

PHARMION CORP  
Form 10-Q  
May 14, 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 March 31, 2004**

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

**For the transition period from      to**

**Commission file number 000-50447**

**PHARMION CORPORATION**

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

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

**84-1521333**  
*(I.R.S. Employer  
Identification No.)*

**2525 28<sup>th</sup> 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 May 13, 2004, there were 25,295,329 shares of the Registrant's Common Stock outstanding.

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**PHARMION CORPORATION**

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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>March 31, 2004</b>	<b>December 31, 2003</b>
	<b>(Unaudited)</b>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 44,327	\$ 88,542
Short-term investments	33,089	
Accounts receivable, net of allowance of \$938 and \$819, respectively	11,127	7,992
Inventories	4,237	4,923
Prepaid royalties	1,343	1,343
Other current assets	2,672	2,779
	<hr/>	<hr/>
Total current assets	96,795	105,579
Product rights, net	29,497	30,651
Property and equipment, net	4,827	5,050
Goodwill	3,542	3,652
Other assets	292	541
	<hr/>	<hr/>
Total assets	<b>\$ 134,953</b>	<b>\$ 145,473</b>
	<hr/>	<hr/>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,756	\$ 4,241
Accrued liabilities	16,926	14,800
	<hr/>	<hr/>
Total current liabilities	19,682	19,041
Long-term liabilities:		
Convertible notes payable		13,374
Deferred tax liability	3,555	3,665
Other long-term liabilities	3,462	4,479
	<hr/>	<hr/>

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Total long-term liabilities	7,017	21,518
Stockholders' equity:		
Common stock, \$.001 par value; 100,000,000 shares authorized and 25,294,763 and 23,948,636 shares issued and outstanding at March 31, 2004 and December 31, 2003	25	24
Preferred stock, \$.001, 10,000,000 shares authorized, no shares issued and outstanding at March 31, 2004 and December 31, 2003		
Additional paid-in capital	236,384	222,218
Deferred compensation	(981)	(1,155)
Other comprehensive income	3,194	4,386
Accumulated deficit	(130,368)	(120,559)
	<u>          </u>	<u>          </u>
Total stockholders' equity	<u>108,254</u>	<u>104,914</u>
Total liabilities and stockholders' equity	<u>\$ 134,953</u>	<u>\$ 145,473</u>

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

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

	<b>Three Months Ended March 31,</b>	
	<b>2004</b>	<b>2003</b>
Net sales	\$ 15,721	\$ 1,658
Operating expenses:		
Cost of sales, including royalties of \$4,581 and \$89 for the three months ended March 31, 2004 and 2003, respectively	6,309	779
Clinical, development and regulatory	6,553	5,578
Selling, general and administrative	10,948	9,121
Product rights amortization	725	201
	<hr/>	<hr/>
Total operating expenses	24,535	15,679
	<hr/>	<hr/>
Loss from operations	(8,814)	(14,021)
Interest and other income (expense), net	(73)	219
	<hr/>	<hr/>
Loss before taxes	(8,887)	(13,802)
Income tax expense	922	91
	<hr/>	<hr/>
Net loss	(9,809)	(13,893)
Less accretion of redeemable convertible preferred stock to redemption value		(2,825)
	<hr/>	<hr/>
Net loss attributable to common stockholders	\$ (9,809)	\$ (16,718)
	<hr/>	<hr/>
Net loss attributable to common stockholders per common share, basic and diluted	\$ (.40)	\$ (21.29)
Shares used in computing net loss attributable to common stockholders per common share, basic and diluted	24,349,920	785,287
Pro forma net loss attributable to common stockholders per common share assuming conversion of preferred stock, basic and diluted (Note 2)		\$ (0.78)
Shares used in computing pro forma net loss attributable to common stockholders per common share assuming conversion of preferred stock, basic		17,816,213

and diluted (Note 2)

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

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

	<b>Three Months Ended March 31,</b>	
	<b>2004</b>	<b>2003</b>
<b>Operating activities</b>		
Net loss	\$ (9,809)	\$ (13,893)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,210	533
Compensation expense related to stock option issuance	174	6
Changes in operating assets and liabilities:		
Accounts receivable, net	(3,349)	(30)
Inventories	623	(773)
Other current assets	60	252
Other long-term assets	247	(241)
Accounts Payable	(1,483)	(1,393)
Accrued and other current liabilities	2,988	1,788
	<hr/>	<hr/>
Net cash used in operating activities	(9,339)	(13,751)
<b>Investing activities</b>		
Purchases of property and equipment	(223)	(591)
Acquisition of business, net of cash acquired	(19)	(11,723)
Purchase of available for sale investments	(33,253)	
	<hr/>	<hr/>
Net cash used in investing activities	(33,495)	(12,314)
<b>Financing activities</b>		
Proceeds from sale of common stock, net of issuance costs	6	
Payment of debt obligations	(967)	(10)
	<hr/>	<hr/>
Net cash used in financing activities	(961)	(10)
Effect of exchange rate changes on cash and cash equivalents	(420)	(163)
Net decrease in cash and cash equivalents	(44,215)	(26,238)
Cash and cash equivalents at beginning of period	88,542	62,604
	<hr/>	<hr/>
Cash and cash equivalents at end of period	\$ 44,327	\$ 36,366
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**Noncash items**

Conversion of debt and accrued interest to common stock	14,161
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The accompanying notes are an integral part of these consolidated financial statements

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**PHARMION CORPORATION**

**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS**

**1. NATURE OF BUSINESS**

Pharmion Corporation (the Company) was incorporated in Delaware on August 26, 1999 and commenced operations in January 2000. The Company is engaged in the acquisition, development and commercialization of pharmaceutical products for the treatment of oncology and hematology patients. The Company's product acquisition and licensing efforts are focused on both late-stage development products as well as those approved for marketing. In exchange for distribution and marketing rights, the Company generally grants the seller royalties on future sales and, in some cases, up-front and scheduled 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 November 5, 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 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.

**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 accounting principles generally accepted in the United States of America 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 months ended March 31, 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 accounting principles generally accepted in the United States of America 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 more significant estimates reflected in these financial statements include estimates of chargebacks from distributors, product returns and rebates, and valuation of stock-based compensation.

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### **Revenue Recognition**

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

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

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

### **Short-term Investments**

Short-term investments consisted 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 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 three months ended March 31, 2004 and 2003, revenues generated from three customers in the United States totaled approximately 10% and 27%, 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 our 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.

**Table of Contents****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 common stock have not been included in the diluted net loss per share calculation because to do so would be antidilutive. Such shares totaled 2,035,537 and 18,871,009 as of March 30, 2004 and 2003, respectively.

**4. LICENSE AGREEMENTS*****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 is 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 entered into an Interim Sales Representation Agreement ( ISRA ) and a Distribution and Development Agreement with Schering AG. Pursuant to these agreements, the Company acquired the exclusive right to market and distribute Refludan® in all countries outside the U.S. and Canada. These agreements were amended on August 20, 2003 and replaced by a full transfer to the Company of all the marketing authorizations and product registrations for Refludan® in the individual countries within the Company's territories. The Company has paid Schering an aggregate of \$6 million and is obligated to make \$7 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 and Thalidomide***

In 2001, the Company acquired the development and commercialization rights to two products being developed for the treatment of certain bone marrow disorders and malignancies. Global rights to azacitidine were licensed from Pharmacia Corporation, now part of Pfizer Inc., and rights in all countries outside the U.S., Canada, and certain Asian countries to Thalomid® (thalidomide) were licensed from both Celgene Corporation and Penn T Limited. 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 these products.

Under the terms of the Company's agreement with Pfizer, the Company is obligated to pay them 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.

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

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appropriate health regulatory authority for sale in any country within the Company's license 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 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, with this amount payable in 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 425,451 shares of common stock at an exercise price of \$8.36 per share. 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.

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

	<u>As of March 31, 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	\$ (875)	\$ 5,000	\$ (750)
Refludan®	12,208	(1,202)	12,208	(865)
Thalidomide	15,390	(1,024)	15,849	(791)
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Total product rights	\$ 32,598	\$ (3,101)	\$ 33,057	\$ (2,406)
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>

**5. CONVERTIBLE NOTES PAYABLE**

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

**6. STOCK OPTION COMPENSATION**

At March 31, 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 \$174,386 for the three months ended March 31, 2004.

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 minimum value method available to nonpublic companies under SFAS 123 for options issued prior to the Company's Initial Public Offering. Under this method, option value is determined as the excess of the fair value of the stock at the date of grant over the present value of both the exercise price (lump sum) and the expected dividend payments (annuity), each discounted at the risk-free rate, over the expected exercise life of the option. A risk-free interest rate of 2.8%, a dividend yield of 0%, an expected life of five years and a volatility of 85% was applied to all 2004 grants. The weighted-average fair value of options granted during 2004 was \$13.08. The effects of applying the fair value method to the results for the three months ended March 31, 2004 and 2003 are as follows:

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	<b>Three Months Ended March 31,</b>	
	<b>2004</b>	<b>2003</b>
	<b>(in thousands)</b>	
Net loss attributable to common shareholders:		
As reported	\$ (9,809)	\$ (16,718)
Plus: stock based compensation recognized under the intrinsic value method	174	
Less: stock based compensation under fair value method	(486)	(135)
	<u>          </u>	<u>          </u>
Pro forma net loss	<u>\$ (10,121)</u>	<u>\$ (16,853)</u>
Net loss attributable to common shareholders per common share:		
As reported (basic and diluted)	\$ (.40)	\$ (21.29)
Pro forma net loss per share (basic and diluted)	\$ (.42)	\$ (21.46)

Option valuation models such as the minimum 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.

**7. OTHER COMPREHENSIVE LOSS**

Total comprehensive loss for the three months ended March 31, 2004 and 2003 was as follows:

	<b>Three Months Ended March 31,</b>	
	<b>2004</b>	<b>2003</b>
	<b>(in thousands)</b>	
Net loss	\$ (9,809)	\$ (13,893)
Other comprehensive income:		
Foreign currency translation	(1,023)	(103)
Unrealized loss on available for sale securities	(169)	
	<u>          </u>	<u>          </u>
Comprehensive loss	<u>\$ (11,001)</u>	<u>\$ (13,996)</u>

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

**8. 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 quarter ended March 31, 2004 resulted primarily from taxable income generated in certain foreign jurisdictions.

**9. GEOGRAPHIC INFORMATION**

Domestic and foreign financial information for the three months ended March 31, 2004 and 2003 was (in thousands):

	<b>Three months ended March 31,</b>	<b>United States</b>	<b>Foreign Entities</b>	<b>Total</b>
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Net Sales	2004	\$ 1,657	\$ 14,064	\$ 15,721
	2003	500	1,158	1,658
Operating Loss	2004	\$ (7,477)	\$ (1,337)	\$ (8,814)
	2003	(8,927)	(5,094)	(14,021)

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**10. SUBSEQUENT EVENT**

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 we 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 formulation and to not further challenge the validity of the thalidomide patent. We 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 us by Lipomed in obtaining regulatory approvals to market Thalidomide Pharmion 50 mg in those countries in which we are currently not approved to do so. In addition, we entered in to a distribution agreement with Lipomed pursuant to which we appointed Lipomed as our exclusive distributor of Thalidomide Pharmion 50 mg in Switzerland and Austria effective May 1, 2004.

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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 which are not historical in nature are forward-looking statements within the meaning of the Private-Securities Litigation Reform Act of 1995. These forward-looking statements include, without limitation, discussion relative to markets for our products and trends in revenue, gross margins and anticipated expense levels, as well as other statements including words such as anticipate, believe, plan, estimate, expect and intend and other similar expressions. All statements regarding the Company 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. Two of these products are approved for marketing and are being sold by us, one in the U.S. and the second in Europe and Australia. The other two products are in late-stage development, one of which we are currently selling in Europe and other international markets on a compassionate use or named patient basis while we pursue full regulatory marketing approval.

Our operations focus on the clinical development of our late-stage product candidates, seeking regulatory marketing approvals for those products in the U.S., Europe, Australia and certain other countries in our licensed territories, and sales and marketing activities for our marketed products, primarily in the U.S., Europe and Australia. We began generating revenues from product sales in July 2002.

**Critical Accounting Policies**

*Revenue Recognition*

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

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 the Company's 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 the Company's 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 March 31, 2004 and 2003.**

*Net sales.* Net sales totaled \$15.7 million for the three months ended March 31, 2004 as compared to \$1.7 million for the three months ended March 31, 2003. Net sales included \$1.7 million and \$.5 million in the U.S. and \$14.0 million and \$1.2 million in Europe and other countries for the three months ended March 31, 2004 and 2003, respectively. The primary reason for the net sales growth in 2004 relates to sales of thalidomide, which totaled \$12.6 million for the three months ended March 31, 2004. We began selling thalidomide on a compassionate use or named patient basis in France and Belgium in April 2003 following our acquisition of Gophar S.A.S., the parent company of Laphal Développement. In July 2003, we began selling thalidomide on a compassionate use or named patient basis in additional countries in Europe and other international markets.

*Cost of sales.* Cost of sales for the three months ended March 31, 2004 totaled \$6.3 million compared to \$.8 million for the three months ended March 31, 2003. Cost of sales reflects the cost of product sold plus royalties due on the sales of our products as well as the logistics costs related to selling our products. Our gross margin for the three months ended March 31, 2004 was 60% as compared to 53% for the comparable period in 2003. We expect the gross margin for our current products will approximate 60% for the foreseeable future.

*Clinical, development and regulatory expenses.* Clinical, development and regulatory expenses totaled \$6.6 million for the three months ended March 31, 2004, an increase of \$1.0 million over the comparable period in 2003. These expenses consist primarily of salaries and benefits and contractor fees, principally with organizations assisting us with our clinical development programs. Under our license agreements, we are responsible for all remaining development and regulatory costs for thalidomide and azacitidine. Although clinical studies for both products were complete at the time we acquired the drugs, we have incurred and expect to continue to incur significant costs analyzing and auditing the data from these studies and initiating additional clinical studies for the products. Of the \$1.0 million increase in clinical, development and regulatory expenses in the first quarter of 2004, \$1.1 million was due to increased salaries and benefits expenses and other non-product specific costs. In the first quarter of 2004, we spent approximately \$4.1 million on azacitidine and thalidomide development, primarily for clinical studies, manufacturing and formulation development, pursuing regulatory authorizations to sell thalidomide in Europe and other international markets and establishing a medical safety, education and distribution system to support our thalidomide sales. This

represented a decrease of \$.1 million in product development expenses from the first quarter of 2003.

*Selling, general and administrative expenses.* Selling, general and administrative expenses totaled \$10.9 million for the three months ended March 31, 2004, an increase of \$1.8 million over the comparable period in 2003. Sales and marketing expenses totaled \$7.1 million for the three months ended March 31, 2004, an increase of \$1.0 million over the first quarter of 2003. In the second half of 2002 and the first half of 2003, we established our sales organizations in the U.S., Europe, and Australia and expanded our marketing staffing to support the commercialization of Innohep® and Refludan® as well as the compassionate use and named patient sales of thalidomide. This resulted in a \$1.2 million increase in personnel related expenses, including salaries, benefits and travel, and expenses of our international sales offices for the three months ended March 31, 2004 over the comparable period in 2003. Product marketing expenses decreased by \$.2 million in the first quarter of 2004 as compared to 2003.



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General and administrative expenses totaled \$3.8 million for the three months ended March 31, 2004, which was \$.8 million greater than general and administrative expenses in the comparable period in 2003. Of this increase, \$.3 million was due to increased legal costs, \$.3 million is due to increased audit fees and other professional fees to support the additional responsibilities of becoming a public company, and \$.2 million to increased insurance costs, principally, directors and officers liability insurance.

*Product rights amortization.* Product rights amortization totaled \$.7 million for the three months ended March 31, 2004, an increase of \$.5 million over the comparable period in 2003. The increase in 2004 is due primarily to the amortization of product rights acquired through the March 2003 acquisition of Laphal, and the renegotiation of the financial terms in August 2003 of the Recludan® rights acquired from Schering A.G..

*Interest and other income (expense), net.* Interest and other income (expense), net, totaled (\$.1) million for the three months ended March 31, 2004, a decrease of \$.3 million as compared to the comparable period in 2002. This decrease is primarily due to an increase in interest expense related to the \$14 million 6% convertible notes issued in April 2003. These notes were converted into shares of common stock on March 1, 2004.

*Income tax expense.* Income tax expense totaled \$.9 million for the three months ended March 31, 2004, an increase of \$.8 million over the comparable period in 2003. The provision for income taxes recorded for the first quarter of 2004 reflects management's estimate of the effective tax rate expected to be applicable for the full fiscal year. The increase in income tax expense is due primarily to additional capital-based taxes in certain jurisdictions and an increase to taxable income in certain foreign countries in which we do business.

## **Liquidity and Capital Resources**

Since our inception, we have incurred significant losses and as of March 31, 2004, we had an accumulated deficit of \$130.4 million. We have not yet achieved profitability, and anticipate that we will continue to incur net losses for the foreseeable future. We 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 profitability. As of March 31, 2004, we had cash and cash equivalents and short-term investments of totaling \$77.4 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 and the aggregate price of the offering registered on our behalf was \$84.0 million. In connection with the offering, we paid \$5.9 million in underwriting discounts and commissions to underwriters and incurred \$1.9 million in other offering expenses. After deducting the underwriting discounts and commissions and offering expenses, 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.

Cash, cash equivalents and short-term investments decreased from \$88.5 million at December 31, 2003 to \$77.4 million at March 31, 2004. This \$11.1 million decrease is due primarily to cash used to fund operations of \$9.5 million, net cash of \$.2 million used to fund capital expenditures and \$1.0 million to repay debt obligations.

We expect that our cash on hand at March 31, 2004 along with cash generated from expected product sales, will be adequate to fund our operations for the next twelve months. In the event that we make additional product acquisitions, we expect that we may need to raise additional funds. Insufficient funds may cause us to delay, reduce the scope of, or eliminate one or more of our planned development, commercialization or expansion activities. Our future capital needs and the adequacy of our available funds will depend on many factors, including the effectiveness of our sales

and marketing activities, the cost of clinical studies and other actions needed to obtain regulatory approval of our products in development, and the timing and cost of any product acquisitions. 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. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could materially adversely impact our growth plans and our financial condition and results of operations. Additional equity financing may be dilutive to the holders of our common stock and debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate our business.

**Table of Contents****Contractual Obligations**

*Commitments.* The following table summarizes our long-term commitments as of March 31, 2004, including commitments pursuant to debt agreements, product licensing agreements and lease obligations (amounts in millions).

<b>Contractual obligations</b>	<b>Total</b>	<b>Less than 1 Year</b>	<b>1-3 Years</b>	<b>4-5 Years</b>	<b>More than 5 Years</b>
Product and company acquisition payments	\$ 7.0	\$ 4.0	\$ 3.0	\$	\$
Product royalty payments	23.6	9.0	14.6		
Clinical development funding	4.3	2.8	1.5		
Operating leases	5.4	1.7	2.5	.9	.3
Inventory purchase commitments	2.5	2.5			
Long-term debt obligations	.6	.3	.3		
<b>Total fixed contractual obligations</b>	<b>\$ 43.4</b>	<b>\$ 20.3</b>	<b>\$ 21.9</b>	<b>\$ .9</b>	<b>\$ .3</b>

**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, 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 \$2.3 million in the rest 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 accounting principles generally accepted in the United States of America, 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 \$9.7 million based on foreign currency exchange rates as of March 31, 2004, if Laphal's products achieve future revenue milestones. The terms of our Innohep® agreement with LEO Pharmaceutical Products Ltd. A/S 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 CONDITIONS**

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

**Risks Related To Our Business**

***We have a history of net losses, and may not achieve or maintain profitability.***

We have incurred net losses since our inception, including a net loss of \$9.8 million for the three months ended March 31, 2004. As of March 31, 2004, we had an accumulated deficit of \$130.4 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, 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 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 azacitidine, which we intend to market as Vidaza, is subject to regulatory approval by governmental authorities in the U.S., 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 regulatory approval. The timing of our submissions, the outcome of reviews by the applicable regulatory authorities in each relevant market, and the initiation and completion of clinical trials are subject to uncertainty, change and unforeseen delays. Moreover, favorable results in later stage clinical trials do not ensure regulatory approval to commercialize a product. Some companies that have believed their products performed satisfactorily in clinical trials have nonetheless failed to obtain regulatory approval of their products. We will not be able to market Thalidomide Pharmion 50mg or Vidaza in any country where the drug is not approved, and if Thalidomide Pharmion 50mg or Vidaza is not approved for sale in 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 and revenues.

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

At the time thalidomide first came on the market in the late 1950's and into the early 1960's, it was not known that the drug could cause birth defects in babies born to women who had taken the drug while pregnant. Although no proper census was ever taken, it has been estimated that there were between 10,000 and 20,000 babies born with birth defects as a result of thalidomide. The majority of these births were in the U.K. and Germany, two of our largest target markets for sales of Thalidomide Pharmion 50mg. As a result, thalidomide's historical reputation in our target markets may 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.

***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

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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.

***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.

***Even if U.S. and European regulatory authorities approve Vidaza for the treatment of the diseases we are targeting, Vidaza may not be commercially successful.***

Even if Vidaza receives regulatory approval, patients and physicians may not readily accept it, which would limit its sales. 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.

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

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



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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 Revimid , from Celgene Corporation;

Vidaza: Thalomid® and Revimid , each from Celgene, and Decitabine, from Supergen Inc.;

Innohep®: Lovenox®, from Aventis, and Fragmin®, from Pharmacia Corporation; and

Refludan®: Argatroban, from GlaxoSmithKline plc.

***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. 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.

***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. Our negative cash flows from operations are expected to continue for at least the next 24 months. The development and approval of our product candidates and the acquisition and development of additional products or product candidates by us, as well as the expansion of our sales, marketing and regulatory organizations, will require a commitment of substantial funds. Our future capital requirements are dependent upon many factors and may be significantly greater than we expect.

We believe, based on our current operating plan, including anticipated sales of our products, that our cash, cash equivalents and marketable securities as of the consummation of this offering will be sufficient to fund our operations for the foreseeable future. If

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our existing resources are insufficient to satisfy our liquidity requirements due to slower than anticipated sales of our products or otherwise, or if we acquire additional products or product candidates, we may need to sell additional equity or debt securities. If we are unable to obtain this additional financing, we may be required to delay, reduce the scope of, or eliminate one or more of our planned development, commercialization or expansion activities, which could harm our financial condition and operating results.

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

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on our senior management, especially Patrick J. Mahaffy, our President and Chief Executive Officer, and Judith A. Hemberger, our Executive Vice President and Chief Operating Officer, whose services are critical to the successful implementation of our product acquisition, development and regulatory strategies. 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 material amounts of 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.

***Our sales of Refludan® may be limited as a result of concerns about its safety.***

In September 2002, following guidance from the European Agency for the Evaluation of Medicinal Products ( EMEA ), Schering AG, from whom we license Refludan®, issued a warning letter to doctors in Germany regarding the incidence of anaphylaxis, a severe allergic reaction, in approximately a dozen patients treated with Refludan® in both the U.S. and Europe, five of which cases resulted in fatalities. Although the possibility of anaphylaxis from Refludan® is a known possible reaction and is indicated in the product's label, the occurrences referenced in the warning letter appeared to be at a higher frequency than had previously been reported. We believe that the growth potential for sales of Refludan® was negatively impacted by the issuance of the warning letter, and that as a result sales may not increase above their current levels.

***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.

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***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.

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

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

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

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

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

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

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

The testing, development and manufacturing of our products are subject to regulation by numerous governmental authorities in the U.S., Europe and elsewhere. These regulations govern or affect the testing, manufacture, safety, 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. In addition, the E.U. rules concerning the authorization of medicinal products are in the process of being amended. We do not expect the new rules to apply until 2005. The final rules are not yet available and as such the impact on our business cannot be known at this time.

**Risks Related to Our Common Stock**

*If a significant number of shares of our common stock are sold into the market, the market price of our common stock could significantly decline, even if our business is doing well.*



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In connection with our initial public offering, certain of our officers, directors and stockholders owning an aggregate of approximately 19.2 million shares of our common stock agreed to not sell any of these shares, subject to specified exemptions, for a period from November 6, 2003. These agreements expired on May 3, 2004, thereby releasing the prohibition on selling these shares. Sales of a substantial number of these shares of our common stock in the public market could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities.

***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 may be volatile and your investment in our common stock could suffer a decline in value.***

We only recently completed our IPO. Prior to this offering, you could not buy or sell our common stock publicly. An active trading market for our common stock may not continue to develop or be sustained.

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 largest stockholders choose to act together, they may be able to control our management and operations, acting in their best interests and not necessarily those of other stockholders.***

Our directors, executive officers and principal stockholders and their affiliates will beneficially own approximately 68.7% of our common stock. Accordingly, they collectively will have the ability to determine the election of all of our directors and to determine the outcome of most corporate actions requiring stockholder approval. 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, the euro, and Swiss francs. We have not undertaken any foreign currency hedges through the use of forward foreign exchange contracts or options. Foreign currency exposures have been managed solely through managing the currency denomination of our cash balances.

**Item 4. *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.

In addition, we reviewed our internal controls, and there have been no changes in our internal controls over financial reporting during the quarter ended March 31, 2004 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

**PART II  
OTHER INFORMATION**

**Item 1. *Legal Proceedings***

We are not engaged in any material legal proceedings except as follows:

During the fourth quarter of 2003, we filed suit against Lipomed AG, and certain of its distributors, in the UK, Switzerland, Germany and Italy for infringement of European Patent EP 0 688211, in connection with their sales of thalidomide for the treatment of angiogenesis-mediated disorders, including multiple myeloma, in these countries. We are the exclusive licensee under this patent in all countries outside of North America, Japan, China, Taiwan and Korea, pursuant to an agreement with Celgene Corporation. Celgene was a co-plaintiff to the proceedings in Switzerland, Italy and Germany. We were seeking injunctive relief that prevents 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 we 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 formulation and to not further challenge the validity of the thalidomide patent. We 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 us by Lipomed in obtaining regulatory approvals to market Thalidomide Pharmion 50 mg in those countries in which we are currently not approved to do so. In addition, we entered into a distribution agreement with Lipomed pursuant to which we appointed Lipomed as our exclusive distributor of Thalidomide Pharmion 50 mg in Switzerland and Austria effective May 1, 2004.

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***Item 2. Changes in Securities and Use of Proceeds***

**Modification of Rights of Registered Securities** None.

**Limitation of Rights of Registered Securities** None.

**Sales of Unregistered Securities** None.

**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 receipt, November 12, 2003, through March 31, 2004, we have used approximately \$17.6 million of the net proceeds from the offering to fund operations, capital expenditures, working capital and other general corporate purposes. The remainder of the proceeds have been invested into short-term investment-grade securities and money market accounts.

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

None.

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

None.

***Item 5. Other Information***

None.

***Item 6. Exhibits and Reports on Form 8-K***

(a) *Exhibits*

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- 10.1\* Employment Agreement, dated as of February 23, 2004, by and between the Registrant and Patrick J. Mahaffy
- 10.2\* Amended and Restated Employment Agreement, dated as of March 1, 2004, by and between the Registrant and Judith A. Hemberger
- 10.3\* Amended and Restated Employment Agreement, dated as of March 1, 2004, by and between the Registrant and Erle T. Mast
- 10.4\* Amended and Restated Employment Agreement, dated as of March 1, 2004, by and between the Registrant and Gillian C. Ivers-Read
- 31.1 Sarbanes-Oxley Act of 2002, Section 302 Certification for President and Chief Executive Officer
- 31.2 Sarbanes-Oxley Act of 2002, Section 302 Certification for Chief Financial Officer
- 32.1 Sarbanes-Oxley Act of 2002, Section 906 Certification for President and Chief Executive Officer and Chief Financial Officer

\*Management Contract or Compensatory Plan or Arrangement

*(b) Reports on Form 8-K*

On February 11, 2004, we filed a report on Form 8-K reporting under Items 7 and 12 that we had issued an announcement of our fourth quarter 2003 financial results.

On February 23, 2004, we filed a report on Form 8-K reporting under Items 5 and 7 that our New Drug Application seeking approval to market Vidaza for the treatment of Myelodysplastic Syndromes was accepted for review by the U.S. Food and Drug Administration.

On March 9, 2004, we filed a report on Form 8-K reporting under Items 5 and 7 that all of our outstanding \$14 million of convertible notes had been converted into shares of our common stock.



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