differ materially from those contained in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those mentioned in the discussion below. As a result, you should not place undue reliance on these forward-looking statements. We undertake nor revise these forward-looking statements to reflect future events or developments.

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 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.

Critical Accounting Policies

Revenue Recognition

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

We report revenue net of allowances for distributor chargebacks, product returns, rebates, and prompt-pay discounts. Significant estimates are required in determining such allowances and are based on historical data, industry

information, and information from customers. If actual results are different from our estimates, we adjust the allowances in the period the difference becomes apparent.

Certain governmental health insurance providers as well as hospitals and clinics that are members of group purchasing organizations may be entitled to price discounts and rebates on 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.

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 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

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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.

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.

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 SFAS No. 95, Statement of Cash Flows. Generally, the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However, SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative.

SFAS No. 123(R) must be adopted no later than the beginning of the first fiscal year after June 15, 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 January 1, 2006.

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 January 1, 2006.

Results of Operations

Comparison of the Company s Results for the Three Months Ended March 31, 2005 and 2004.

Net sales. Net sales totaled $51.7 million for the three months ended March 31, 2005 as compared to $15.7 million for the three months ended March 31, 2004. Net sales included $28.9 million and $1.7 million in the U.S. and

$22.8 million and $14.0 million in Europe and other countries for the three months ended March 31, 2005 and 2004, respectively. The primary reason for the net sales growth is due to the commercial launch of Vidaza in the U.S. on July 1, 2004, which resulted in net sales of $27.5 million for the three months ended March 31, 2005. The growth has also resulted from an increase in thalidomide sales, which totaled $20.3 million for the three months ended March 31, 2005, as compared to $12.6 million for the quarter ended March 31, 2004. We began selling thalidomide on a compassionate use or named patient basis in France and Belgium in April 2003 following our acquisition of Gophar S.A.S., the parent company of Laphal Développement. In July 2003, we began selling thalidomide on a compassionate use or named