

PHARMION CORP  
Form 10-Q  
November 12, 2004

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

**Form 10-Q**

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

**For the quarterly period ended September 30, 2004**

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

**For the transition period from            to**

**Commission file number 000-50447**

**PHARMION CORPORATION**

*(Exact name of registrant as specified in its charter)*

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

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

As of November 5, 2004, there were 31,656,158 shares of the Registrant's Common Stock outstanding.

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**PART I  
FINANCIAL INFORMATION**

**Item 1. Consolidated Financial Statements**

**PHARMION CORPORATION**

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

	<b>September 30, 2004</b>	<b>December 31, 2003</b>
	<b>(Unaudited)</b>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 195,129	\$ 88,542
Short-term investments	115,157	
Accounts receivable, net of allowances of \$1,443 and \$819, respectively	31,473	7,992
Inventories	3,136	4,923
Other current assets	3,990	4,122
Total current assets	348,885	105,579
Product rights, net	28,234	30,651
Property and equipment, net	4,598	5,050
Goodwill	3,586	3,652
Other assets	208	541
Total assets	\$ 385,511	\$ 145,473
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,672	\$ 4,241
Accrued liabilities	32,611	14,800
Total current liabilities	36,283	19,041
Long-term liabilities:		
Convertible notes payable		13,374
Deferred tax liability	3,599	3,665
Other long-term liabilities	1,320	4,479

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Total long-term liabilities	4,919	21,518
Stockholders' equity:		
Common stock, \$.001 par value; 100,000,000 shares authorized and 31,545,634 and 23,948,636 shares issued and outstanding at September 30, 2004 and December 31, 2003	32	24
Preferred stock, \$.001, 10,000,000 shares authorized, no shares issued and outstanding at September 30, 2004 and December 31, 2003		
Additional paid-in capital	482,055	222,218
Deferred compensation	(766)	(1,155)
Other comprehensive income	3,693	4,386
Accumulated deficit	(140,705)	(120,559)
	<u>          </u>	<u>          </u>
Total stockholders' equity	<u>344,309</u>	<u>104,914</u>
Total liabilities and stockholders' equity	<u>\$ 385,511</u>	<u>\$ 145,473</u>

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net sales	\$ 42,576	\$ 7,673	\$ 78,692	\$ 13,760
Operating expenses:				
Cost of sales, including royalties of \$9,817 and \$1,695 for the three months ended September 30, 2004 and 2003, respectively; and royalties of \$19,532 and \$1,934 for the nine months ended September 30, 2004 and 2003, respectively	14,169	2,681	27,931	7,140
Clinical, development and regulatory	7,383	5,436	21,116	16,897
Selling, general and administrative	18,592	7,867	42,808	25,479
Product rights amortization	720	613	2,160	1,259
Total operating expenses	40,864	16,597	94,015	50,775
Income (loss) from operations	1,712	(8,924)	(15,323)	(37,015)
Interest and other income (expense), net	911	(290)	722	28
Income (loss) before taxes	2,623	(9,214)	(14,601)	(36,987)
Income tax expense	2,978	40	5,545	154
Net loss	(355)	(9,254)	(20,146)	(37,141)
Less accretion of redeemable convertible preferred stock to redemption value		(2,825)		(8,474)
Net loss attributable to common stockholders	\$ (355)	\$ (12,079)	\$ (20,146)	\$ (45,615)

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	_____	_____	_____	_____
Net loss attributable to common stockholders per common share, basic and diluted	\$ (0.01)	\$ (14.35)	\$ (0.75)	\$ (56.10)
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Shares used in computing net loss attributable to common stockholders per common share, basic and diluted	30,381,691	841,477	26,688,333	813,055
Pro forma net loss attributable to common stockholders per common share assuming conversion of preferred stock, basic and diluted		\$ (0.52)		\$ (2.08)
		<u>          </u>		<u>          </u>
Shares used in computing pro forma net loss attributable to common stockholders per common share assuming conversion of preferred stock, basic and diluted		17,872,433		17,844,011

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

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	<b>Nine Months Ended September 30,</b>	
	<b>2004</b>	<b>2003</b>
<b>Operating activities</b>		
Net loss	\$ (20,146)	\$(37,141)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,650	2,349
Compensation expense related to stock option issuance	389	406
Other	305	181
Changes in operating assets and liabilities:		
Accounts receivable, net	(23,564)	(3,780)
Inventories	1,650	(2,213)
Other current assets	135	(985)
Other long-term assets	332	475
Accounts payable	(528)	233
Accrued liabilities	18,416	2,448
	<hr/>	<hr/>
Net cash used in operating activities	(19,361)	(38,027)
<b>Investing activities</b>		
Purchases of property and equipment	(996)	(1,965)
Acquisition of business, net of cash acquired	(19)	(12,265)
Purchase of product rights		(1,000)
Purchase of available-for-sale investments	(131,855)	
Sale and maturity of available-for-sale investments	16,308	
	<hr/>	<hr/>
Net cash used in investing activities	(116,562)	(15,230)
<b>Financing activities</b>		
Proceeds from sale of common stock, net of issuance costs	245,683	70
Proceeds from issuance of convertible notes and warrants		14,000
Payment of debt obligations	(2,950)	(177)
	<hr/>	<hr/>
Net cash provided by financing activities	242,733	13,893
Effect of exchange rate changes on cash and cash equivalents	(223)	293
	<hr/>	<hr/>
Net increase (decrease) in cash and cash equivalents	106,587	(39,071)



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Cash and cash equivalents at beginning of period	88,542	62,604
	<u>          </u>	<u>          </u>
Cash and cash equivalents at end of period	\$ 195,129	\$ 23,533
	<u>          </u>	<u>          </u>

**Noncash items**

Warrants granted in connection with issuance of convertible notes		730
Conversion of debt and accrued interest to common stock	14,161	
Financed property and equipment acquisitions	58	
Financed product rights acquisition		8,208

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

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**PHARMION CORPORATION**

**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS**

**1. NATURE OF BUSINESS**

Pharmion Corporation (the Company) was incorporated in Delaware on August 26, 1999 and commenced operations in January 2000. The Company is engaged in the acquisition, development and commercialization of pharmaceutical products for the treatment of oncology and hematology patients. The Company's product acquisition and licensing efforts are focused on both development stage 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 cash payments. To date, the Company has acquired the distribution and marketing rights to four products. The Company has established operations in the United States, Europe and Australia. Through a distributor network, the Company can reach the hematology and oncology community in additional countries in the Middle East and Asia.

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

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

On July 7, 2004, the Company completed a public offering of common stock. A total of 5,290,000 shares of common stock were sold at a price to the public of \$48.00 per share, resulting in net proceeds to the Company of \$238.0 million.

**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 2003 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 and results of operations and cash flows for the three and nine months ended September 30, 2004 and 2003. The results of operations for the interim periods are not necessarily indicative of the results to be expected for the year ending December 31, 2004 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.

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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.

### **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.

### **Concentration of Credit Risk**

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

The Company's products are sold both to wholesale distributors and directly to hospitals and clinics. Ongoing credit evaluations of customers are performed and collateral is generally not required. The Company maintains a reserve for potential credit losses, and such losses have been within management's expectations. In the nine months ended September 30, 2004 and 2003, revenues generated from the Company's five largest customers in the United States totaled approximately 34% and 29%, respectively, of consolidated net revenues. Revenues generated from international customers were individually less than 5% of consolidated net revenues.

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

Immediately prior to the effective date of the Company's initial public offering (November 12, 2003), all of the Company's shares of redeemable convertible preferred stock outstanding converted into an aggregate of 17,030,956 shares of common stock. Unaudited pro forma net loss per share is computed by dividing net loss before accretion of redeemable convertible preferred stock to redemption value by the weighted average number of common shares

outstanding, including the pro forma effects of conversion of all outstanding redeemable convertible preferred stock into shares of the Company's common stock as of January 1, 2003.

### 3. NET LOSS PER COMMON SHARE

The Company applies SFAS No. 128, *Earnings per Share*, which establishes standards for computing and presenting earnings per share. Basic and diluted net loss per common share is calculated by dividing net 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, since the effects of potentially dilutive securities are antidilutive for all periods presented. Potential incremental common shares include shares of common stock issuable upon exercise of stock options and warrants and upon the conversion of redeemable convertible preferred stock and convertible notes outstanding during the period. The potential shares of

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common stock have not been included in the diluted net loss per share calculation because to do so would be antidilutive. Such shares totaled 2,229,083 and 20,632,148 as of September 30, 2004 and 2003, respectively.

**4. LICENSE AGREEMENTS AND PRODUCT RIGHTS*****Innohep***

In June 2002, the Company entered into an 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, in exchange for this license, the Company paid \$5 million which was capitalized as product rights and is being amortized over the 10 year period during which the Company expects to generate significant revenues. On the closing date, the Company paid an additional \$2.5 million which is creditable against royalty payments otherwise due during the period ending March 1, 2005. In addition, the Company is obligated to pay LEO Pharma royalties at the rate of 30% of net sales on annual net sales of up to \$20 million and at the rate of 35% of net sales on annual net sales exceeding \$20 million, less in each case the Company's purchase price from LEO Pharma of the units of product sold. The agreement has a term of ten years.

***Refludan***

In May 2002, the Company acquired the exclusive right to market and distribute Refludan® in all countries outside the U.S. and Canada. The Company has paid Schering an aggregate of \$8 million and is obligated to make \$5 million in 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 was \$12.2 million, which was capitalized to product rights and is being amortized over the 10-year period during which the Company expects to generate revenue. Additional payments of up to \$7.5 million will be due Schering upon achievement of certain milestones. Because such payments are contingent upon future events, they are not reflected in the accompanying financial statements. In addition, the Company pays Schering a 14% royalty on net sales of Refludan® (8% in 2003) until the aggregate royalty payments total \$12.0 million measured from January 2004. At that time, the royalty rate will be reduced to 6%.

***Azacitidine***

In 2001, the Company acquired the development and commercialization rights to azacitidine for the treatment of certain bone marrow disorders. Global rights to azacitidine were licensed from Pharmacia Corporation, now part of Pfizer Inc. The Company is responsible for all costs associated with the development, regulatory review, and commercialization of this product.

Under the terms of the Company's agreement with Pfizer, the Company is obligated to pay a royalty of up to 20% on net sales of azacitidine. The license from Pfizer has a term extending for the longer of the last to expire of valid patent claims in any given country or ten years from the first commercial sale of the product in a particular country. In May 2004, the Company received approval from the FDA to market azacitidine under the branded name Vidaza® in the United States. The Company began selling Vidaza on July 1, 2004.

***Thalidomide***

In 2001, the Company acquired the development and commercialization rights to Thalomid® (thalidomide) in all countries outside the U.S., Canada, and certain Asian countries. The license was purchased from both Celgene Corporation and Penn T Limited, which was acquired by Celgene in October 2004. In the second quarter of 2003, the Company began selling thalidomide on a compassionate use or named patient basis throughout Europe and other

international markets while it pursues marketing authorizations in those countries. The Company is responsible for all costs associated with the development, regulatory review, and commercialization of this product.

Under the Company's agreements with Penn and Celgene, the Company will pay a combined royalty of 36% of net sales, less the Company's purchase price from Penn of the units of product sold, on all sales of thalidomide once it is approved by the appropriate health regulatory authority for sale in any country within the Company's licensed territory. Until such approvals are obtained, the combined royalty payment obligations to Celgene and Penn are generally lower than 36%. The Company's royalty payment obligations to Celgene and Penn are also subject to certain minimum yearly payment thresholds. In connection with our ongoing

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relationship with Celgene, and to further the clinical development of thalidomide, particularly in multiple myeloma, the Company has also agreed to fund an aggregate of \$8.0 million of Celgene's clinical trial development costs for clinical studies of thalidomide. As of September 30, 2004 the Company was obligated to pay Celgene an aggregate of \$2.8 million in quarterly installments through 2005. The Company issued a warrant to Celgene to purchase 1,701,805 shares of Series B Preferred Stock at \$2.09 per share in November 2001 which expires seven years from the date of grant. Immediately prior to the effective date of the IPO, this warrant was converted into the right to purchase 425,452 shares of common stock at an exercise price of \$8.36 per share and it was exercised in September 2004. The agreements with Celgene and Penn each have a ten year term running from the date of receipt of the first regulatory approval for thalidomide in the United Kingdom, subject, in the case of the Celgene agreement to Celgene having a right to terminate the agreement if the Company has not obtained that approval by November 2006.

On March 25, 2003, the Company acquired 100% of the outstanding stock of Gophar S.A.S. and its wholly owned subsidiary, Laphal Développement. As part of this purchase, we acquired Laphal's thalidomide formulation. A portion of the Laphal purchase price was allocated to the thalidomide product rights. The thalidomide product rights are being amortized over their estimated economic life of 15 years.

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

	<u>As of September 30, 2004</u>		<u>As of December 31, 2003</u>	
	<u>Gross Carrying Amount</u>	<u>Accumulated Amortization</u>	<u>Gross Carrying Amount</u>	<u>Accumulated Amortization</u>
Amortized product rights:				
Innohep®	\$ 5,000	\$(1,125)	\$ 5,000	\$ (750)
Refludan®	12,208	(1,876)	12,208	(865)
Thalidomide	15,583	(1,556)	15,849	(791)
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Total product rights	<u>\$32,791</u>	<u>\$(4,557)</u>	<u>\$33,057</u>	<u>\$(2,406)</u>

**5. INVENTORY**

Inventory at September 30, 2004 and December 31, 2003 consisted of the following (in thousands):

	<u>September 30, 2004</u>	<u>December 31, 2003</u>
Raw materials	\$ 499	\$
Finished goods	2,637	4,923
	<u>          </u>	<u>          </u>



Total inventory	\$3,136	\$4,923
	▬	▬

## 6. CONVERTIBLE NOTES PAYABLE

In April 2003, the Company issued \$14 million of 6% convertible notes with interest payable annually. Holders of the notes also received warrants to purchase an aggregate of 424,243 shares of the Company's common stock at a price of \$11.00 per share. The value of the warrants was reflected as an additional debt discount to be amortized over the term of the debt or 5 years. Effective March 1, 2004, the \$14 million of convertible notes plus accrued interest were converted into 1,342,170 shares of common stock. The remaining unamortized debt discount was recorded as a decrease to equity.

## 7. STOCK OPTION COMPENSATION

At September 30, 2004, 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. The Company recorded compensation expense totaling \$388,908 for the nine months ended September 30, 2004.

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Pro forma information regarding net loss is required by Statement of Financial Accounting Standard No. 123 ( 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 nine months ended September 30, 2004 and 2003 are (in thousands):

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2004</b>	<b>2003</b>	<b>2004</b>	<b>2003</b>
Net loss attributable to common shareholders:				
As reported	\$ (355)	\$ (12,079)	\$ (20,146)	\$ (45,615)
Plus: stock based compensation recognized under the intrinsic value method	94	163	389	406
Less: stock based compensation under fair value method	(1,259)	(235)	(2,308)	(553)
Pro forma net loss	<u>\$ (1,520)</u>	<u>\$ (12,151)</u>	<u>\$ (22,065)</u>	<u>\$ (45,762)</u>
Net loss attributable to common shareholders per common share:				
As reported (basic and diluted)	\$ (0.01)	\$ (14.35)	\$ (0.75)	\$ (56.10)
Pro forma net loss per share (basic and diluted)	\$ (0.05)	\$ (14.44)	\$ (0.83)	\$ (56.28)

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

The weighted-average fair value per share was \$19.48 and \$9.01 for stock options granted in the nine months ended September 30, 2004 and 2003, respectively. The assumptions used to develop the estimated fair value of the options granted utilizing the Black-Scholes pricing model are:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2004</b>	<b>2003</b>	<b>2004</b>	<b>2003</b>
Risk-free interest rate	2.80%	2.80%	2.80%	2.80%
Expected stock price volatility	85%	86%	85%	86%

Expected option term until exercise (years)	5	5	5	5
Expected dividend yield	0%	0%	0%	0%

## 8. OTHER COMPREHENSIVE LOSS

Total comprehensive loss for the three and nine months ended September 30, 2004 and 2003 was (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net loss	\$ (355)	\$ (9,254)	\$ (20,146)	\$ (37,141)
Other comprehensive income:				
Foreign currency translation	610	435	(615)	1,312
Unrealized gain (loss) on available for sale securities	167		(78)	
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Comprehensive income (loss)	\$ 422	\$ (8,819)	\$ (20,839)	\$ (35,829)
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>

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

## 9. 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 nine months ended September 30, 2004 resulted primarily from taxable income generated in certain foreign jurisdictions.

## 10. COMMITMENTS AND CONTINGENCIES

During the fourth quarter of 2003, the Company filed suit against Lipomed AG, and certain of its distributors, in the UK, Switzerland, Germany and Italy for patent infringement in connection with their sales of thalidomide for the treatment of angiogenesis-mediated disorders, including multiple myeloma, in these countries. The Company was seeking injunctive relief that would have prevented the defendants from making any further sales of thalidomide for the treatment of angiogenesis-mediated disorders, including multiple myeloma, in the four countries in which the Company brought suit, and damages against the defendants. In April 2004, all parties to the litigation agreed to a settlement of all claims. Lipomed agreed to cease selling its thalidomide

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formulation and to not further challenge the validity of the thalidomide patent. The Company agreed to make a 1.25 million payment to Lipomed toward the legal costs incurred by Lipomed in connection with the suit and in consideration of future assistance to be provided to the Company by Lipomed in obtaining regulatory approvals to market Thalidomide Pharmion 50 mg in those countries in which the Company is currently not approved to do so. In addition, the Company entered in to a distribution agreement with Lipomed pursuant to which Lipomed was appointed as the exclusive distributor of Thalidomide Pharmion 50 mg in Switzerland and Austria effective May 1, 2004.

**11. GEOGRAPHIC INFORMATION**

Domestic and foreign financial information for the three and nine months ended September 30, 2004 and 2003 was (in thousands):

		<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
		<b>2004</b>	<b>2003</b>	<b>2004</b>	<b>2003</b>
United States	Net sales	\$ 22,496	\$ 912	\$ 26,735	\$ 2,269
Foreign entities	Net sales	20,080	6,761	51,957	11,491
		<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Total	Net sales	\$ 42,576	\$ 7,673	\$ 78,692	\$ 13,760
		<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
United States	Operating income (loss)	\$ 290	\$ (5,133)	\$(16,835)	\$(23,603)
Foreign entities	Operating income (loss)	1,422	(3,791)	1,512	(13,412)
		<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Total	Operating income (loss)	\$ 1,712	\$ (8,924)	\$(15,323)	\$(37,015)
		<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>

**12. WARRANT EXERCISE**

In June 2004, a stock purchase warrant was exercised by a business partner, resulting in the issuance of 44,026 shares of common stock. The option holder utilized the cashless exercise option allowed under the warrant agreement and surrendered 16,580 shares to the Company as consideration for this exercise. In September 2004, a second business partner exercised two stock purchase warrants which resulted in the issuance of 789,089 shares of common stock. Total exercise proceeds received by the Company for the September warrant exercise were \$7.6 million.

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

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

**FORWARD-LOOKING STATEMENTS**

All statements, trend analysis and other information contained in this Form 10-Q that are not historical in nature are forward-looking statements within the meaning of the Private-Securities Litigation Reform Act of 1995. These forward-looking statements include, without limitation, discussion relative to markets for our products and trends in revenue, gross margins and anticipated expense levels, as well as other statements including words such as anticipate, believe, plan, estimate, expect and intend and other similar expressions. All statements regarding our expected financial position and operating results, business strategy, financing plans, forecast trends relating to our industry are forward-looking statements. These forward-looking statements are subject to business and economic risks and uncertainties, and our actual results of operations may differ materially from those contained in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those mentioned in the discussion below. As a result, you should not place undue reliance on these forward-looking statements. We undertake no obligation to update or revise these forward-looking statements to reflect future events or developments.

**Overview**

Our goal is to create a global pharmaceutical company focused on in-licensing, developing and commercializing therapeutic products for the treatment of hematology and oncology patients. We were formed in August 1999 and commenced operations in January 2000 with the completion of our first round of equity financing. To date, we have licensed the rights to four products on either a global or regional basis. Three of these products are approved for marketing and are being sold by us, Innohep® in the U.S. and Refludan® in Europe and Australia. The third product, Vidaza®, was approved for marketing in the United States in May 2004 and we began selling it on July 1, 2004. We have filed for approval to market Vidaza in Europe and this submission is under review by European regulatory authorities. We are currently selling the fourth product, Thalidomide, in Europe and other international markets on a compassionate use or named patient basis while we pursue full regulatory marketing approval.

**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.

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### *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.

## **Results of Operations**

### **Comparison of the Company's Results for the Three Months Ended September 30, 2004 and 2003.**

*Net sales.* Net sales totaled \$42.6 million for the three months ended September 30, 2004 as compared to \$7.7 million for the three months ended September 30, 2003. Net sales included \$22.5 million and \$0.9 million in the U.S. and \$20.1 million and \$6.8 million in Europe and other countries for the three months ended September 30, 2004 and 2003, respectively. The primary reason for the net sales growth in 2004 is due to the commercial launch of Vidaza in the U.S. on July 1, 2004, which resulted in net sales of \$20.4 million for the three months ended September 30, 2004. The growth has also resulted from an increase in thalidomide sales, which totaled \$17.8 million for the three months ended September 30, 2004, as compared to \$5.2 million for the quarter ended September 30, 2003. We began selling thalidomide on a compassionate use or named patient basis in France and Belgium in April 2003 following our acquisition of Gophar S.A.S., the parent company of Laphal Développement. In July 2003, we began selling thalidomide on a compassionate use or named patient basis in additional countries in Europe and other international markets. The growth in thalidomide sales experienced in 2004 is due both to increased volume of product sold as well as an increase in the average selling price of thalidomide in certain markets.

*Cost of sales.* Cost of sales for the three months ended September 30, 2004 totaled \$14.2 million compared to \$2.7 million for the three months ended September 30, 2003. 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 September 30, 2004 was 67% as compared to 65% for the comparable period in 2003. The increase to gross margin is due primarily to the U.S. launch of Vidaza in July 2004, as the gross margin on Vidaza is higher than that of our other products. We expect the gross margin for our products will remain in the mid to high sixty-percent range for the foreseeable future.

*Clinical, development and regulatory expenses.* Clinical, development and regulatory expenses totaled \$7.4 million for the three months ended September 30, 2004 as compared to \$5.4 million for the three months ended September 30, 2003. 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. Employee related costs, including compensation, travel, recruiting and relocation expenses, increased by \$1.9 million in the third quarter of 2004 as compared to the third quarter of 2003. This increase is due to increased staffing levels to support regulatory, clinical

development and medical and safety monitoring activities for thalidomide and Vidaza, including the U.S. and E.U. submissions of applications for marketing approval of Vidaza, 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. In addition, registration and regulatory maintenance fees for Vidaza and Innohep increased by \$.5 million in the third quarter of 2004. These costs were partially offset by a decrease in pre-approval clinical and manufacturing formulation development costs incurred in the third quarter of 2003 for Vidaza.

*Selling, general and administrative expenses.* Selling, general and administrative expenses totaled \$18.6 million for the three months ended September 30, 2004 as compared to \$7.9 million for the three months ended September 30, 2003. Sales and marketing expenses totaled \$13.0 million for the three months ended September 30, 2004, an increase of \$8.6 million over the comparable period of 2003. This increase is due to the growth in commercial sales of thalidomide in Europe and the launch of Vidaza in the U.S. in the third



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quarter of 2004. In the U.S., we expanded our field based commercial organization by approximately 50 employees during the second quarter of 2004 and incurred additional marketing and sales costs for the U.S. launch of Vidaza. These activities increased third quarter 2004 sales and marketing expenses in the U.S. by \$5.9 million as compared to the third quarter of 2003. Sales and marketing expenses in Europe and our rest-of-world markets for the third quarter of 2004 increased by \$2.7 million over the third quarter of 2003 due to the expansion of our commercial organizations to support the sale of thalidomide in these markets.

General and administrative expenses totaled \$5.6 million for the three months ended September 30, 2004 as compared to \$3.4 million for the three months ended September 30, 2003. This \$2.2 million increase is due to increased costs to support the commercial growth of our Company as well as higher costs associated with becoming a public company following our initial public offering completed in November 2003, including increased legal and accounting fees, directors and officers liability insurance premiums, investor relations costs, and consulting fees associated with the implementation of Section 404 of the Sarbanes-Oxley Act of 2002. In addition, business development and market research costs increased \$.4 million in the third quarter of 2004 as compared to 2003 as we have significantly expanded our search and evaluation activities of potential product acquisition candidates.

*Product rights amortization.* Product rights amortization totaled \$0.7 million for the three months ended September 30, 2004 as compared to \$0.6 million for the three months ended September 30, 2003. The slight increase in the third quarter of 2004 is due to the renegotiation of the financial terms of the Refludan® rights acquired from Schering A.G. in August 2003, which increased the value of capitalized product rights for Refludan®. The third quarter of 2004 reflects a full quarter of amortization based on the revised Refludan® product rights value in comparison to the third quarter of 2003 that captured only two months of amortization at the increased product rights value.

*Income tax expense.* Income tax expense totaled \$3.0 million for the three months ended September 30, 2004 as compared to \$40,000 for the three months ended September 30, 2003. The provision for income taxes recorded for the third quarter of 2004 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 to an increase in taxable income in certain foreign countries in which we do business and additional capital-based taxes due in certain jurisdictions.

**Comparison of the Company's Results for the Nine Months Ended September 30, 2004 and 2003.**

*Net sales.* Net sales totaled \$78.7 million for the nine months ended September 30, 2004 as compared to \$13.8 million for the nine months ended September 30, 2003. Net sales included \$26.7 million and \$2.3 million in the U.S. and \$52.0 million and \$11.5 million in Europe and other countries for the nine months ended September 30, 2004 and 2003, respectively. The primary reason for the net sales growth in 2004 is an increase in sales of thalidomide, which totaled \$45.7 million for the nine months ended September 30, 2004, compared to \$7.1 million for the comparable period of 2003. We began selling thalidomide on a compassionate use or named patient basis in France and Belgium in April 2003 following our acquisition of Laphal. In July 2003, we began selling thalidomide on a compassionate use or named patient basis in additional countries in Europe and other international markets. Vidaza was commercially launched in the U.S. in July 2004, resulting in net sales of \$20.4 million for the nine months ended September 30, 2004. Sales of our other products, primarily Innohep® and Refludan®, totaled \$12.6 million for the nine months ended September 30, 2004, an increase of \$5.9 million over the comparable period in 2003.

*Cost of sales.* Cost of sales for the nine months ended September 30, 2004 totaled \$27.9 million compared to \$7.1 million for the nine months ended September 30, 2003. 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 nine months ended September 30, 2004 was 65% as compared to 48% for the comparable period in

2003. Cost of sales for the nine months ended September 30, 2003 included inventory charges totaling \$2.1 million relating to Refludan. These charges reduced our gross margin for this period by 15 percentage points. Commercial sales of Vidaza began in July 2004 which resulted in a 3% increase to the 2004 margins realized on a year to date basis. We expect the gross margin for our products will remain in the mid to high sixty-percent range for the foreseeable future.

*Clinical, development and regulatory expenses.* Clinical, development and regulatory expenses totaled \$21.1 million for the nine months ended September 30, 2004 as compared to \$16.9 million for the nine months ended September 30, 2003. 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. Employee related costs, including compensation, travel, recruiting and relocation expenses, increased by \$3.6 million for the nine months ended September 30, 2004 as compared to the comparable period of 2003. This increase is due to increased staffing levels to support regulatory, clinical development and medical and safety monitoring activities for thalidomide and Vidaza, including the U.S. and E.U. submissions of applications for marketing approval of Vidaza,

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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. Third-party regulatory expenses increased \$2.0 million in 2004 due primarily to E.U. submission of the marketing authorization application for Vidaza and activities associated with our efforts to obtain approval to market thalidomide in Europe. Also, regulatory expenses in 2004 included \$1.1 million relating to the settlement of a patent infringement suit filed by us against Lipomed, AG. These increases in expenses were partially offset by a decrease in pre-approval clinical and manufacturing formulation development costs incurred in the nine months ended September 30, 2003 for Vidaza.

*Selling, general and administrative expenses.* Selling, general and administrative expenses totaled \$42.8 million for the nine months ended September 30, 2004 as compared to \$25.5 million for the nine months ended September 30, 2003. Sales and marketing expenses totaled \$29.2 million for the nine months ended September 30, 2004, an increase of \$14.1 million over the comparable period of 2003. This increase is due to the commercial launch of thalidomide in Europe in the second half of 2003 and the U.S. launch of Vidaza in the third quarter of 2004. In the U.S., we expanded our field based commercial organization by approximately 50 employees during the second quarter of 2004. We also incurred increased sales and marketing costs associated with the commercial launch of Vidaza in July 2004. These activities increased sales and marketing expenses for the nine months ended September 30, 2004 in the U.S. by \$7.6 million as compared to the comparable period of 2003. Sales and marketing expenses in Europe and our rest-of-world markets for the nine months ended September 30, 2004 have increased by \$6.5 million over the comparable period of 2003 as we expanded our commercial organizations to support the sales of thalidomide in these countries.

General and administrative expenses totaled \$13.6 million for the nine months ended September 30, 2004 as compared to \$10.4 million for the nine months ended September 30, 2003. This \$3.2 million increase is due to increased costs to support the commercial growth of our Company as well as higher costs associated with becoming a public company following our initial public offering completed in November 2003, including increased legal and accounting fees, directors and officers liability insurance premiums, investor relations costs, and consulting fees associated with the implementation of Section 404 of the Sarbanes-Oxley Act of 2002. In addition, business development and market research costs increased \$.5 million for the nine months ended September, 30, 2004 as compared to the same period in 2003 as we have significantly expanded our search and evaluation activities of potential product acquisition candidates.

*Product rights amortization.* Product rights amortization totaled \$2.2 million for the nine months ended September 30, 2004 as compared to \$1.3 million for the nine months ended September 30, 2003. The increase in 2004 is due to having a full nine months of amortization of product rights acquired through the purchase of Laphal Développement in April 2003. In addition, the renegotiation of the financial terms of Recludan® rights acquired from Schering in August 2003 resulted in an increase to the value of the capitalized product rights and has increased the related amortization expense for the first nine months of 2004.

*Income tax expense.* Income tax expense totaled \$5.5 million for the nine months ended September 30, 2004 as compared to \$154,000 for the nine months ended September 30, 2003. Although we have incurred pre-tax losses on a consolidated basis, certain of our foreign subsidiaries generate taxable income, and therefore incur income tax expense. The provision for income taxes recorded for 2004 reflects our 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 for the nine months ended September 30, 2004 in comparison to the same prior year period is due to an increase to taxable income in certain foreign countries in which we do business and additional capital-based taxes due in certain jurisdictions.

## **Liquidity and Capital Resources**

Since our inception, we have incurred significant losses and as of September 30, 2004, we had an accumulated deficit of \$140.7 million. We have not yet achieved profitability, and expect that our regulatory and development and selling, general and administrative expenses will continue to grow and, as a result, we will need to generate significant net sales to achieve and sustain profitability. As of September 30, 2004, we had cash and cash equivalents of \$195.1 million and short-term investments totaling \$115.2 million. 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 preferred 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. Immediately prior to the closing of our initial public offering, all outstanding shares of our redeemable convertible preferred stock converted into shares of our common stock. 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

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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 and cash equivalents have increased from \$88.5 million at December 31, 2003 to \$195.1 million at September 30, 2004. This \$106.6 million increase is due primarily to the net cash proceeds obtained from our public offering in July 2004 of \$238.0 million offset by cash used to fund operations of \$19.4 million, net cash of \$.9 million used to fund capital expenditures, \$3.0 million to repay debt obligations and net cash of \$115.0 million used to purchase available for sale 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 and short term investments on hand at September 30, 2004 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.

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*Commitments.* The following table summarizes our long-term commitments as of September 30, 2004, including commitments pursuant to debt agreements, product licensing agreements and lease obligations (amounts in thousands).

Contractual obligations	Total	Less than		4-5 Years	More than 5 Years
		1 Year	1-3 Years		
Product royalty payments	\$19,053	\$ 9,353	\$ 9,700	\$	\$
Inventory purchase commitments	5,692	5,692			
Product and company acquisition payments	5,000	4,000	1,000		
Operating leases	4,805	1,722	2,307	530	246
Clinical development funding	2,750	2,250	500		
Long-term debt obligations	643	447	196		
Total fixed contractual obligations	\$37,943	\$23,464	\$13,703	\$ 530	\$ 246

**Product and company acquisition payments.** We have future payment obligations associated with our acquisition of Laphal and our licensing of Refludan®. Certain of these payments are fixed and determinable while the timing and amount of others are contingent upon future events such as achieving revenue milestones. Under the terms of our agreements with Schering relating to the licensing of Refludan®, we agreed to make an aggregate of \$13.0 million of fixed payments to Schering, payable in quarterly installments of \$1.0 million through the end of 2005 and a royalty of 14% of our net sales commencing in January 2004 and up to \$7.5 million of contingent payments described below.

**Product royalty payments.** Pursuant to our thalidomide product license agreements with Celgene and Penn T Limited, we are required to make additional quarterly payments to the extent that the royalty and license payments due under those agreements do not meet certain minimums. These minimum royalty and license payment obligations expire the earlier of 2006 or the date we obtain regulatory approval to market thalidomide in the E.U. Pursuant to our Innohep® product license agreement with LEO Pharmaceutical Products Ltd. A/S, we are required to make additional annual royalty payments through 2006 to the extent that the annual royalties paid do not meet the minimum royalty targets. The amounts reflected in the summary above represent the minimum amounts due under these agreements.

**Clinical development funding.** We have entered into an agreement with Celgene to provide funding to support clinical development studies sponsored by Celgene analyzing thalidomide as a treatment for various types of cancers. Under our agreement, we will pay Celgene an additional \$750,000 during the remainder of 2004 and \$2.0 million in 2005.

**Operating leases.** Our commitment for operating leases relates to our corporate and sales offices located in the U.S., Europe, Thailand and Australia. These leases expire on various dates through 2008.

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

initial 3-6 month periods representing binding purchase commitments.

***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 fixed payments required, payments totaling up to \$7.5 million are due if milestones relating to revenue and gross margin targets for Refludan® are achieved. The terms of our Laphal acquisition require two additional payments of 4.0 million each, or an aggregate of \$9.9 million based on foreign currency exchange rates as of September 30, 2004, if Laphal's products achieve future revenue milestones. The terms of our Innohep® agreement with LEO 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 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 has the right to terminate the license agreement.

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**FACTORS AFFECTING OUR BUSINESS**

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 achieve or maintain profitability.***

We have incurred net losses since our inception, including a net loss of \$20.1 million for the nine months ended September 30, 2004. As of September 30, 2004, we had an accumulated deficit of \$140.7 million. We expect to make substantial expenditures to further develop and commercialize our products, including costs and expenses associated with completing clinical trials, seeking regulatory approvals and marketing of our products. We will need to generate significantly greater revenues to achieve and then maintain profitability. As a result, we are unsure when we will become profitable, if at all. If we fail to achieve profitability within the time frame expected by investors or securities analysts, the market price of our common stock may decline.

***We have a limited operating history.***

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

***We may not receive regulatory approvals for Thalidomide Pharmion 50mg or, 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, while our ability to commercialize Vidaza in markets outside the U.S. is subject to regulatory approval by governmental authorities in Europe and elsewhere. We cannot assure you that the results of the clinical trials conducted, we intend to conduct or we are required to conduct for Thalidomide Pharmion 50mg and Vidaza will support our applications for 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. Further, if we fail to obtain the required regulatory approvals to market and sell thalidomide in the U.K. by November 2006, Celgene Corporation has the right to terminate this license agreement with us on thirty days notice. Loss of any of these licenses or the exclusivity right provided therein could harm our financial condition and operating results.

Moreover, favorable results in later stage clinical trials do not ensure regulatory approval to commercialize a product. Some companies that have believed their products performed satisfactorily in clinical trials have nonetheless failed to obtain regulatory approval of their products. We will not be able to market Thalidomide Pharmion 50mg or Vidaza in any country where the drug is not approved, and if Thalidomide Pharmion 50mg or Vidaza is not approved for sale in any market where we have acquired rights to the product, we will only be able to sell it in such market, if at all, on a compassionate use or named patient basis, which may limit sales.

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

At the time thalidomide first came on the market in the late 1950's and into the early 1960's, it was not known that the drug could cause birth defects in babies born to women who had taken the drug while pregnant. Although no



proper census was ever taken, it has been estimated that there were between 10,000 and 20,000 babies born with birth defects as a result of thalidomide. The majority of these births were in the U.K. and Germany, two of our largest target markets for sales of Thalidomide Pharmion 50mg. As a result, thalidomide's historical reputation in our target markets may present a substantial barrier to its market acceptance. Thalidomide's potential for causing severe birth defects and its negative historical reputation may limit the extent of its market acceptance among both doctors and patients, despite the efficacy that it has been proven to have in patients afflicted with a number of different diseases. In addition, any report of a birth defect attributed to the current use of thalidomide could result in a material decrease in our sales of thalidomide, and may result in the forced withdrawal of thalidomide from the market.

*Although Vidaza has been approved in the U.S., it may not be commercially successful.*

Vidaza was approved for marketing in the U.S. in May 2004 and we filed for marketing approval in Europe in September of 2004. Although the drug is approved in the U.S., patients and physicians may not readily accept it, which would limit its sales.

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

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

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

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

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

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

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

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

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

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***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 Food and Drug Administration, or 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, 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.

The primary competition for our products currently are:

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

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

Innohep®: Lovenox®, from Aventis, Fragmin®, from Pharmacia Corporation and Arixtra, from Sanofi-Synthelabs; and

Refludan®: Argatroban, from GlaxoSmithKline plc.

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

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

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We believe, based on our current operating plan, including anticipated sales of our products, that our cash, cash equivalents and short-term investments will be sufficient to fund our operations for the foreseeable future. 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 the acquisition of additional products, thereby limiting our ability to execute our growth strategy.

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

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

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

Our commercial success will depend in part on obtaining and maintaining a strong proprietary position for our products both in the U.S., Europe and elsewhere. Of our four current products, only Thalidomide Pharmion 50mg and Refludan® currently have any patent protection under issued patents. As a result, we must rely in large part on orphan drug exclusivity, trade secrets, process patents, know-how and continuing technological innovations to protect our intellectual property and to enhance our competitive position. Even if we are granted orphan drug exclusivity, competitors are not prohibited from developing or marketing different drugs for an indication. As a result, the competitive advantage gained by orphan drug exclusivity can be overcome by other products. Until we are granted a marketing authorization, while we are selling Thalidomide Pharmion 50mg on a compassionate use and named patient basis, we do not have orphan drug exclusivity, which means competitors may sell thalidomide in our markets.

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.

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

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

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

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

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

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

difficulties in compliance with foreign laws and regulations;

changes in foreign regulations and customs;

changes in foreign currency exchange rates and currency controls;

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

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

negative consequences from changes in tax laws;

difficulties associated with staffing and managing foreign operations;

longer accounts receivable cycles in some countries; and

differing labor regulations.

**Risks Related To Our Industry**

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

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



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

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

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

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

Physicians may prescribe drugs for uses that are not described in the product's labeling for uses that differ from those tested in clinical studies and approved by the FDA or similar regulatory authorities in other countries. These off-label uses are common across medical specialties and may constitute the best treatment for many patients in varied circumstances. Regulatory authorities generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications on the subject of off-label use. Companies cannot actively promote approved drugs for off-label uses, but in some countries outside of the E.U. they may disseminate to physicians articles published in peer-reviewed journals 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, labelling, storage, record-keeping, approval, advertising and promotion of our products and product candidates, as well as safe working conditions and the experimental use of animals. Noncompliance with any applicable regulatory requirements can result in refusal of the government to approve products for marketing, criminal prosecution and fines, recall or seizure of products, total or partial suspension of production, prohibitions or limitations on the commercial sale of products or refusal to allow us to enter into supply contracts. Regulatory authorities typically have the authority to withdraw approvals that have been previously granted.

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

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**Risks Related to Our Common Stock**

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

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

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

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

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

We only recently completed our initial public offering. An active trading market for our common stock may not continue to develop or be sustained. Since our initial public offering, the price of our common stock as reported by the Nasdaq National Market has ranged from a low of \$11.00 to a high of \$58.49.

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

actual or anticipated fluctuations in our operating results;

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

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

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

public concern as to the safety of our products;

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

our inability to raise additional capital;

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

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

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*If our officers, directors and the venture capital firms with which they are affiliated choose to act together, they could significantly influence matters requiring approval by stockholders and their interests might not always coincide with the interests of other stockholders.*

Our officers and directors, and the venture capital firms with which certain of our directors are affiliated, beneficially own approximately 17% of our common stock. Accordingly, were these stockholders to act together they would have significant influence on all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combinations. They may exercise this ability in a manner that advances their best interests and not necessarily those of other stockholders.

**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 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, U.K. 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.

***Sarbanes-Oxley 404 Compliance:***

We are performing a detailed assessment of our internal controls as required for all publicly-owned companies by the Sarbanes-Oxley Act of 2002. As a result of this process, we may identify control deficiencies in our system of internal controls. As we move to the testing phase of our project, we expect to validate these potential control deficiencies and to assess whether or not they rise to the level of significant deficiencies or material weaknesses. In the meantime, we will investigate any potential control deficiencies, and, where appropriate, we will remediate them. To ensure that we address these issues thoroughly, effectively, and timely, we have supplemented our internal control review with the services of outside specialists. Although we have made this project a top priority for the Company, there can be no assurances that any control deficiencies identified and validated will be remediated before the end of the Company's fiscal year or that any remaining unresolved control deficiencies will not rise to the level of significant deficiencies or material weaknesses.

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**PART II  
OTHER INFORMATION**

**Item 1. *Legal Proceedings***

We are not engaged in any material legal proceedings.

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

**(a) Sales of Unregistered Securities**

None.

**(b) Use of Proceeds from Registered Securities**

On November 12, 2003, we closed the sale of 6,000,000 shares of our common stock in our initial public offering. The registration statement on Form S-1 (Reg. No. 333-108122), we filed to register our common stock in the offering was declared effective by the SEC on November 5, 2003. After deducting expenses of the offering, we received net offering proceeds of approximately \$76.2 million.

From the time of the initial receipt, November 12, 2003, through September 30, 2004, we have used approximately \$22.8 million of the net proceeds from our initial public offering to fund operations, the commercial launch and clinical development of Vidaza, ongoing Thalidomide clinical development, capital expenditures, working capital needs and other general corporate purposes. The remainder of the proceeds have been invested into short-term investment-grade securities and money market accounts.

**(c) Issuer Purchases of Equity Securities**

None.

**Item 3. *Defaults Upon Senior Securities***

None.

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

None.

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**Item 5. Other Information**

None.

**Item 6. Exhibits**

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



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**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: November 12, 2004

PHARMION CORPORATION

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

Date: November 12, 2004

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<b>Exhibit No.</b>	<b>Description</b>
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