PHARMION CORP
Form 10-Q
August 13, 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 June 30, 2004

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

For the transition period from to

Commission file number 000-50447

PHARMION CORPORATION

(Exact name of registrant as specified in its charter)

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

2525 28th Street, Boulder, Colorado 80304
(Address of principal executive offices)

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

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

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

As of August 9, 2004, there were 30,689,315 shares of the Registrant s Common Stock outstanding.

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)

	June 30, 2004	December 31, 2003
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 19,677	$ 88,542
Short-term investments	47,012	
Accounts receivable, net of allowance of $886 and $819, respectively	15,355	7,992
Inventories	4,482	4,923
Prepaid royalties	987	1,343
Other current assets	3,407	2,779
Total current assets	90,920	105,579
Product rights, net	28,671	30,651
Property and equipment, net	4,802	5,050
Goodwill	3,514	3,652
Other assets	225	541
Total assets	$ 128,132	$ 145,473
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 5,579	$ 4,241
Accrued liabilities	18,429	14,800
Total current liabilities	24,008	19,041
Long-term liabilities:		
Convertible notes payable		13,374
Deferred tax liability	3,528	3,665
Other long-term liabilities	2,400	4,479

Total long-term liabilities	5,928	21,518
Stockholders equity:		
Common stock, $.001 par value; 100,000,000 shares authorized and 25,381,763 and 23,948,636 shares issued and outstanding at June 30, 2004 and December 31, 2003	25	24
Preferred stock, $0.001, 10,000,000 shares authorized, no shares issued and outstanding at June 30, 2004 and December 31, 2003		
Additional paid-in capital	236,465	222,218
Deferred compensation	(860)	(1,155)
Other comprehensive income	2,917	4,386
Accumulated deficit	(140,351)	(120,559)
Total stockholders equity	98,196	104,914
Total liabilities and stockholders equity	$ 128,132	$ 145,473

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

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PHARMION CORPORATION

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Net sales	$ 20,396	$ 4,429	$ 36,116	$ 6,087
Operating expenses:				
Cost of sales, including royalties of $5,134 and $150 for the three months ended June 30, 2004 and 2003, respectively; and royalties of $9,715 and $239 for the six months ended June 30, 2004 and 2003, respectively	7,453	3,681	13,762	4,459
Clinical, development and regulatory	7,180	5,883	13,733	11,461
Selling, general and administrative	13,268	8,491	24,216	17,612
Product rights amortization	716	445	1,440	646
Total operating expenses	28,617	18,500	53,151	34,178
Loss from operations	(8,221)	(14,071)	(17,035)	(28,091)
Interest and other income (expense), net	(117)	100	(190)	318
Loss before taxes	(8,338)	(13,971)	(17,225)	(27,773)
Income tax expense	1,645	23	2,567	114
Net loss	(9,983)	(13,994)	(19,792)	(27,887)
Less accretion of redeemable convertible preferred stock to redemption value		(2,825)		(5,650)
Net loss attributable to common stockholders	$ (9,983)	$ (16,819)	$ (19,792)	$ (33,537)
Net loss attributable to common stockholders per common share, basic and diluted	$ (0.39)	$ (20.72)	$ (0.80)	$ (41.99)

Shares used in computing net loss attributable to common stockholders per common share, basic and diluted	25,292,801	811,813	24,821,361	798,607
Pro forma net loss attributable to common stockholders per common share assuming conversion of preferred stock, basic and diluted		$ (0.78)		$ (1.56)
Shares used in computing pro forma net loss attributable to common stockholders per common share assuming conversion of preferred stock, basic and diluted		17,842,769		17,829,563

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

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PHARMION CORPORATION

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

	Six Months Ended June 30,	
	2004	**2003**
Operating activities		
Net loss	$ (19,792)	$ (27,887)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,416	1,318
Compensation expense related to stock option issuance	295	243
Other	147	87
Changes in operating assets and liabilities:		
Accounts receivable, net	(7,699)	(3,270)
Inventories	204	(1,215)
Other current assets	(292)	(287)
Other long-term assets	314	253
Accounts payable	1,345	568
Accrued liabilities	4,451	6,379
Net cash used in operating activities	(18,611)	(23,811)
Investing activities		
Purchases of property and equipment	(700)	(1,776)
Acquisition of business, net of cash acquired	(19)	(12,156)
Purchase of product rights		(4,000)
Purchase of available-for-sale investments	(50,586)	
Sale and maturity of available-for-sale investments	3,179	
Net cash used in investing activities	(48,126)	(17,932)
Financing activities		
Proceeds from sale of common stock, net of issuance costs	87	47
Proceeds from issuance of convertible notes and warrants		14,000
Payment of debt obligations	(1,946)	(89)
Net cash provided by (used in) financing activities	(1,859)	13,958
Effect of exchange rate changes on cash and cash equivalents	(269)	(144)

Net decrease in cash and cash equivalents	(68,865)	(27,929)
Cash and cash equivalents at beginning of period	88,542	62,604
Cash and cash equivalents at end of period	$ 19,677	$ 34,675
Noncash items		
Warrants granted in connection with issuance of convertible notes		730
Conversion of debt and accrued interest to common stock	14,161	

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

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PHARMION CORPORATION

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF BUSINESS

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

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

On November 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.

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 and six months ended June 30, 2004 and 2003. The results of operations for the interim periods are not necessarily indicative of the results to be expected for the year ending December 31, 2004 or for any other interim period or for any other future year.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of

expenses during the reporting period. Actual results could differ from those estimates or assumptions. The more significant estimates reflected in these financial statements include estimates of chargebacks from distributors, product returns and rebates, and valuation of stock-based compensation.

Revenue Recognition

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

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

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

Short-term Investments

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

Inventories

Inventories consist of 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 six months ended June 30, 2004 and 2003, revenues generated from the Company s three largest customers in the United States totaled approximately 11% and 21%, respectively, of consolidated net revenues. Revenues generated from international customers were individually less than 5% of consolidated net revenues.

Pro Forma Net Loss Per Share

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

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

3. NET LOSS PER COMMON SHARE

The Company applies SFAS No. 128, *Earnings per Share,* which establishes standards for computing and presenting earnings per share. Basic and diluted net loss per common share is calculated by dividing net loss applicable to common stockholders by the weighted average number of unrestricted common shares outstanding for the period. Diluted net loss per common share is the same as basic net loss per common share, since the effects of potentially dilutive securities are antidilutive for all periods presented. Potential incremental common shares include shares of common stock issuable upon exercise of stock options and warrants and upon the conversion of redeemable convertible preferred stock and convertible notes outstanding during the period. The potential shares of common stock have not been included in the diluted net loss per share calculation because to do so would be antidilutive. Such shares totaled 2,031,237 and 20,630,981 as of June 30, 2004 and 2003, respectively.

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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 $7 million and is obligated to make $6 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 that were 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. In May 2004, the Company received approval from the FDA to market azacitidine under the branded name Vidaza® in the United States. The Company began selling Vidaza on July 1, 2004.

Under the Company s agreements with Penn and Celgene, the Company will pay a combined royalty of 36% of net sales, less the Company s purchase price from Penn of the units of product sold, on all sales of thalidomide once it is

approved by the appropriate health regulatory authority for sale in any country within the Company s licensed territory. Until such approvals are obtained, the combined royalty payment obligations to Celgene and Penn are generally lower than 36%. The Company s royalty payment obligations to Celgene and Penn are also subject to certain minimum yearly payment thresholds. In connection with our ongoing relationship with Celgene, and to further the clinical development of thalidomide, particularly in multiple myeloma, the Company has also agreed to fund an aggregate of $8.0 million of Celgene s clinical trial development costs for clinical studies of thalidomide. As of June 30, 2004 the Company was obligated to pay Celgene an aggregate of $3.5 million in quarterly installments through 2005. The Company issued a warrant to Celgene to purchase 1,701,805 shares of Series B Preferred Stock at $2.09 per share in November 2001 which expires seven years from the date of grant. Immediately prior to the effective date of the IPO, this warrant was converted into the right to purchase 425,451 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.

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

	As of June 30, 2004		As of December 31, 2003	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Amortized product rights:				
Innohep®	$ 5,000	$ (1,000)	$ 5,000	$ (750)
Refludan®	12,208	(1,539)	12,208	(865)
Thalidomide	15,272	(1,270)	15,849	(791)
Total product rights	$ 32,480	$ (3,809)	$ 33,057	$ (2,406)

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 June 30, 2004, the Company had two stock option plans. The Company has elected to account for stock-based compensation arrangements using the intrinsic value method under the provisions of Accounting Principles Board Opinion No. 25 (APB 25), *Accounting for Stock Issued to Employees* and its related interpretations. Under this method, when the exercise price is less than the market price for the underlying stock on the date of grant, a non-cash charge to compensation expense is recorded ratably over the term of the option vesting period in an amount equal to the difference between the value calculated using the exercise price and the fair value. The company uses the fair value method to account for nonemployee stock-based compensation.

During 2003, options were granted to employees and directors at exercise prices that were less than the estimated fair value of the underlying shares of common stock as of the grant date. In accordance with APB 25, deferred compensation expense is being recognized for the excess of the estimated fair value of the Company s common stock as of the grant date over the exercise price of the options and amortized to expense on a straight-line basis over the vesting periods of the related options, which is generally 4 years. The Company recorded compensation expense totaling $295,072 for the six months ended June 30, 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 Black-Scholes valuation model.

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A risk-free interest rate of 2.8%, a dividend yield of 0%, an expected life of five years and a volatility of 85% were applied to all 2004 grants. The weighted-average fair value of options granted during 2004 was $17.84. The effects of applying the fair value method to the results for the three and six months ended June 30, 2004 and 2003 are (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Net loss attributable to common shareholders:				
As reported	$ (9,983)	$ (16,819)	$ (19,792)	$ (33,537)
Plus: stock based compensation recognized under the intrinsic value method	121	243	295	243
Less: stock based compensation under fair value method	(595)	(205)	(1,086)	(334)
Pro forma net loss	$ (10,457)	$ (16,781)	$ (20,583)	$ (33,628)
Net loss attributable to common shareholders per common share:				
As reported (basic and diluted)	$ (.39)	$ (20.72)	$ (.80)	$ (41.99)
Pro forma net loss per share (basic and diluted)	$ (.41)	$ (20.67)	$ (.83)	$ (42.11)

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

7. OTHER COMPREHENSIVE LOSS

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Net loss	$ (9,983)	$ (13,994)	$ (19,792)	$ (27,887)
Other comprehensive income:				
Foreign currency translation	(201)	980	(1,224)	877
Unrealized loss on available for sale securities	(75)		(245)	

Comprehensive loss	$ (10,259)	$ (13,014)	$ (21,261)	$ (27,010)

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 six and three months ended June 30, 2004 resulted primarily from taxable income generated in certain foreign jurisdictions.

9. COMMITMENTS AND CONTINGENCIES

During the fourth quarter of 2003, the Company filed suit against Lipomed AG, and certain of its distributors, in the UK, Switzerland, Germany and Italy for patent infringement in connection with their sales of thalidomide for the treatment of angiogenesis-mediated disorders, including multiple myeloma, in these countries. The Company was seeking injunctive relief that would have prevented the defendants from making any further sales of thalidomide for the treatment of angiogenesis-mediated disorders, including multiple myeloma, in the four countries in which the Company brought suit, and damages against the defendants. In April 2004, all parties to the litigation agreed to a settlement of all claims. Lipomed agreed to cease selling its thalidomide formulation and to not further challenge the validity of the thalidomide patent. The Company agreed to make a 1.25 million payment to Lipomed toward the legal costs incurred by Lipomed in connection with the suit and in consideration of future assistance to be provided to the Company by Lipomed in obtaining regulatory approvals to market Thalidomide Pharmion 50 mg in those countries in which the Company is currently not approved to do so. In addition, the Company entered in to a distribution agreement with Lipomed pursuant to which Lipomed was appointed as the exclusive distributor of Thalidomide Pharmion 50 mg in Switzerland and Austria effective May 1, 2004.

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10. GEOGRAPHIC INFORMATION

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

		Three Months Ended June 30,		Six Months Ended June 30,	
		2004	2003	2004	2003
United States	Net sales	$ 2,582	$ 857	$ 4,239	$ 1,357
Foreign entities	Net sales	17,814	3,572	31,877	4,730
Total	Net sales	$ 20,396	$ 4,429	$ 36,116	$ 6,087
United States	Operating income (loss)	$ (9,648)	$ (9,544)	$ (17,125)	$ (18,471)
Foreign entities	Operating income (loss)	1,427	(4,527)	90	(9,620)
Total	Operating income (loss)	$ (8,221)	$ (14,071)	$ (17,035)	$ (28,091)

11. SUBSEQUENT EVENT

On July 7, 2004, the Company completed a secondary offering of common stock. A total of 5,290,000 shares of common stock were sold to the public at $48.00 per share, resulting in net proceeds to the Company of approximately $238 million.

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 our expected financial position and operating results, business strategy, financing plans, forecast trends relating to our industry are forward-looking statements. These forward-looking statements are subject to business and economic risks and uncertainties, and our actual results of operations may differ materially from those contained in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those mentioned in the discussion below. As a result, you should not place undue reliance on these forward-looking statements. We

undertake no obligation to update or revise these forward-looking statements to reflect future events or developments.

Overview

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

Critical Accounting Policies

Revenue Recognition

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

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common practice that ownership transfers upon receiving the product and, accordingly, in these circumstances revenue is recognized upon delivery (freight on board destination) when title effectively transfers.

We report revenue net of allowances for distributor chargebacks, product returns, rebates, and prompt-pay discounts. Significant estimates are required in determining such allowances and are based on historical data, industry information, and information from customers. If actual results are different from our estimates, we adjust the allowances in the period the difference becomes apparent.

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

Inventories

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

Long-Lived Assets

Our long-lived assets consist primarily of product rights and property and equipment. In accordance with Statement of Financial Accounting Standards No. 144 (SFAS 144), *Accounting for the Impairment or Disposal of Long-Lived Assets,* we evaluate our ability to recover the carrying value of long-lived assets used in our business, considering changes in the business environment or 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 June 30, 2004 and 2003.

Net sales. Net sales totaled $20.4 million for the three months ended June 30, 2004 as compared to $4.4 million for the three months ended June 30, 2003. Net sales included $2.6 million and $.9 million in the U.S. and $17.8 million and $3.5 million in Europe and other countries for the three months ended June 30, 2004 and 2003, respectively. The primary reason for the net sales growth in 2004 is an increase in sales of thalidomide, which totaled $15.3 million for the three months ended June 30, 2004, compared to $1.9 million for the comparable period of 2003. We began selling thalidomide on a compassionate use or named patient basis in France and Belgium in April 2003 following our acquisition of 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 June 30, 2004 totaled $7.5 million compared to $3.7 million for the three months ended June 30, 2003. Cost of sales reflects the cost of product sold plus royalties due on the sales of our products as well as the distribution costs related to selling our products. Our gross margin for the three months

ended June 30, 2004 was 63% as compared to 17% for the comparable period in 2003. Cost of sales for the three months ended June 30, 2003 included inventory charges totaling $2.1 million relating to Refludan. These charges reduced our gross margin for this period by 47 percentage points. We expect the gross margin for our products will remain in the low to mid sixty-percent range for the foreseeable future.

Clinical, development and regulatory expenses. Clinical, development and regulatory expenses totaled $7.2 million for the three months ended June 30, 2004 as compared to $5.9 million for the three months ended June 30, 2003. These expenses generally consist of regulatory, clinical and manufacturing development, and medical and safety monitoring costs for both products in development as well as products being sold. Clinical, development and regulatory expenses for the second quarter of 2004 included a net charge of approximately $1.1 million relating to the settlement of a patent infringement suit filed by us against Lipomed, AG. In addition, medical and safety monitoring costs incurred to support our commercial products, primarily due to the support of the sales of thalidomide increased by $0.6 million in the second quarter of 2004 as compared to second quarter of 2003. These increases in expenses were partially offset by reduced pre-approval clinical and manufacturing development costs for Vidaza as those activities were completed in 2003.

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Selling, general and administrative expenses. Selling, general and administrative expenses totaled $13.3 million for the three months ended June 30, 2004 as compared to $8.5 million for the three months ended June 30, 2003. Sales and marketing expenses totaled $9.1 million for the three months ended June 30, 2004, an increase of $4.3 million over the comparable period of 2003. This increase is due to the commercial launch of thalidomide in Europe in the second half of 2003 and preparation for the July 1, 2004 U.S. launch of Vidaza in the second quarter of 2004. Sales and marketing expenses in Europe and our rest-of-world markets for the second quarter of 2004 increased by $2.2 million over the second quarter of 2003 as we expanded our commercial organizations to support the sales of thalidomide in these countries. In the U.S., we expanded our field based commercial organization from approximately 30 to 75 employees during the second quarter of 2004. We also incurred increased marketing and launch preparation costs for the U.S. launch of Vidaza. These activities increased second quarter 2004 sales and marketing expenses in the U.S. by $2.1 million as compared to the second quarter of 2003.

General and administrative expenses totaled $4.2 million for the three months ended June 30, 2004 as compared to $3.7 million for the three months ended June 30, 2003. This $0.5 million increase is due to increased costs to support the responsibilities of becoming a public company following our initial public offering completed in November 2003, including increased legal and accounting fees, directors and officers liability insurance premiums, investor relations costs, and consulting fees relating to our implementation of Section 404 of the Sarbanes-Oxley Act of 2002.

Product rights amortization. Product rights amortization totaled $0.7 million for the three months ended June 30, 2004 as compared to $0.4 million for the three months ended June 30, 2003. The increase in the second quarter of 2004 is due to the renegotiation of the financial terms in August 2003 of the Refludan® rights acquired from Schering A.G., which resulted in an increase in the capitalized product rights costs for Refludan® and, as such, the related amortization expense for the second quarter of 2004.

Income tax expense. Income tax expense totaled $1.6 million for the three months ended June 30, 2004 as compared to $23,000 for the three months ended June 30, 2003. The provision for income taxes recorded for the second quarter of 2004 reflects management s estimate of the effective tax rate expected to be applicable for the full fiscal year in each of our taxing jurisdictions. The increase in income tax expense is due to an increase to taxable income in certain foreign countries in which we do business and additional capital-based taxes due in certain jurisdictions.

Comparison of the Company s Results for the Six Months Ended June 30, 2004 and 2003.

Net sales. Net sales totaled $36.1 million for the six months ended June 30, 2004 as compared to $6.1 million for the six months ended June 30, 2003. Net sales included $4.2 million and $1.4 million in the U.S. and $31.9 million and $4.7 million in Europe and other countries for the six months ended June 30, 2004 and 2003, respectively. The primary reason for the net sales growth in 2004 is an increase in sales of thalidomide, which totaled $27.9 million for the six months ended June 30, 2004, compared to $1.9 million for the comparable period of 2003. We began selling thalidomide on a compassionate use or named patient basis in France and Belgium in April 2003 following our acquisition of Laphal. In July 2003, we began selling thalidomide on a compassionate use or named patient basis in additional countries in Europe and other international markets. Sales of our other products, primarily from Innohep® and Refludan®, totaled $8.2 million for the six months ended June 30, 2004, an increase of $4.0 million over the comparable period in 2003.

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Cost of sales. Cost of sales for the six months ended June 30, 2004 totaled $13.8 million compared to $4.5 million for the six months ended June 30, 2003. Cost of sales reflects the cost of product sold plus royalties due on the sales of our products as well as the distribution costs related to selling our products. Our gross margin for the six months ended June 30, 2004 was 62% as compared to 27% for the comparable period in 2003. Cost of sales for the six months ended June 30, 2003 included inventory charges totaling $2.1 million relating to Refludan. These charges reduced our gross margin for this period by 34 percentage points. We expect the gross margin for our products will remain in the low to mid sixty-percent range for the foreseeable future.

Clinical, development and regulatory expenses. Clinical, development and regulatory expenses totaled $13.7 million for the six months ended June 30, 2004 as compared to $11.5 million for the six months ended June 30, 2003. These expenses generally consist of regulatory, clinical and manufacturing development, and medical and safety monitoring costs for both products in development as well as products being sold. The $2.2 million increase in these expenses for the second half of 2004 was due to two primary factors. First, clinical, development and regulatory expenses for the first six months of 2004 included a net charge of approximately $1.1 million relating to the April 2004 settlement of a patent infringement suit filed by us against Lipomed. Second, medical and safety monitoring costs incurred to support our commercial products increased by $1.1 million in the first six months of 2004 as compared to comparable period of 2003, primarily due to the support of the sales of thalidomide.

Selling, general and administrative expenses. Selling, general and administrative expenses totaled $24.2 million for the six months ended June 30, 2004 as compared to $17.6 million for the six months ended June 30, 2003. Sales and marketing expenses totaled