

PHARMION CORP  
Form 10-Q  
August 08, 2005

**Table of Contents**

**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 June 30, 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**

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

**84-1521333**

*(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 R No £

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

As of August 5, 2005, there were 31,833,316 shares of the Registrant's Common Stock outstanding.

---

**PHARMION CORPORATION  
TABLE OF CONTENTS**

	<b>Page No.</b>
<b><u>Part I Financial Information</u></b>	
<b><u>Item 1 Consolidated Financial Statements</u></b>	
<b><u>Consolidated Balance Sheets as of June 30, 2005 (Unaudited) and December 31, 2004</u></b>	3
<b><u>Consolidated Statements of Operations for the three and six months ended June 30, 2005 (Unaudited) and 2004 (Unaudited)</u></b>	4
<b><u>Consolidated Statements of Cash Flows for the six months ended June 30, 2005 (Unaudited) and 2004 (Unaudited)</u></b>	5
<b><u>Notes to Unaudited Consolidated Financial Statements</u></b>	6
<b><u>Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	12
<b><u>Item 3 Quantitative and Qualitative Disclosures About Market Risk</u></b>	25
<b><u>Item 4 Controls and Procedures</u></b>	26

**Part II Other Information**

<u>Item 1 Legal Proceedings</u>	26
<u>Item 2 Unregistered Sales of Equity Securities and Use of Proceeds</u>	26
<u>Item 3 Defaults Upon Senior Securities</u>	26
<u>Item 4 Submission of Matters to a Vote of Security Holders</u>	27
<u>Item 5 Other Information</u>	27
<u>Item 6 Exhibits</u>	27
<u>Amended/Restated 2001 Non-Employee Director Stock Option Plan</u>	
<u>Amended/Restated 2000 Stock Incentive Plan</u>	
<u>Section 302 Certification for President and CEO</u>	
<u>Section 302 Certification for CFO</u>	
<u>Section 906 Certification for President and CEO and CFO</u>	

**Table of Contents**

**PART I  
FINANCIAL INFORMATION**

**Item 1. Consolidated Financial Statements**

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

	<b>June 30, 2005 (Unaudited)</b>	<b>December 31, 2004</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 54,169	\$ 119,658
Short-term investments	173,098	125,885
Accounts receivable, net of allowances of \$3,013 and \$2,210, respectively	32,776	35,193
Inventories	5,900	3,688
Other current assets	4,366	4,396
 Total current assets	 270,309	 288,820
Product rights, net	109,154	108,478
Goodwill	13,162	9,426
Property and equipment, net	6,911	4,284
Other assets	192	223
 Total assets	 \$ 399,728	 \$ 411,231
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 7,101	\$ 9,891
Accrued liabilities	33,555	45,563
 Total current liabilities	 40,656	 55,454
Deferred tax liability	3,189	3,606
Other long-term liabilities	992	218
 Total liabilities	 44,837	 59,278
Stockholders equity:		
Common stock, \$0.001 par value; 100,000,000 shares authorized and 31,831,904 and 31,780,715 shares issued and outstanding at June 30, 2005 and December 31, 2004, respectively	32	32
Preferred stock, \$0.001, 10,000,000 shares authorized, no shares issued and outstanding at June 30, 2005 and December 31, 2004		
Additional paid-in capital	482,701	482,661
Deferred compensation	(369)	(680)
Other comprehensive income	800	8,036
Accumulated deficit	(128,273)	(138,096)

Edgar Filing: PHARMION CORP - Form 10-Q

Total stockholders' equity	354,891	351,953
Total liabilities and stockholders' equity	\$ 399,728	\$ 411,231

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

3

---

**Table of Contents**

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

	<b>Three Months Ended</b>		<b>Six Months Ended,</b>	
	<b>June 30,</b>		<b>June, 30</b>	
	<b>2005</b>	<b>2004</b>	<b>2005</b>	<b>2004</b>
Net sales	\$ 56,257	\$ 20,396	\$ 107,994	\$ 36,116
Operating expenses:				
Cost of sales, including royalties of \$10,927 and \$5,134 for the three months ended June 30, 2005 and 2004, respectively; and royalties of \$21,035 and \$9,715 for the six months ended June 30, 2005 and 2004, respectively	15,120	7,453	29,067	13,762
Clinical, development and regulatory	9,800	7,180	19,263	13,733
Selling, general and administrative	22,618	13,268	43,298	24,216
Product rights amortization	2,227	716	4,466	1,440
Total operating expenses	49,765	28,617	96,094	53,151
Operating income (loss)	6,492	(8,221)	11,900	(17,035)
Interest and other income (expense), net	1,215	(117)	2,994	(190)
Income (loss) before taxes	7,707	(8,338)	14,894	(17,225)
Income tax expense	2,153	1,645	5,071	2,567
Net income (loss)	\$ 5,554	\$ (9,983)	\$ 9,823	\$ (19,792)
Net income (loss) per common share:				
Basic	\$ 0.17	\$ (0.39)	\$ 0.31	\$ (0.80)
Diluted	\$ 0.17	\$ (0.39)	\$ 0.30	\$ (0.80)
Weighted average number of common and common equivalent shares used to calculate net income (loss) per common share:				
Basic	31,822,267	25,292,801	31,813,574	24,821,361
Diluted	32,856,145	25,292,801	32,945,504	24,821,361

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

**Table of Contents**

**PHARMION CORPORATION**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)  
(Unaudited)

	<b>Six Months Ended</b>	
	<b>June 30,</b>	
	<b>2005</b>	<b>2004</b>
<b>Operating activities</b>		
Net income (loss)	\$ 9,823	\$(19,792)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	5,678	2,416
Compensation expense related to stock option issuance	108	295
Other	82	147
Changes in operating assets and liabilities:		
Accounts receivable, net	1	(7,699)
Inventories	(2,738)	204
Other current assets	(335)	(292)
Other long-term assets	21	314
Accounts payable	(2,306)	1,345
Accrued liabilities	(3,494)	4,451
Net cash provided by (used in) operating activities	6,840	(18,611)
<b>Investing activities</b>		
Purchases of property and equipment	(4,148)	(700)
Addition to product rights	(5,000)	
Payments for acquisition of business	(10,072)	(19)
Purchase of available-for-sale investments	(111,996)	(50,586)
Sale and maturity of available-for-sale investments	64,732	3,179
Net cash used in investing activities	(66,484)	(48,126)
<b>Financing activities</b>		
Proceeds from exercise of common stock options	243	87
Payment of debt obligations	(2,108)	(1,946)
Net cash used in financing activities	(1,865)	(1,859)
Effect of exchange rate changes on cash and cash equivalents	(3,980)	(269)
Net decrease in cash and cash equivalents	(65,489)	(68,865)
Cash and cash equivalents at beginning of period	119,658	88,542
Cash and cash equivalents at end of period	\$ 54,169	\$ 19,677
<b>Noncash items</b>		
Financed addition to product rights	1,870	
Conversion of debt and accrued interest to common stock		14,161

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





**Table of Contents**

**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 the fourth is 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 June 30, 2005 and results of operations and cash flows for the three and six months ended June 30, 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.

**Table of Contents**

**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 \$3.0 million and \$.3 million for the six months ended June 30, 2005 and 2004, respectively.

The Company has entered into domestic and international standby letters of credit to guarantee both current and future commitments of office lease agreements. The aggregate amount outstanding under the letters of credit was approximately \$1.8 million at June 30, 2005 and is secured by restricted cash held in U.S. cash accounts.

**Short-term Investments**

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

**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 initially 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.

**Table of Contents**

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 six months ended June 30, 2005 and 2004, revenues generated from the Company's three largest customers in the U.S. totaled approximately 46% and 11%, respectively, of consolidated net revenues. Additionally, the three largest U.S. customers each totaled approximately 15% and 4% of consolidated net revenues for the period ended June 30, 2005 and 2004, respectively. Revenues generated from international customers were individually less than 5% of consolidated net revenues.

**Accounting for Stock-Based Compensation**

At June 30, 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.

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 and six months ended June 30, 2005 and 2004 are (in thousands):

	<b>Three Months Ended June</b>		<b>Six Months Ended June</b>	
	<b>30,</b>		<b>30,</b>	
	<b>2005</b>	<b>2004</b>	<b>2005</b>	<b>2004</b>
Net income (loss):				
As reported	\$ 5,554	\$ (9,983)	\$ 9,823	\$ (19,792)
Plus: stock based compensation recognized under the intrinsic value method	52	121	108	295
Less: stock based compensation under fair value method	(1,891)	(595)	(3,872)	(1,086)
Pro forma net income (loss)	\$ 3,715	\$ (10,457)	\$ 6,059	\$ (20,583)
Net income (loss) per common share:				
Basic, as reported	\$ 0.17	\$ (0.39)	\$ 0.31	\$ (0.80)
Basic, pro forma	\$ 0.12	\$ (0.41)	\$ 0.19	\$ (0.83)
Diluted, as reported	\$ 0.17	\$ (0.39)	\$ 0.30	\$ (0.80)
Diluted, pro forma	\$ 0.11	\$ (0.41)	\$ 0.18	\$ (0.83)

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.

Edgar Filing: PHARMION CORP - Form 10-Q

The weighted-average fair value per share was \$15.92 and \$17.84 for stock options granted in the six months ended June 30, 2005 and 2004, respectively. The assumptions used to develop the estimated fair value of the options granted utilizing the Black-Scholes pricing model are:

	<b>Six Months Ended June</b>	
	<b>30,</b>	
	<b>2005</b>	<b>2004</b>
Risk-free interest rate	3.8%	2.8%
Expected stock price volatility	58%	85%
Expected option term until exercise (years)	4	5
Expected dividend yield	0%	0%

8

---

**Table of Contents****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.

**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 and six months ended June 30, 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:

	<b>Three Months Ended June</b>		<b>Six Months Ended June 30,</b>	
	<b>2005</b>	<b>2004</b>	<b>2005</b>	<b>2004</b>
Basic	31,822,267	25,292,801	31,813,574	24,821,361
Effect of dilutive securities:				
Stock options	1,033,878		1,131,930	
Diluted	32,856,145	25,292,801	32,945,504	24,821,361

The total number of potential common shares excluded from diluted earnings per share computation because they were anti-dilutive was 1,048,356 and 1,970,632 for the three months ended June 30, 2005 and 2004, respectively, and 921,929 and 2,003,084 for the six months ended June 30, 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

**Table of Contents**

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. 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.

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.

***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.

**Table of Contents**

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

	As of June 30, 2005		As of December 31, 2004	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Amortized product rights:				
Thalidomide	\$ 102,118	\$ (5,785)	\$ 97,242	\$ (2,509)
Refludan	12,208	(2,887)	12,208	(2,213)
Innohep	5,000	(1,500)	5,000	(1,250)
Total product rights	\$ 119,326	\$ (10,172)	\$ 114,450	\$ (5,972)

**5. INVENTORIES**

Inventories at June 30, 2005 and December 31, 2004 consisted of the following (in thousands):

	June 30, 2005	December 31, 2004
Raw materials	\$ 1,572	\$ 351
Finished goods	4,328	3,337
Total inventories	\$ 5,900	\$ 3,688

**6. OTHER COMPREHENSIVE INCOME (LOSS)**

Total comprehensive income (loss) for the three and six months ended June 30, 2005 and 2004 was (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Net income (loss)	\$ 5,554	\$ (9,983)	\$ 9,823	\$ (19,792)
Other comprehensive income (loss):				
Foreign currency translation (loss)	(4,863)	(201)	(7,291)	(1,224)
Unrealized gain (loss) on available for sale securities	103	(75)	55	(245)
Comprehensive income (loss)	\$ 794	\$ (10,259)	\$ 2,587	\$ (21,261)

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 and six months ended June 30, 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 June 30, 2005 and 2004 and the six months ended June 30, 2005 and 2004 was (in thousands):



	<b>Three Months Ended June</b>		<b>Six Months Ended June</b>	
	<b>2005</b>	<b>2004</b>	<b>2005</b>	<b>2004</b>
United States net sales	\$ 32,066	\$ 2,582	\$ 60,981	\$ 4,239
Foreign entities net sales	24,191	17,814	47,013	31,877
<b>Total net sales</b>	<b>\$ 56,257</b>	<b>\$ 20,396</b>	<b>\$ 107,994</b>	<b>\$ 36,116</b>
United States operating income (loss)	\$ 4,294	\$ (9,648)	\$ 8,981	\$ (17,125)
Foreign entities operating income	2,198	1,427	2,919	90
<b>Total operating income (loss)</b>	<b>\$ 6,492</b>	<b>\$ (8,221)</b>	<b>\$ 11,900</b>	<b>\$ (17,035)</b>

**Table of Contents**

***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 and the factors set forth under Factors Affecting our Business Conditions below. As a result, you should not place undue reliance on these forward-looking statements. We undertake no obligation to 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/m<sup>2</sup> is being sold by us on a compassionate use or named patient basis in Europe and other international markets while we pursue marketing authorization from the European Agency for the Evaluation of Medicinal Products, or EMEA. In May 2004, Vidaza®, was approved for marketing in the U.S. and we commenced sales of the product in July 2004. We have filed for approval to market Vidaza in Europe and Australia and these submissions are under review by the respective regulatory authorities. In addition, we sell Innohep® in the U.S. and Refludan® in Europe and other international markets. With our combination of regulatory, development and commercial capabilities, we intend to continue to build a balanced portfolio of approved and pipeline products targeting the hematology and oncology markets.

**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.



**Table of Contents***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 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.

**Table of Contents****Results of Operations****Comparison of the Company's Results for the Three Months Ended June 30, 2005 and 2004.**

*Net sales.* Net sales totaled \$56.3 million for the three months ended June 30, 2005 as compared to \$20.4 million for the three months ended June 30, 2004. Net sales included \$32.1 million and \$2.6 million in the U.S. and \$24.2 million and \$17.8 million in Europe and other countries for the three months ended June 30, 2005 and 2004, respectively. The primary reason for the net sales increase is due to the commercial launch of Vidaza in the U.S. on July 1, 2004, which resulted in net sales of \$31.5 million for the three months ended June 30, 2005. The increase is also attributable to an increase in thalidomide sales, which totaled \$21.4 million for the three months ended June 30, 2005, as compared to \$15.3 million for the quarter ended June 30, 2004. The growth in thalidomide sales in the second quarter of 2005 is due to increased volume, resulting from greater demand on a compassionate and named patient basis.

*Cost of sales.* Cost of sales for the three months ended June 30, 2005 totaled \$15.1 million compared to \$7.5 million for the three months ended June 30, 2004. Cost of sales reflects the cost of product sold plus royalties due on the sales of our products as well as the distribution costs related to selling our products. Our gross margin for the three months ended June 30, 2005 was 73% as compared to 63% for the comparable period in 2004. The increase is due in part to the U.S. launch of Vidaza in July 2004, as the gross margin on Vidaza is higher than that of our other products. Additionally, we experienced improved gross margins on thalidomide sales as a result of the restructuring of our license and supply agreements in the fourth quarter of 2004. We expect the gross margin for our products will remain in the low 70% range for the foreseeable future.

*Clinical, development and regulatory expenses.* Clinical, development and regulatory expenses totaled \$9.8 million for the three months ended June 30, 2005 as compared to \$7.2 million for the three months ended June 30, 2004, an increase of \$2.6 million. These expenses generally consist of regulatory, clinical and manufacturing development, and medical and safety monitoring costs for our products. The increase was primarily due to a \$2.2 million increase in clinical study costs related to ongoing survival and alternative dosing studies for Vidaza and further development studies for thalidomide. Additionally, employee related costs, including compensation, travel, recruiting and relocation expenses, increased by \$1.2 million due to increased staffing levels to support regulatory, clinical development and medical and safety monitoring activities for thalidomide and Vidaza including commercial launch of Vidaza in the U.S., growth of compassionate use sales of thalidomide in Europe and other international markets, and initiation of clinical studies for Vidaza and thalidomide. These costs were partially offset by a \$.8 million decrease in pre-approval clinical manufacturing formulation development, professional fees and meeting costs incurred in 2004 for Vidaza.

*Selling, general and administrative expenses.* Selling, general and administrative expenses totaled \$22.6 million for the three months ended June 30, 2005 as compared to \$13.3 million for the three months ended June 30, 2004. Sales and marketing expenses totaled \$15.2 million for the three months ended June 30, 2005, an increase of \$6.1 million over the comparable period of 2004. This increase is due to expansion of our commercial organization and sales and marketing activities in the U.S. for Vidaza and in our European and other international markets to support the significant growth of thalidomide sales. Field sales and sales management expenses in the U.S. increased by \$2.7 million in the second quarter of 2005 due to the expansion of our sales force organization to support Vidaza sales, which was launched on July 1, 2004. We increased our U.S. field-based organization from approximately 30 employees at the beginning of the second quarter of 2004 to approximately 75 employees in the second quarter of 2005. European and international field sales and sales management expenses increased by \$1.5 million in the second quarter of 2005 due to increased selling activities to support the increased sales growth of thalidomide. Marketing expenses increased by \$2.0 million in the second quarter of 2005 due primarily to the U.S. launch of Vidaza and increased activities to support the growth of thalidomide in Europe and other international markets.

General and administrative expenses totaled \$7.4 million for the three months ended June 30, 2005 as compared to \$4.2 million for the three months ended June 30, 2004. Of the \$3.2 million increase, \$1.5 million of it is due to increased costs to support the commercial growth of our Company. In addition, we incurred \$1.7 million of costs associated with the relocation of one of our international offices in the second quarter of 2005.

*Product rights amortization.* Product rights amortization totaled \$2.2 million for the three months ended June 30, 2005 as compared to \$.7 million for the three months ended June 30, 2004. The increase in the second quarter of 2005 is due to the restructuring of our thalidomide license and supply agreements in the fourth quarter of 2004 which resulted in a \$1.5 million increase in amortization expense.

*Interest and other income (expense), net.* Interest and other income (expense), net, totaled \$1.2 million for the three months ended

**Table of Contents**

June 30, 2005, an increase of \$1.3 million over the second quarter of 2004. The increase is due to increased interest income as a result of higher balances of cash, cash equivalents and short-term investments resulting from the equity offering completed in July 2004.

*Income tax expense.* Income tax expense totaled \$2.2 million for the three months ended June 30, 2005 as compared to \$1.6 million for the three months ended June 30, 2004. The provision for income taxes recorded for the second quarter of 2005 reflects management's estimate of the effective tax rate expected to be applicable for the full fiscal year in each of our taxing jurisdictions. The increase in income tax expense is due primarily to an increase in taxable income in certain foreign countries in which we do business.

**Comparison of the Company's Results for the Six Months Ended June 30, 2005 and 2004.**

*Net sales.* Net sales totaled \$108.0 million for the six months ended June 30, 2005 as compared to \$36.1 million for the six months ended June 30, 2004. Net sales included \$61.0 million and \$4.2 million in the U.S. and \$47.0 million and \$31.9 million in Europe and other countries for the six months ended June 30, 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 \$59.0 million for the six months ended June 30, 2005. The growth also resulted from an increase in thalidomide sales, which totaled \$41.7 million for the six months ended June 30, 2005, as compared to \$27.9 million for the six months ended June 30, 2004. The growth in thalidomide sales for the six months ended June 30, 2005 is due to increased volume resulting from greater demand on a compassionate and named patient basis as well as being approved for marketing in Turkey and Israel in mid 2004.

*Cost of sales.* Cost of sales for the six months ended June 30, 2005 totaled \$29.1 million compared to \$13.8 million for the six months ended June 30, 2004. Cost of sales reflects the cost of product sold plus royalties due on the sales of our products as well as the distribution costs related to selling our products. Our gross margin for the six months ended June 30, 2005 was 73% as compared to 62% for the comparable period in 2004. The increase is due in part to the U.S. launch of Vidaza in July 2004, as the gross margin on Vidaza is higher than that of our other products. Additionally, we experienced improved gross margins on thalidomide sales as a result of the restructuring of our license and supply agreements in the fourth quarter of 2004. We expect the gross margin for our products will remain in the low 70% range for the foreseeable future.

*Clinical, development and regulatory expenses.* Clinical, development and regulatory expenses totaled \$19.3 million for the six months ended June 30, 2005 as compared to \$13.7 million for the six months ended June 30, 2004, an increase of \$5.6 million. These expenses generally consist of regulatory, clinical and manufacturing development, and medical and safety monitoring costs for both products in development as well as products being sold. The increase was primarily due to a \$4.0 million increase in clinical study costs related to ongoing survival and alternative dosing studies for Vidaza and further development studies for thalidomide. Additionally, employee related costs, including compensation, travel, recruiting and relocation expenses, increased by \$2.3 million due to increased staffing levels to support regulatory, clinical development and medical and safety monitoring activities for thalidomide and Vidaza, including the commercial launch of Vidaza in the U.S., growth of compassionate use sales of thalidomide in Europe and other international markets and initiation of clinical studies for Vidaza and thalidomide. These costs were offset by a \$.8 million decrease in pre-approval clinical, manufacturing formulation development, professional fees and meeting costs incurred in the six months ended June 30, 2004 for Vidaza.

*Selling, general and administrative expenses.* Selling, general and administrative expenses totaled \$43.3 million for the six months ended June 30, 2005 as compared to \$24.2 million for the six months ended June 30, 2004. Sales and marketing expenses totaled \$30.0 million for the six months ended June 30, 2005, an increase of \$13.8 million over the comparable period of 2004. This increase is due to expansion of our commercial organization and sales and marketing activities in the U.S. for Vidaza and in our European and other international markets to support the significant growth of thalidomide sales. Field sales and sales management expenses in the U.S. increased by \$5.6 million in the six month period ended June 30, 2005 due to the expansion of our sales force organization to support the launch of Vidaza on July 1, 2004. We increased our U.S. field-based organization from approximately 30 employees at the beginning of 2004 to approximately 75 employees by the end of the second quarter of 2005. European and international field sales and sales management expenses increased by \$3.2 million for the six months ended June 30, 2005 due to increased selling activities to support the increased sales growth of thalidomide.

Marketing expenses increased by \$5.1 million for the six months ended June 30, 2005 due primarily to the U.S. launch of Vidaza and increased activities to support the growth of thalidomide in Europe and other international markets.

General and administrative expenses totaled \$13.3 million for the six months ended June 30, 2005 as compared to \$8.0 million for the six months ended June 30, 2004. Of the \$5.3 million increase, \$2.9 million of it is due to increased costs to support the commercial growth of our Company. In addition, we incurred \$2.4 million of costs associated with the relocation of one of our international



**Table of Contents**

offices in the first half of 2005.

*Product rights amortization.* Product rights amortization totaled \$4.5 million for the six months ended June 30, 2005 as compared to \$1.4 million for the six months ended June 30, 2004. The increase in 2005 is due to the restructuring of our thalidomide license and supply agreements in the fourth quarter of 2004 which resulted in a \$3.1 million increase in amortization expense.

*Interest and other income (expense), net.* Interest and other income (expense), net, totaled \$3.0 million for the six months ended June 30, 2005, an increase of \$3.2 million over the six months ended June 30, 2004. The increase is due to increased interest income as a result of higher balances of cash, cash equivalents and short-term investments resulting from the equity offering completed in July 2004. In addition, in March 2004, \$14 million of 6% convertible notes, originally issued in April 2003, were converted into shares of our common stock, thereby eliminating the interest expense associated with these notes.

*Income tax expense.* Income tax expense totaled \$5.1 million for the six months ended June 30, 2005 as compared to \$2.6 million for the six months ended June 30, 2004. The provision for income taxes recorded for 2005 reflects management's estimate of the effective tax rate expected to be applicable for the full fiscal year in each of our taxing jurisdictions. The increase in income tax expense is due primarily to an increase in taxable income in certain foreign countries in which we do business.

**Liquidity and Capital Resources**

Since our inception, we have incurred significant losses and as of June 30, 2005, we had an accumulated deficit of \$128.3 million. We achieved profitability on a quarterly basis for the first time in the fourth quarter of 2004 and again for the first and second quarters of 2005; however, we have yet to achieve profitability on a full year basis. We expect that our clinical, development and regulatory and selling, general and administrative expenses will continue to grow and, as a result, we will need to generate significant net sales to sustain profitability. To date, our operations have been funded primarily with proceeds from the sale of equity and the issuance of convertible notes. Net proceeds from our stock sales in 2000 through 2002 totaled \$125.0 million and the issuance of convertible notes in 2003 provided net proceeds of \$14.0 million. On November 12, 2003, we completed our initial public offering. We sold 6,000,000 shares of our common stock in the offering at a price of \$14.00 per share. We received net proceeds from the offering of approximately \$76.2 million. On March 1, 2004, the convertible notes and accrued interest thereon were converted into 1,342,170 shares of common stock. On July 7, 2004, we completed a public offering of our common stock, in which we sold 5,290,000 shares of common stock in the offering at a price to the public of \$48.00 per share. We received net proceeds from the offering of approximately \$238.0 million.

Cash, cash equivalents and short-term investments decreased from \$245.5 million at December 31, 2004 to \$227.3 million at June 30, 2005. This \$18.2 million decrease is due to the net effect of \$6.8 million of cash generated from operations less \$25.0 million in cash used primarily for payments due for product and Company acquisitions, capital expenditures, and the effect of exchange rates on cash, cash equivalents and short-term investments.

We expect to incur increases in our total operating expenses in future periods to support the commercialization and clinical development programs of our current products. We believe, however, that our cash, cash equivalents and short term investments on hand at June 30, 2005 and the cash generated from expected product sales will be adequate to fund our operations for at least the next 12 months. Our future capital needs and the adequacy of our available funds will depend on many factors, including the effectiveness of our sales and marketing activities in generating product sales, the cost of clinical studies and other actions needed to obtain regulatory approval or expanded approved indications of our existing products, and the timing and cost of any future acquisitions. If additional funds are required, we may raise such funds from time to time through public or private sales of equity or debt securities or from bank or other loans. Our failure to raise capital when needed could adversely impact our growth plans and financial condition. Additional equity financing may be dilutive to the holders of our common stock and debt financing may involve significant cash payment obligations and covenants that restrict our ability to operate our business.

**Contractual Obligations**

*Commitments.* The following table summarizes our long-term commitments as of June 30, 2005, including commitments pursuant to debt agreements, product licensing agreements and lease obligations (amounts in

thousands).

**Table of Contents**

		Less than		4-5	More than 5
Contractual obligations	Total	1 Year	1-3 Years	Years	Years
Operating leases	\$12,213	\$ 3,845	\$ 7,433	\$ 935	\$
Clinical development funding	7,667	3,667	4,000		
Inventory purchase commitments	7,550	7,550			
Product royalty payments	5,659	3,647	2,012		
Product acquisition payments	4,000	3,000	1,000		
Long-term debt obligations	331	260	71		
Total fixed contractual obligations	\$37,420	\$ 21,969	\$ 14,516	\$ 935	\$

**Operating leases.** Our commitment for operating leases relates to our corporate and sales offices located in the U.S., Europe, Thailand and Australia. These lease commitments expire on various dates through 2010.

**Clinical development funding.** We have entered into two agreements with Celgene to provide funding to support clinical development studies sponsored by Celgene studying thalidomide as a treatment for various types of cancers. Under these agreements, we will pay Celgene \$4.7 million in 2005 and \$2.67 million in each of 2006 and 2007.

**Product acquisition payments.** We have future payment obligations associated with our licensing of Refludan. Certain of these payments are fixed and determinable while the timing and amount of others are contingent upon future events such as achieving revenue milestones. Under the terms of our agreements with Schering relating to the licensing of Refludan, we agreed to make an aggregate of \$10.0 million of fixed payments to Schering, payable in quarterly installments of \$1.0 million through the end of 2005 for our license of Refludan and a royalty of 14% of our net sales of Refludan commencing in January 2004 and up to \$7.5 million of contingent payments described below. In addition, we agreed to make two \$1.0 million payments due in 2006 and 2007 to a third party in connection with the settlement of a patent dispute associated with thalidomide.

**Product royalty payments.** The Innohep license agreement with LEO Pharma, requires annual minimum royalty payments through 2006.

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

**Contingent product and company acquisition payments.** The contractual summary above reflects only payment obligations for product and company acquisitions that are fixed and determinable. We also have contractual payment obligations, the amount and timing of which are contingent upon future events. In accordance with U.S. generally accepted accounting principles, contingent payment obligations are not recorded on our balance sheet until the amount due can be reasonably determined. Under the agreements with Schering, in addition to the \$10 million of fixed payments required, payments totaling up to \$7.5 million are due if milestones relating to revenue and gross margin targets for Refludan are achieved. The terms of our Innohep agreement with LEO Pharma provide for additional royalties due in the event that the quarterly royalties paid to them do not meet minimum royalty targets for 2007 to 2012. These targets are calculated based on sales forecasts that will be determined in the future. The terms of our agreement with LEO Pharma also provide that we will pay additional royalties if the net sales forecasts defined in the agreement are not achieved for any two consecutive years. If we elect not to pay those additional royalties, LEO Pharma has the right to terminate the license agreement.

**Factors Affecting Our Business Conditions**

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

**Risks Related to Our Business**

*We have a history of net losses, and may not maintain profitability in the future.*

We have incurred annual net losses since our inception, including a net loss of \$17.5 million on an annual basis for the fiscal year ended December 31, 2004. As of June 30, 2005, we had an accumulated deficit of \$128.3 million. Although we have achieved profitability for each of the past three quarters, we expect to make substantial expenditures to further develop and commercialize our

**Table of Contents**

products, including costs and expenses associated with completing clinical trials, seeking regulatory approvals and marketing of our products. Furthermore, our expenditures could increase significantly if we acquire additional products or product candidates. Accordingly, we may need to generate greater revenues to maintain profitability. If we fail to maintain profitability on a continuous basis within the time frame expected by investors or securities analysts, or if we fail to achieve the level of profitability expected by investors or securities analysts, the market price of our common stock may decline.

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

The success of our business is largely dependent on the commercial success of Vidaza. Vidaza has been on the market in the U.S. for only one year and we do not have long-term data on the use of the product by physicians and patients. As a consequence, we cannot make assurances that Vidaza will gain widespread acceptance from members of the medical community or that the initial acceptance of Vidaza we have observed thus far will be maintained. Acceptance will be a function of its continued acceptance by regulators, physicians, patients and other key decision-makers as a safe, superior therapeutic as compared to currently existing or future treatments for MDS. Moreover, the FDA is currently considering for approval new therapeutics for treating MDS that have been under development by our competitors. Even if Vidaza does achieve market acceptance, we may not be able to maintain that market acceptance over time if these new products are introduced and are more favorably received than Vidaza or render Vidaza obsolete.

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

***We may not receive regulatory approvals for Thalidomide Pharmion 50mg or, outside of the U.S., for Vidaza, or approvals may be delayed.***

Our ability to fully commercialize Thalidomide Pharmion 50mg is subject to regulatory approval by governmental authorities in Europe and our other markets, and our ability to commercialize Vidaza outside the U.S. is subject to regulatory approval by governmental authorities in Europe and elsewhere. In May 2004, we withdrew our multiple myeloma applications with the EMEA for Thalidomide Pharmion 50mg, based on the EMEA's stated view that additional clinical data would be required before it can reach an opinion on whether or not Thalidomide Pharmion 50mg should be approved as a treatment for multiple myeloma. In July 2005, we announced the completion of the scientific advice procedure with the EMEA regarding the clinical data needed to support a marketing authorization for thalidomide in relapsed/refractory multiple myeloma. Based on this scientific advice, we plan to initiate a four arm randomized study of 400-500 patients in this indication. We expect to enroll the first patient into the study in the fourth quarter of 2005 and we expect to complete the study in 2007. We intend to resubmit our application with additional clinical data from this study to support a marketing approval for the treatment of relapsed/ refractory multiple myeloma patients. We have not yet sought scientific advice related to clinical data required to support a marketing authorization for thalidomide in newly-diagnosed patients. In September 2004 the EMEA accepted for review our Marketing Authorization Application for Vidaza for the treatment of MDS based on data from the same clinical studies accepted by the FDA for approval of Vidaza in the U.S.

We cannot assure you that the results of our ongoing clinical trials for Thalidomide Pharmion 50mg and the data submitted to the EMEA for approval of Vidaza will support our applications for these regulatory approvals. The timing of our submissions, the outcome of reviews by the applicable regulatory authorities in each relevant market, and the initiation and completion of clinical trials are subject to uncertainty, change and unforeseen delays. Moreover, favorable results in later stage clinical trials do not ensure regulatory approval to commercialize a product. Some companies that have believed their products performed satisfactorily in clinical trials have nonetheless failed to obtain regulatory approval of their products. We will not be able to market Thalidomide Pharmion 50mg or Vidaza in any

country where the drug is not approved, and if Thalidomide Pharmion 50mg or Vidaza is not approved for sale in a market where we have acquired rights to the product, we will only be able to sell it in such market, if at all, on a compassionate use or named patient basis, which may limit sales and revenues.

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

At the time thalidomide first came on the market in the late 1950's and into the early 1960's, it was not known that the drug could cause birth defects in babies born to women who had taken the drug while pregnant. Although no proper census was ever taken, it has been estimated that there were between 10,000 and 20,000 babies born with birth defects as a result of thalidomide. The majority of

**Table of Contents**

these births were in the U.K. and Germany, two of our largest target markets for sales of Thalidomide Pharmion 50mg. As a result, thalidomide's historical reputation in our target markets may delay or prevent regulatory approval in Europe or may present a substantial barrier to its market acceptance. Thalidomide's potential for causing severe birth defects and its negative historical reputation may limit the extent of its market acceptance among both doctors and patients, despite the efficacy that it has been proven to have in patients afflicted with a number of different diseases. In addition, any report of a birth defect attributed to the current use of thalidomide could result in a material decrease in our sales of thalidomide, and may result in the forced withdrawal of thalidomide from the market.

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

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

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

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

Any of these factors could cause us to delay or suspend clinical trials, regulatory submissions, required approvals or commercialization of our products or product candidates, entail higher costs and result in our being unable to effectively commercialize our products. Furthermore, if our third-party manufacturers fail to deliver the required commercial quantities of bulk drug substance or finished product on a timely basis and at commercially reasonable prices, and we are unable to promptly find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volume and on a timely basis, we would likely be unable to meet demand for our products and we would lose potential revenues. Moreover, failure of our third party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of Vidaza and our other products.

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

Our operating results may vary significantly from period to period due to many factors, including the amount and timing of sales of our products, the availability and timely delivery of a sufficient supply of our products, the timing and amount of operating expenses, particularly for development activities, announcements regarding clinical trial

results and product introductions by us or our competitors, the availability and timing of third-party reimbursement and the timing of regulatory submissions and approvals. If our operating results do not match the expectations of securities analysts and investors as a result of these and other factors, the trading price of our common stock will likely decrease.

*If we breach any of the agreements under which we license commercialization rights to products or technology from others, we*



**Table of Contents**

*could lose license rights that are important to our business.*

We license commercialization rights to products and technology that are important to our business, and we expect to enter into similar licenses in the future. For instance, we acquired our first four products through exclusive licensing arrangements. Under these licenses we are subject to commercialization and development, sublicensing, royalty, insurance and other obligations. If we fail to comply with any of these requirements, or otherwise breach these license agreements, the licensor may have the right to terminate the license in whole or to terminate the exclusive nature of the license. Loss of any of these licenses or the exclusivity rights provided therein could harm our financial condition and operating results.

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

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

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

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

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

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

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

**Table of Contents**

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

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

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

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

*Refludan*: Argatroban, from GlaxoSmithKline.

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

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

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

***Failure to achieve our revenue targets or raise additional funds in the future may require us to delay, reduce the scope of, or eliminate one or more of our planned activities.***

We may need to generate greater revenues to maintain profitability on an annual basis. The product development, including clinical trials, manufacturing development and regulatory approvals of Vidaza and thalidomide, and the acquisition and development of additional product candidates by us will require a commitment of substantial funds. Our future capital requirements are dependent upon many factors and may be significantly greater than we expect.

We believe, based on our current operating plan, including anticipated sales of our products, that our cash, cash equivalents and marketable securities as of June 30, 2005 will be sufficient to fund our operations through at least the next twelve months. If our existing resources are insufficient to satisfy our liquidity requirements due to slower than anticipated sales of our products or otherwise, or if we acquire additional products or product candidates, we may need to sell additional equity or debt securities. If we are unable to obtain this additional financing, we may be required to delay, reduce the scope of, or eliminate one or more of our planned development, commercialization or expansion activities, which could harm our financial condition and operating results.

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

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on our senior management, especially Patrick J. Mahaffy, our President and Chief Executive Officer, and Judith A. Hemberger, our Executive Vice President and Chief Operating Officer, whose services are critical to the successful implementation of our product acquisition, development and regulatory strategies. Each of Mr. Mahaffy and Dr. Hemberger has entered into an employment agreement with us for a term that runs until the agreement is otherwise terminated by us or them. Their employment agreements provide that they cannot compete with us for a period of one year after their employment with us is terminated. If we lose their services or the services of one or more of the other members of our senior management or other key employees, our ability to successfully implement our business strategy could be seriously harmed. We are not aware of any present intention of any of these individuals to leave our company. We do not maintain key person life insurance on any of the members of our senior management.

Replacing key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these

**Table of Contents**

additional key personnel.

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

Our commercial success will depend in part on obtaining and maintaining a strong proprietary position for our products both in the U.S., Europe and elsewhere. Of our four current products, Thalidomide Pharmion 50mg and Refludan currently have patent protection under issued patents. In addition, we have one issued patent covering certain polymorphic forms of Vidaza drug substance and have received a notice of allowance from the U.S. patent and trademark office indicating that a second patent will issue in the U.S. covering methods of isolating a crystalline form of Vidaza drug substance. However, we must still rely in large part on orphan drug exclusivity, trade secrets, know-how and continuing technological innovations to protect our intellectual property and to enhance our competitive position. Even if we are granted orphan drug exclusivity, competitors are not prohibited from developing or marketing different drugs for an indication. As a result, competitors could overcome the competitive advantage gained by orphan drug exclusivity by introducing other products in the same indication. Until we are granted a marketing authorization, while we are selling Thalidomide Pharmion 50mg on a compassionate use and named patient basis, we do not have orphan drug exclusivity and we must rely on our use patent protection to prevent competitors from selling thalidomide in our markets.

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

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

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

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

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

We prepare our financial statements to conform with generally accepted accounting principles, or GAAP, in the United States. These accounting principles are subject to interpretation by the American Institute of Certified Public Accountants, the Financial Accounting Standards Board, or FASB, the SEC and various bodies formed to promulgate and interpret appropriate accounting policies. A change in those accounting principles or interpretations could have a significant effect on our reported financial results and may affect our reporting of transactions completed before a change is announced or adopted. Changes to those rules or the questioning of current practices may adversely affect

our reported financial results or the way we conduct our business. For example, accounting policies affecting certain aspects of our business, including rules relating to employee stock option grants, have recently been revised. In December 2004, the FASB issued a revision of SFAS No. 123, Accounting for Stock-Based Compensation, which amends SFAS No. 123 to require the recognition of employee stock options as compensation based on their fair value at the time of grant (with limited exceptions). These new rules, which must be adopted by the beginning of the first fiscal year after June 15, 2005, will require

## **Table of Contents**

us, commencing on January 1, 2006, to change our accounting policy and record an expense for our stock-based compensation plans using the fair value method, and will result in additional accounting charges as described in Management's Discussion and Analysis of Financial Condition and Results of Operations - Recently Issued Accounting Standards.

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

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

difficulties in compliance with foreign laws and regulations;

changes in foreign regulations and customs;

changes in foreign currency exchange rates and currency controls;

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

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

negative consequences from changes in tax laws;

difficulties associated with staffing and managing foreign operations;

longer accounts receivable cycles in some countries; and

differing labor regulations.

### **Risks Related to Our Industry**

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

Our ability to achieve acceptable levels of reimbursement for drug treatments by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize, and attract collaborative partners to invest in the development of, product candidates. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 together with rulemaking by the Centers for Medicare and Medicaid Services, or CMS, changed the methodology for Medicare reimbursement of pharmaceutical products administered in physician offices and hospital outpatient facilities, including Vidaza and Innohep. Under the new regulations, reimbursements will now be the average selling price, or ASP, of a product plus 6%, rather than a specified discount from the average wholesale price, or AWP, as was the case under prior regulations. The new ASP-based reimbursement regime generally will reduce the reimbursement physicians will receive under Medicare for most office-administered injectable drugs, including Vidaza and Innohep. Although the actual impact of these reimbursement changes is not currently well known, there is a risk that the new reimbursement policies will adversely affect product use by physicians, thereby reducing our sales for these products.

In other countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals and the level of reimbursement are subject to governmental control. We cannot be sure that reimbursement in the U.S., Europe or elsewhere will be available for any products we may develop or, if already available, will not be decreased or eliminated in the future. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products, and may not be able to obtain a satisfactory financial return on our products.

Third-party payers increasingly are challenging prices charged for medical products and services. Also, the trend toward managed health care in the U.S. and the changes in health insurance programs, as well as legislative proposals to reform health care or reduce government insurance programs, may result in lower prices for pharmaceutical products, including any products that may be offered by us. Cost-cutting measures that health care providers are instituting, and the effect of any health care reform, could harm our ability to sell any products that are successfully developed by us and approved by regulators. Moreover, we are unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be

**Table of Contents**

enacted in the future or what effect this legislation or regulation would have on our business. In the event that governmental authorities enact legislation or adopt regulations which affect third-party coverage and reimbursement, demand for our products may be reduced thereby harming our sales and profitability.

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

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

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

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

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

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

The regulatory requirements relating to the manufacturing, testing, and marketing of our products may change from time to time. For example, at present, member states in the E.U. are in the process of incorporating into their domestic laws the provisions contained in the E.U. Directive on the implementation of good clinical practice in the conduct of clinical trials. The Directive imposes more onerous requirements in relation to certain aspects of the conduct of clinical trials than are currently in place in many member states. This may impact our ability to conduct clinical trials and the ability of independent investigators to conduct their own research with support from us.

**Risks Related to Our Common Stock**

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

Our amended and restated certificate of incorporation, bylaws, Delaware law and our employment agreements with members of senior management contain provisions which could delay or prevent a third party from acquiring shares of



our common stock or

**Table of Contents**

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

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

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

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

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

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

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

actual or anticipated fluctuations in our operating results;

our announcements or our competitors' announcements of clinical trial results or regulatory approval of new products;

changes in our growth rates or our competitors' growth rates;

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

public concern as to the safety of our products;

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

our inability to raise additional capital;

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

changes in stock market analyst recommendations regarding our common stock, other comparable companies or the pharmaceutical industry generally.

**Item 3. *Quantitative and Qualitative Disclosures About Market Risk***

We currently invest our excess cash balances in money market accounts that are subject to interest rate risk. The amount of interest

**Table of Contents**

income we earn on these funds will decline with a decline in interest rates. However, due to the short-term nature of money market accounts, an immediate decline in interest rates would not have a material impact on our financial position, results of operations or cash flows.

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

**Item 4. Controls and Procedures**

***Evaluation of Disclosure Controls and Procedures:***

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

***Changes in Internal Controls:***

There were no changes in our internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**PART II  
OTHER INFORMATION**

**Item 1. Legal Proceedings**

For a description of our currently outstanding legal proceedings, please see our Quarterly Report on Form 10-Q for the quarter ended March 31, 2005, which was filed with the SEC. No material developments to these matters has occurred during the period covered by this report.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

None.

**Item 3. Defaults Upon Senior Securities**

None.

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

At our 2005 Annual Meeting of Shareholders held on June 1, 2005 (the Annual Meeting), our shareholders: (i) elected three Class II Directors each to serve for a term to expire in 2008 (Item No. 1); (ii) ratified the appointment of Ernst & Young LLP as independent auditors for the fiscal year ending December 31, 2005 (Item No. 2); (iii) approved an amendment to the Company's 2000 Stock Incentive Plan to increase by 1,500,000 shares the number of shares of common stock reserved for issuance under the 2000 Stock Incentive Plan (Item No. 3); and (iv) approved an amendment to the Company's 2001 Non-Employee Director Stock Option Plan to increase by 100,000 shares the number of shares of common stock reserved for issuance under the 2001 Non-Employee Director Stock Option Plan (Item No. 4). The tabulation of votes for each of the proposals is set forth below:

**Item No. 1**

Election of three Class II Directors for a three-year term:

<b>Directors Class II</b>	<b>Votes For</b>	<b>Votes Withheld</b>
Patrick J. Mahaffy	27,770,510	1,175,259
James Blair	25,623,678	3,322,091
Cam L. Garner	26,394,249	2,551,520

The terms of office as directors of the Company for Judith A. Hemberger, Thorlef Spickschen, Brian Atwood, James Barrett and Edward McKinley continued after the Annual Meeting.

**Item No. 2**

Ratification of the appointment of Ernst & Young LLP as independent auditors of the Company for the 2005 fiscal year:

<b>FOR</b>	<b>AGAINST</b>	<b>ABSTAIN</b>
28,856,699	88,441	629

**Item No. 3**

Approval of the proposed amendment to the Company's 2000 Stock Incentive Plan:

<b>FOR</b>	<b>AGAINST</b>	<b>ABSTAIN</b>	<b>Broker Non-Vote</b>
13,281,032	7,801,347	18,229	7,845,161

**Item No. 4**

Approval of the proposed amendment to the Company's 2001 Non-Employee Director Stock Option Plan:

<b>FOR</b>	<b>AGAINST</b>	<b>ABSTAIN</b>	<b>Broker Non-Vote</b>
12,267,143	8,816,261	17,204	7,845,161

**Item 5. Other Information**

None.

**Item 6. Exhibits**

10.1\* Amended and Restated 2001 Non-Employee Director Stock Option Plan

10.2\* Amended and Restated 2000 Stock Incentive Plan

31.1 Sarbanes-Oxley Act of 2002, Section 302 Certification for President and Chief Executive Officer

31.2 Sarbanes-Oxley Act of 2002, Section 302 Certification for Chief Financial Officer

32.1 Sarbanes-Oxley Act of 2002, Section 906 Certification for President and Chief Executive Officer and Chief Financial Officer

\* Management Contract or Compensatory Plan or Arrangement.



**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

PHARMION CORPORATION

By: */s/ Patrick J. Mahaffy*  
*President and Chief Executive Officer*  
*(Principal Executive Officer)*

Date: August 8, 2005

PHARMION CORPORATION

By: */s/ Erle T. Mast*  
*Chief Financial Officer*  
*(Principal Financial and Accounting Officer)*

Date: August 8, 2005

**Table of Contents**

**Exhibit Index**

- 10.1\* Amended and Restated 2001 Non-Employee Director Stock Option Plan
- 10.2\* Amended and Restated 2000 Stock Incentive Plan
- 31.1 Sarbanes-Oxley Act of 2002, Section 302 Certification for President and Chief Executive Officer
- 31.2 Sarbanes-Oxley Act of 2002, Section 302 Certification for Chief Financial Officer
- 32.1 Sarbanes-Oxley Act of 2002, Section 906 Certification for President and Chief Executive Officer and Chief Financial Officer
- \* Management Contract or Compensatory Plan or Arrangement.