

ENDO PHARMACEUTICALS HOLDINGS INC

Form 10-Q

August 09, 2004

**Table of Contents**

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

**Washington, DC 20549**

**FORM 10-Q**

(Mark One)

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2004.

OR

- 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: 001-15989

**ENDO PHARMACEUTICALS HOLDINGS INC.**

(Exact Name of Registrant as Specified in Its Charter)

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

**13-4022871**  
(I.R.S. Employer  
Identification Number)

**100 Painters Drive**  
**Chadds Ford, Pennsylvania 19317**  
(Address of Principal Executive Offices)

**(610) 558-9800**  
(Registrant's Telephone Number, Including Area Code)

**Not applicable**  
(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Sections 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter periods 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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practical date:

Common Stock, \$.01 par value: 131,799,817 shares as of August 5, 2004.

---

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**INDEX**

	<b>Page</b>
<u>Forward-Looking Statements</u>	3
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
<u>Item 1. Financial Statements</u>	
<u>Condensed Consolidated Balance Sheets (Unaudited)</u> <u>June 30, 2004 and December 31, 2003</u>	4
<u>Condensed Consolidated Statements of Operations</u> <u>(Unaudited) Three and Six Months Ended June 30,</u> <u>2004 and 2003</u>	5
<u>Condensed Consolidated Statements of Cash Flows</u> <u>(Unaudited) Six Months Ended June 30, 2004 and 2003</u>	6
<u>Notes to Condensed Consolidated Financial Statements</u> <u>(Unaudited)</u>	7
<u>Management's Discussion and Analysis of Financial</u>	
<u>Item 2. Condition and Results of Operations</u>	18
<u>Overview</u>	18
<u>Critical Accounting Policies</u>	19
<u>Results of Operations</u>	22
<u>Three Months Ended June 30, 2004 Compared to the</u> <u>Three Months Ended June 30, 2003</u>	22
<u>Six Months Ended June 30, 2004 Compared to the Six</u> <u>Months Ended June 30, 2003</u>	23
<u>Liquidity and Capital Resources</u>	25
<u>Quantitative and Qualitative Disclosures About Market</u>	
<u>Item 3. Risk</u>	30
<u>Item 4. Controls and Procedures</u>	30
<b><u>PART II. OTHER INFORMATION</u></b>	
<u>Item 1. Legal Proceedings</u>	31
<u>Item 2. Changes in Securities and Use of Proceeds</u>	32
<u>Item 3. Defaults Upon Senior Securities</u>	32
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	33
<u>Item 5. Other Information</u>	33
<u>Item 6. Exhibits and Reports on Form 8-K</u>	33
<b><u>SIGNATURES</u></b>	
<u>AMENDMENT NO. 2 TO THE AMENDED AND RESTATED CREDIT AGREEMENT</u>	
<u>2004 STOCK INCENTIVE PLAN</u>	
<u>CERTIFICATION</u>	
<u>CERTIFICATION</u>	
<u>CERTIFICATION</u>	
<u>CERTIFICATION</u>	



**Table of Contents**

**Forward-Looking Statements**

We have made forward-looking statements in this document within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended. These statements, including estimates of future net sales, future net income and future earnings per share, contained in the section titled Management's Discussion and Analysis of Financial Condition and Results of Operations, are subject to risks and uncertainties. Forward-looking statements include the information concerning our possible or assumed results of operations. Also, statements including words such as believes, expects, anticipates, intends, estimates, or similar expressions are forward-looking statements. We have based these forward-looking statements on our current expectations and projections about the growth of our business, our financial performance and the development of our industry. Because these statements reflect our current views concerning future events, these forward-looking statements involve risks and uncertainties. Investors should note that many factors, as more fully described in Management's Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this Report could affect our future financial results and could cause our actual results to differ materially from those expressed in forward-looking statements contained in this Report. Important factors that could cause our actual results to differ materially from the expectations reflected in the forward-looking statements in this Report include, among others:

our ability to successfully develop, commercialize and market new products;

results of pre-clinical or clinical trials on new products;

our ability to obtain regulatory approval of any of our pipeline products;

competition for the business of our branded and generic products, and in connection with our acquisition of rights to intellectual property assets;

market acceptance of our future products;

government regulation of the pharmaceutical industry;

our dependence on a small number of products;

our dependence on outside manufacturers for the manufacture of our products;

our dependence on third parties to supply raw materials and to provide services for certain core aspects of our business;

new regulatory action or lawsuits relating to the use of narcotics in most of our core products;

our exposure to product liability claims and product recalls and the possibility that we may not be able to adequately insure ourselves;

our ability to protect our proprietary technology;

our ability to successfully implement our acquisition and in-licensing strategy;

the availability of controlled substances that constitute the active ingredients of some of our products and products in development;

the availability of third-party reimbursement for our products; and

our dependence on sales to a limited number of large pharmacy chains and wholesale drug distributors for a large portion of our total net sales.

We do not undertake any obligation to update our forward-looking statements after the date of this Report for any reason, even if new information becomes available or other events occur in the future.

**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****ENDO PHARMACEUTICALS HOLDINGS INC.****CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)****(In thousands, except share data)**

	<b>June 30, 2004</b>	<b>December 31, 2003</b>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$231,687	\$ 229,573
Accounts receivable, net	139,437	101,284
Inventories	98,964	50,450
Prepaid expenses	4,917	7,145
Deferred income taxes	82,532	85,144
	<hr/>	<hr/>
Total current assets	557,537	473,596
	<hr/>	<hr/>
PROPERTY AND EQUIPMENT, Net	23,144	20,246
GOODWILL	181,079	181,079
OTHER INTANGIBLES, Net	46,918	42,043
DEFERRED INCOME TAXES	24,381	31,045
OTHER ASSETS	7,112	5,871
	<hr/>	<hr/>
<b>TOTAL ASSETS</b>	<b>\$840,171</b>	<b>\$ 753,880</b>
	<hr/>	<hr/>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 68,945	\$ 65,071
Accrued expenses	128,131	108,567
Income taxes payable	280	12,036
	<hr/>	<hr/>
Total current liabilities	197,356	185,674
	<hr/>	<hr/>
OTHER LIABILITIES	1,335	589
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS EQUITY		
Preferred Stock, \$.01 par value; 40,000,000 shares authorized; none issued		

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-Q

Common Stock, \$.01 par value; 175,000,000 shares authorized; 131,796,610 and 131,769,766 issued and outstanding at June 30, 2004 and December 31, 2003, respectively	1,318	1,318
Additional paid-in capital	691,863	691,631
Accumulated deficit	(51,890)	(124,612)
Accumulated other comprehensive income (loss)	189	(720)
	<u>          </u>	<u>          </u>
Total stockholders' equity	641,480	567,617
	<u>          </u>	<u>          </u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$840,171	\$ 753,880
	<u>          </u>	<u>          </u>

See notes to condensed consolidated financial statements.



Table of Contents**ENDO PHARMACEUTICALS HOLDINGS INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)****(In thousands, except per share data)**

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2004</b>	<b>2003</b>	<b>2004</b>	<b>2003</b>
NET SALES	\$ 143,968	\$ 152,027	\$ 297,457	\$ 304,301
COST OF SALES	28,915	26,258	61,788	53,835
GROSS PROFIT	115,053	125,769	235,669	250,466
COSTS AND EXPENSES:				
Selling, general and administrative	43,017	41,801	81,759	77,917
Research and development	19,245	9,438	29,001	21,502
Depreciation and amortization	2,262	1,365	4,089	2,717
Loss on disposal of other intangible, including license termination fee of \$3,000			3,800	
Compensation related to stock options (primarily selling, general and administrative)				48,514
OPERATING INCOME	50,529	73,165	117,020	99,816
INTEREST (INCOME) EXPENSE, Net of interest (expense) income of \$(235), \$196, \$(450) and \$287, respectively	(228)	22	(218)	153
INCOME BEFORE INCOME TAX	50,757	73,143	117,238	99,663
INCOME TAX	19,209	27,975	44,516	38,136
NET INCOME	\$ 31,548	\$ 45,168	\$ 72,722	\$ 61,527
NET INCOME PER SHARE:				
Basic	\$ 0.24	\$ 0.34	\$ 0.55	\$ 0.49
Diluted	\$ 0.24	\$ 0.34	\$ 0.55	\$ 0.46
WEIGHTED AVERAGE SHARES:				
Basic	131,792	131,734	131,786	125,014
Diluted	132,789	132,667	132,759	132,419

See notes to condensed consolidated financial statements.



**Table of Contents****ENDO PHARMACEUTICALS HOLDINGS INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)****(In thousands)**

	<b>Six Months Ended</b>	
	<b>June 30,</b>	
	<b>2004</b>	<b>2003</b>
	<u>2004</u>	<u>2003</u>
<b>OPERATING ACTIVITIES:</b>		
Net income	\$ 72,722	\$ 61,527
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	4,089	2,717
Amortization of deferred financing costs	200	199
Deferred income taxes	8,713	(19,207)
Compensation related to stock options		48,514
Loss on disposal of other intangible	3,800	
Gain on disposal of property and equipment	(21)	
Changes in assets and liabilities which provided (used) cash:		
Accounts receivable	(38,153)	79
Inventories	(48,514)	(4,180)
Other assets	2,259	(476)
Accounts payable	3,874	7,004
Accrued expenses	17,935	25,780
Income taxes payable	(11,756)	17,165
	<u>15,148</u>	<u>139,122</u>
<b>INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	(2,638)	(2,309)
Proceeds from the sale of property and equipment	220	
Payment of license termination fee	(3,000)	
License fees	(7,250)	(25,000)
	<u>(12,668)</u>	<u>(27,309)</u>
<b>FINANCING ACTIVITIES:</b>		
Capital lease obligations repayments	(598)	(277)
Exercise of pre-merger Endo warrants		2
Exercise of Endo Pharmaceutical Holdings Inc. Stock Options	232	34
	<u>(366)</u>	<u>(241)</u>
Net cash used in financing activities	<u>(366)</u>	<u>(241)</u>

NET INCREASE IN CASH AND CASH EQUIVALENTS	2,114	111,572
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	229,573	56,902
	<u>          </u>	<u>          </u>
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$231,687	\$168,474
	<u>          </u>	<u>          </u>
SUPPLEMENTAL INFORMATION:		
Interest paid	\$ 201	\$ 191
Income taxes paid	\$ 46,707	\$ 39,884
SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES		
Purchase of property and equipment financed by capital leases	\$ 2,973	\$ 246

See notes to condensed consolidated financial statements.

**Table of Contents****ENDO PHARMACEUTICALS HOLDINGS INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)  
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2004****1. BASIS OF PRESENTATION**

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission for interim financial information. In the opinion of management, the accompanying condensed consolidated financial statements of Endo Pharmaceuticals Holdings Inc. (the Company or we ) and its subsidiaries, which are unaudited, include all normal and recurring adjustments necessary to present fairly the Company's financial position as of June 30, 2004 and the results of our operations and our cash flows for the periods presented. The accompanying condensed consolidated balance sheet as of December 31, 2003 is derived from the Company's audited financial statements. Since certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted, we suggest that these condensed consolidated financial statements be read in conjunction with the consolidated financial statements and notes thereto as of and for the year ended December 31, 2003 contained in the Company's Annual Report on Form 10-K. Certain prior period amounts have been reclassified to conform to the current period presentation.

**2. RECENT ACCOUNTING PRONOUNCEMENTS**

In December 2003, the Financial Accounting Standards Board issued FASB Interpretation No. 46R (FIN 46R), *Consolidation of Variable Interest Entities*. FIN 46R replaces the same titled FIN 46 that was issued in January 2003. FIN 46R identifies when entities must be consolidated with the financial statements of a company where the investors in an entity do not have the characteristics of a controlling financial interest or the entity does not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support. The adoption, on March 31, 2004, of FIN 46R did not have a material impact on our financial position, results of operations or liquidity.

**3. INVENTORIES**

Inventories are comprised of the following at June 30, 2004 and December 31, 2003, respectively (in thousands):

	<b>June 30, 2004</b>	<b>December 31, 2003</b>
	<hr/>	<hr/>
Raw Materials	\$15,804	\$12,615
Work-in-Process	27,799	18,195
Finished Goods	55,361	19,640
	<hr/>	<hr/>
Total	\$98,964	\$50,450
	<hr/>	<hr/>

**4. GOODWILL AND OTHER INTANGIBLES**

Our goodwill and other intangible assets consist of the following (in thousands):

	<b>June 30, 2004</b>	<b>December 31, 2003</b>
Goodwill	\$181,079	\$181,079
Amortizable Intangibles:		
Licenses	\$ 49,750	\$ 43,500
Patents	3,200	3,200
	52,950	46,700
Less accumulated amortization	(6,032)	(4,657)
Other Intangibles, net	\$ 46,918	\$ 42,043

Goodwill and other intangibles represent a significant portion of our assets and stockholders' equity. As of June 30, 2004, goodwill

**Table of Contents**

and other intangibles comprised approximately 27% of our total assets and 36% of our stockholders' equity. SFAS No. 142, Goodwill and Other Intangible Assets (SFAS No. 142), prescribes a two-step method for determining goodwill impairment. In the first step, we determine the fair value of our one reporting unit. If the net book value of our reporting unit exceeds the fair value, we would then perform the second step of the impairment test which requires allocation of our reporting unit's fair value to all of its assets and liabilities in a manner similar to a purchase price allocation, with any residual fair value being allocated to goodwill. An impairment charge will be recognized only when the implied fair value of our reporting unit's goodwill is less than its carrying amount. As a result of the significance of goodwill, our results of operations and financial position in a future period could be negatively impacted should an impairment of goodwill occur.

We have one reportable segment, pharmaceutical products. Goodwill arose as a result of the August 26, 1997 acquisition of certain branded and generic pharmaceutical products, related rights and certain assets of the then DuPont Merck Pharmaceutical Company (n/k/a Bristol-Myers Squibb Pharma Company) and the July 17, 2000 acquisition of Algos. Although goodwill arose in two separate transactions, the components of our operating segment have been integrated and are managed as one reporting unit. Our components extensively share assets and other resources with the other components of our business and have similar economic characteristics. In addition, our components do not maintain discrete financial information. Accordingly, the components of our business have been aggregated into one reporting unit and are evaluated as such for goodwill impairment. Goodwill is evaluated for impairment on an annual basis on January 1st of each year unless events or circumstances indicate that an impairment may have occurred between annual dates. Goodwill was evaluated for impairment upon the adoption of SFAS No. 142 on January 1, 2002 and, based on the fair value of our reporting unit, no impairment was identified. On January 1, 2004 and 2003, our goodwill was evaluated for impairment and, based on the fair value of our reporting unit, no impairment was identified.

The cost of license fees is capitalized and is being amortized using the straight-line method over the licenses' estimated useful lives ranging from eleven to twenty years. The cost of acquired patents is capitalized and is being amortized using the straight-line method over their estimated useful lives of seventeen years.

Estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2003 is as follows (in thousands):

2004	\$3,311
2005	3,366
2006	3,366
2007	3,366
2008	3,366

**5. COMPREHENSIVE INCOME**

Comprehensive income includes the following components for the three and six months ended June 30, 2004 and 2003 (in thousands):

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>	<b>June 30,</b>	<b>June 30,</b>	<b>June 30,</b>
	<b>2004</b>	<b>2003</b>	<b>2004</b>	<b>2003</b>
Net income	\$31,548	\$45,168	\$72,722	\$61,527

Other comprehensive income:				
Unrealized gains on securities, net of tax	66	948	909	362
	<u>        </u>	<u>        </u>	<u>        </u>	<u>        </u>
Total comprehensive income	\$31,614	\$46,116	\$73,631	\$61,889
	<u>                    </u>	<u>                    </u>	<u>                    </u>	<u>                    </u>

## 6. COMPENSATION RELATED TO STOCK OPTIONS

### Endo Pharma LLC 1997 Executive and Employee Stock Option Plans and Endo Pharma LLC 2000 Supplemental Executive and Employee Stock Option Plans

On November 25, 1997, the Company established the 1997 Employee Stock Option Plan and the 1997 Executive Stock Option Plan (collectively, the 1997 Stock Option Plans ). On July 17, 2000, the 1997 Stock Option Plans were amended and restated. The Endo Pharma LLC 1997 Stock Option Plans are these amended and restated 1997 Stock Options Plans and reserve an aggregate of



**Table of Contents**

25,615,339 shares of common stock of the Company held by Endo Pharma LLC for issuance. Stock options granted under the Endo Pharma LLC 1997 Stock Option Plans expire on August 26, 2007. Upon exercise of these stock options, only currently outstanding shares of common stock of the Company held by Endo Pharma LLC will be issued. Exercise of these stock options will not result in the issuance of additional shares in the Company and will not dilute the public stockholders.

Pursuant to the Algos merger and related recapitalization of the Company on July 17, 2000, the Endo Pharma LLC 2000 Supplemental Stock Option Plans were established. The Endo Pharma LLC 2000 Supplemental Stock Option Plans reserve an aggregate of 10,672,314 shares of common stock of the Company held by Endo Pharma LLC for issuance. The Endo Pharma LLC 2000 Supplemental Stock Option Plans were only effective on January 1, 2003 in the event that we had not received the approval from the U.S. Food and Drug Administration for MorphiDex® for the treatment of pain by December 31, 2002. Stock options granted under the Endo Pharma LLC 2000 Supplemental Stock Option Plans expire on August 26, 2007.

The Endo Pharma LLC 2000 Supplemental Stock Option Plans became effective on January 1, 2003, resulting in the issuance of 10,672,314 stock options to certain employees and members of management. Because 9,188,186 of these stock options were immediately vested upon their issuance, the Company recorded a non-cash compensation charge of approximately \$48.5 million in the first quarter of 2003 for the difference between the market price of the common stock of \$7.70 and the weighted average exercise price of these stock options of \$2.42. No additional shares of Company common stock will be issued, however, because these stock options are exercisable only into shares of Company common stock that are held by Endo Pharma LLC. Accordingly, exercise of these stock options will not result in the issuance of additional shares in the Company and will not dilute the public stockholders.

The Class C stock options under the Endo Pharma LLC 1997 Stock Option Plans vest in four discrete tranches contingent upon (i) the common stock of the Company exceeding a defined average closing price threshold for ninety consecutive trading days, (ii) the closing price of the common stock of the Company on the last trading day of such ninety consecutive trading day period being greater than or equal to 85% of the defined closing price and (iii) the holder being a director, officer or employee of the Company or any of its subsidiaries on such date. The defined average closing price thresholds are as follows:

<b>Option Class</b>	<b>Common Stock Closing Price Threshold</b>
C1A and C1B	\$ 4.28
C2	\$ 6.62
C3	\$10.58
C4	\$17.29

As these share price targets have been achieved, resulting in the vesting of each tranche of options, the Company has recorded non-cash compensation charges related to the vesting of certain of the options. Under performance-based options, the measurement of expense is calculated and recorded as a non-cash charge at the time performance is achieved as the difference between the market price of the stock and the exercise price of the options. As these charges have been recorded by the Company in connection with the above options, they have been significant. The exercise of these options will not, however, result in the issuance of additional shares of Company common stock.

During the year ended December 31, 2003, 4,810,936 Class C4 stock options vested upon achievement of the aforementioned conditions. We recorded a \$96.0 million compensation charge related to the vesting of these

performance-based stock options. The amount represents the estimated difference in the market price and the exercise price of the vested stock options.

During the year ended December 31, 2002, 6,924,363 Class C3 stock options vested upon achievement of the aforementioned conditions. We recorded a \$34.7 million compensation charge related to the vesting of these performance-based stock options. The amount represents the estimated difference in the market price and the exercise price of the vested stock options.

During the year ended December 31, 2001, 4,594,535 Class C2 stock options vested upon achievement of the aforementioned conditions. We recorded a \$37.3 million compensation charge related to the vesting of these performance-based stock options. The amount represents the estimated difference in the market price and the exercise price of the vested stock options.

During the year ended December 31, 2000, 5,880,713 Class C1A and C1B stock options vested upon achievement of the aforementioned conditions. We recorded a \$15.3 million compensation charge related to the vesting of these performance-based stock

## **Table of Contents**

options. The amount represents the estimated difference in the market price and the exercise price of the vested stock options.

The Class C1A, C1B, C2, C3 and C4 stock options are generally exercisable upon the earlier of (i) the occurrence of a sale, disposition or transfer of Company common stock, after which neither Endo Pharma LLC nor Kelso & Company hold any shares of Company common stock or (ii) January 1, 2006 and since neither of these conditions have been met, these options are not currently exercisable.

The shares of Company common stock that individuals receive upon exercise of stock options pursuant to the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans are currently subject to significant restrictions that are set forth in stockholders agreements.

### **Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan**

All the options we have granted pursuant to the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan have exercise prices equal to the market price of our common stock on the date granted and, under accounting principles generally accepted in the United States, a measurement date occurs on the date of each grant. Consequently, we do not expect to incur a charge upon the vesting or exercise of those options. Unlike the stock options granted under the Endo Pharma LLC Stock Option Plans, the exercise of the stock options granted pursuant to the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan will dilute our public stockholders.

### **Endo Pharmaceuticals Holdings Inc. 2004 Stock Incentive Plan**

In May 2004, our stockholders approved the Endo Pharmaceuticals Holdings Inc. 2004 Stock Incentive Plan. The maximum number of shares of Company stock reserved for issuance under the 2004 Plan is 4,000,000 shares. The 2004 Plan provides for the grant of stock options, stock appreciation rights, shares of restricted stock, performance shares, performance units or other share-based awards that may be granted to executive officers and other employees of the Company, including officers and directors who are employees, to non-employee directors and to consultants to the Company. Unlike the stock options granted under the Endo Pharma LLC Stock Option Plans, the exercise of the stock options granted pursuant to the Endo Pharmaceuticals Holdings Inc. 2004 Stock Incentive Plan will dilute our public stockholders. No awards have been granted pursuant to this plan.

### **Stock-Based Compensation**

We have adopted the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*, while following Accounting Principles Board ( APB ) No. 25, *Accounting for Stock Issued to Employees*, and related interpretations in accounting for all of our stock option plans. Under APB No. 25, no compensation expense is recognized when the exercise price of stock options equals at least the market price of the underlying stock at the date of grant or when a measurement date has not yet been reached. Accordingly, with respect to the stock options granted under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan, no compensation expense has been recognized. If we were to have adopted the accounting provisions of SFAS No. 123, we would have been required to record compensation expense based on the fair value of all of these stock options on the date of grant.

**Table of Contents**

Pro-forma information regarding net income is required to be presented as if we had accounted for our stock options under the provisions of SFAS No. 123. We estimated the fair value of our stock options as of the respective date of grant, using the Black-Scholes option-pricing model. The following assumptions were used for such estimates: no dividend yield; expected volatility of 70% and 60% in 2004 and 2003, respectively; risk-free interest rate of 3.2% and 4.0% in 2004 and 2003, respectively; and a weighted average expected life of the options of 5 years. Had the accounting provisions of SFAS No. 123 been adopted, net income would have been as follows (in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Net income, as reported	\$ 31,548	\$ 45,168	\$ 72,722	\$ 61,527
APB 25 Compensation Expense				48,514
Tax effect of APB 25 compensation expense				(18,580)
SFAS 123 compensation expense	(1,075)	(585)	(2,513)	(66,142)
Tax effect of SFAS 123 compensation expense	409	223	957	25,331
Pro forma net income	\$ 30,882	\$ 44,806	\$ 71,166	\$ 50,650
Basic earnings per share, as reported	\$ 0.24	\$ 0.34	\$ 0.55	\$ 0.49
Basic earnings per share, pro forma	\$ 0.23	\$ 0.34	\$ 0.54	\$ 0.41
Diluted earnings per share, as reported	\$ 0.24	\$ 0.34	\$ 0.55	\$ 0.46
Diluted earnings per share, pro forma	\$ 0.23	\$ 0.34	\$ 0.54	\$ 0.38
Weighted average shares outstanding				
Basic	131,792	131,734	131,786	125,014
Diluted	132,789	132,667	132,759	132,419

**7. WARRANTS****Class A Transferable Warrants and Class B Non-Transferable Warrants**

The Class A Transferable Warrants and Class B Non-Transferable Warrants were exercisable at an exercise price of \$.01 per share into a specified number of shares of Company common stock depending on the timing of the FDA's approval of MorphiDex® for one or more pain indications. Because MorphiDex® was not approved prior to March 31,

2003, the Class A Transferable Warrants (NASDAQ: ENDPW) and Class B Non-Transferable Warrants expired on such date and have no economic value. The Company de-listed the Class A Transferable Warrants (NASDAQ: ENDPW) upon their expiration.

### **Pre-Merger Endo Warrants**

The warrants issued to the holders of Company common stock prior to the Algos merger received warrants (known as the Pre-Merger Endo Warrants ), which were exercisable at an exercise price of \$0.01 per share into a specified number of shares of Company common stock. As of December 31, 2002, there were outstanding 71.3 million of these warrants. As the FDA did not approve Morphidex® before December 31, 2002, these warrants became exercisable. Each of these outstanding 71.3 million warrants was exercisable into 0.416667 shares of common stock of Endo Pharmaceuticals Holdings Inc. All of these warrants were exercised into 29,687,602 shares of common stock at an exercise price of \$0.01 per share. The warrants were exercisable until July 8, 2003.

## **8. RELATED PARTY TRANSACTIONS**

**Tax Sharing Agreement.** On July 14, 2000, Endo Pharma LLC was formed in connection with the Algos merger to ensure that the stock options granted pursuant to the Endo Pharma LLC Stock Option Plans diluted only the Endo common stock held by persons and entities that held such shares prior to our merger with Algos. Upon the exercise of these stock options, only currently outstanding shares of our common stock held by Endo Pharma LLC will be delivered. Because Endo Pharma LLC, and not us, will provide the shares upon the exercise of these options, we have entered into a tax sharing agreement with Endo Pharma LLC under which we will be required to pay to Endo Pharma LLC upon the occurrence of a liquidity event, as described further below, the amount of the tax benefits usable by us as a result of the exercise of these stock options into shares of our common stock held by Endo Pharma LLC. As of June 30, 2004, approximately 3.8 million of these stock options had been exercised into shares of our common stock held by Endo Pharma LLC. Upon exercise of any of these Endo Pharma LLC stock options, we generally will be permitted to deduct as a compensation charge, for federal income tax purposes, an amount equal to the difference between the market price of our common stock and the exercise price paid upon exercise of these options (as of June 30, 2004, approximately \$38 million), which is estimated

**Table of Contents**

to result in a tax benefit amount of approximately \$15 million. Under the tax sharing agreement, we are required to pay this \$15 million to Endo Pharma LLC upon the occurrence of a liquidity event, as described further below, to the extent that a compensation charge deduction is usable by us to reduce our taxes and based upon the assumption that all other deductions of Endo are used prior thereto. If payments are made pursuant to the tax sharing agreement, they will be reflected as a reduction of stockholders' equity in the accompanying financial statements.

Using a weighted average exercise price of \$2.60 per share and an assumed effective tax rate of 38.3%, if all 36.3 million stock options under the Endo Pharma LLC Stock Option Plans were vested and exercised (including the 3.8 million stock options already exercised as discussed above):

upon exercise, assuming the market price of our common stock is then \$20.00 per share, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$632 million, which could result in a tax benefit amount of approximately \$242 million payable to Endo Pharma LLC.

upon exercise, assuming the market price of our common stock is then \$25.00 per share, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$813 million, which could result in a tax benefit amount of approximately \$311 million payable to Endo Pharma LLC.

upon exercise, assuming the market price of our common stock is then \$30.00 per share, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$994 million, which could result in a tax benefit amount of approximately \$381 million payable to Endo Pharma LLC.

Under the terms of the tax sharing agreement, we must pay all such tax benefit amounts to Endo Pharma LLC to the extent these tax benefits are usable by us, as described above. However, these payments need only be made to Endo Pharma LLC upon the occurrence of a liquidity event, which is generally defined as a transaction or series of transactions resulting in (a) a sale of greater than 20% on a fully diluted basis of our common equity (either through (i) a primary offering by us, (ii) a secondary sale by Endo Pharma LLC or other holders of common stock pursuant to a registration rights agreement or (iii) a combination of both such primary and secondary offerings), (b) a change in control of Endo or (c) a sale of all or substantially all of our assets. In accordance with the tax sharing agreement, no payments have been made or accrued to date. On July 8, 2003, a secondary sale by Endo Pharma LLC was closed which represented a sale of, on a fully diluted basis, approximately 12% of our common equity which did not, by itself, trigger a payment under the tax sharing agreement, and was not a liquidity event. That offering may, however, be combined with future offerings to result in a series of transactions that will trigger a payment obligation pursuant to the tax sharing agreement. A secondary sale of 11 million shares by Endo Pharma LLC is expected to close on August 9, 2004 with an over-allotment option for an additional 1.65 million shares. This offering, when combined with the 16.6 million shares sold in July 2003, will constitute a liquidity event and thus will trigger a payment obligation as discussed below. Endo Pharma LLC has informed us that, subject to a variety of factors, including market conditions and stock price levels, it may initiate additional secondary offerings of our common stock in the future.

On April 30, 2004 the tax sharing agreement was amended to provide for a specific schedule upon which payments currently contemplated by the tax sharing agreement would be made once a liquidity event has occurred. The amendment provides that upon the occurrence of a liquidity event, we will pay to Endo Pharma LLC, within 30 business days, the amount of the tax benefits usable by us in each of the previous taxable years for which we have filed a federal income tax return. In addition, the amended tax sharing agreement provides that with respect to all taxable years following the occurrence of a liquidity event, the amount of the tax benefits usable by us in each such year will be paid to Endo Pharma LLC in two installments: (i) 50% of the estimated amount shall be paid within 15 business days of our receipt from our independent auditors of an opinion on our final audited financial statements, and (ii) the remaining amount shall be paid within 30 business days of the filing of our federal income tax return. Finally, the amendment also clarifies two matters related to determining the occurrence of when a liquidity event has occurred:

(i) the amendment establishes a formula for calculating when a sale of 20% of the common equity of Endo has occurred, and (ii) the amendment specifies that secondary sales of Endo common stock include sales pursuant to a shelf registration statement.

Under the amended tax sharing agreement, the sale of the 11 million shares of our common stock expected to close on August 9, 2004 when added to the 16.6 million shares sold in July 2003 will cause a liquidity event to occur, and we will be obligated to pay to Endo Pharma LLC, within 30 business days, the tax benefit amounts attributable to 2001 and 2002 of approximately \$2 million and \$1 million, respectively. We will also be obligated to pay to Endo Pharma LLC, 50% of the estimated tax benefit amount of approximately \$9 million attributable to 2003 within 30 business days, and the remaining 50% of the tax benefit amount attributable to 2003 within 30 business days of the date on which we file our 2003 tax return with the Internal Revenue Service (which we estimate will occur in September 2004). In addition, since 3.8 million shares underlying stock options granted under the Endo Pharma LLC

## **Table of Contents**

stock option plans will be exercised into common stock and sold in the offering expected to close on August 9, 2004, at a price of \$17.46, with a weighted average exercise price of \$2.44, an assumed tax rate of 38.3% and assuming the attributable compensation charge deductions are usable to reduce our taxes in 2004, we will be obligated to pay Endo Pharma LLC a tax benefit of approximately \$22 million. If the over-allotment option is exercised, resulting in the exercise of 0.6 million additional options at an average exercise price of \$2.44, and assuming a tax rate of 38.3% and that the attributable compensation charge deductions are useable to reduce our taxes in 2004, we will be obligated to pay to Endo Pharma LLC an additional tax benefit of approximately \$3 million. Fifty percent of the tax benefit amount attributable to this offering and any additional offering in 2004 will be due within 15 business days of the date we receive an opinion on our audited 2004 financial statements from our independent registered public accounting firm (which we estimate will occur within 60 days of our fiscal year-end of December 31, 2004) and the remaining fifty percent of the tax benefit amount attributable to 2004 is due within 30 business days of the date on which we file our 2004 tax return with the Internal Revenue Service (which we estimate will occur in September 2005). This estimated tax benefit amount payment to Endo Pharma LLC attributable to Endo Pharma LLC stock options exercised in 2004 may increase if certain holders of Endo Pharma LLC stock options exercise additional stock options in 2004.

On April 30, 2004, we filed a shelf registration statement on Form S-3, as amended on June 10, June 14 and June 25, 2004, providing for the sale by Endo Pharma LLC and certain other selling stockholders to be named therein, including certain of our directors and officers, from time to time, of up to 30 million currently issued and outstanding shares of our common stock. The shelf registration statement was declared effective by the Securities and Exchange Commission on June 28, 2004. After the closing of the August 9, 2004 offering of the 11 million shares (or 12.65 million shares if the over allotment option is exercised in full) discussed above, up to 19 million shares (or 17.35 million shares if over-allotment option is exercised in full) will remain eligible for sale by Endo Pharma LLC under this shelf registration statement. The shelf registration statement enables one or more offerings of common stock, subject to market conditions. The nature and terms of any offering will be established at the time of the offering and set forth in a prospectus supplement. Any offering would not increase the number of our outstanding shares of common stock and we would not receive any proceeds from any offering covered by this shelf registration.

## **9. COMMITMENTS AND CONTINGENCIES**

**License and Collaboration Agreements** We enter into licenses and collaboration agreements to develop, use, market and promote certain of our products from or with other pharmaceutical companies and universities. A description of the material terms of our significant third party license and collaboration agreements follows:

### *Penwest Pharmaceuticals*

In September 1997, we entered into a collaboration agreement with Penwest Pharmaceuticals to exclusively co-develop opioid analgesic products for pain management, using Penwest's patent-protected proprietary technology, for commercial sale worldwide. On April 2, 2002, we amended and restated this agreement to provide, among other things, that this collaboration would cover only that opioid analgesic product currently under development by the parties, namely, oxymorphone ER. We have historically shared on an equal basis the costs of products developed under this agreement and will, in the future, share costs and profits on an equal basis (subject to the recoupment discussed below). On March 18, 2003, we received notice from Penwest that it was exercising its right under the agreement to cease funding its share of the development and pre-launch marketing costs of oxymorphone ER on account of their concern about their ability to access external capital funding opportunities in the future. Accordingly, we are now responsible for funding 100% of these remaining costs until oxymorphone ER is approved by the FDA, at which time we will recoup from the royalties due to Penwest the full amount of what Penwest should have contributed had it not exercised such right. On May 7, 2004, we announced that the FDA is requiring us to initiate a new clinical trial to provide additional safety and efficacy data of oxymorphone ER in support of our New Drug Application (NDA) for this developmental product. On July 7, 2004, we announced that we had reached agreement with the FDA



as to the design of a new clinical trial to provide additional safety and efficacy data of oxymorphone ER in support of our NDA for this developmental product. We had submitted the trial protocol to FDA under the Special Protocol Assessment (SPA) process. Under the terms of the SPA, we will initiate a 12-week, multicenter, double-blinded, placebo-controlled trial of oxymorphone ER. We have exclusive U.S. marketing rights with respect to oxymorphone ER, subject to the terms and conditions contained in this agreement.

*DURECT Corporation*

On November 8, 2002, we entered into a Development, Commercialization and Supply License Agreement with DURECT Corporation, which relates to DURECT's development product, CHRONOGESIC. On January 28, 2004, we amended the

**Table of Contents**

Agreement with DURECT, essentially modifying our funding obligations of the ongoing development costs of CHRONOGESIC to take into account the program delay. The clinical development program of CHRONOGESIC is on temporary hold pending DURECT's implementation of some necessary design and manufacturing enhancements to CHRONOGESIC. DURECT has informed us that it anticipates that the implementation of these design and manufacturing enhancements will delay the restart of the clinical development program. On July 21, 2004, DURECT announced that it would not be resuming human clinical trials of the CHRONOGESIC product in 2004. DURECT had initiated the process of clinical manufacturing of CHRONOGESIC following a series of promising results of in vitro studies and in vivo animal studies of the most recent CHRONOGESIC system design. However, they learned recently from a further animal study that they have not yet solved the pre-mature shutdown problem (a stoppage in the delivery of drug before the intended full duration of delivery). DURECT continues to work to address this issue in order to bring this product to market.

Under the terms of this agreement, as amended, for the period commencing January 1, 2004 until the earlier of January 1, 2005 or the commencement of a specified clinical trial, we will fund 25% of the ongoing development costs for the CHRONOGESIC product in the U.S. and Canada excluding system redesign costs and pharmacokinetic trials necessitated by any system redesign up to an aggregate amount of \$250,000 for the period. Once a specified clinical trial of CHRONOGESIC is started or beginning on January 1, 2005 (whichever is earlier), unless the agreement is earlier terminated, we will be obligated to fund 50% of the ongoing development costs of CHRONOGESIC. We will also reimburse DURECT for a portion of its prior development costs upon the achievement of certain milestones. Milestone payments made by Endo under this agreement could total up to \$52.0 million. In addition, under this agreement, DURECT licensed to us the exclusive promotional rights to CHRONOGESIC in the U.S. and Canada. We will be responsible for marketing, sales and distribution, including providing technical support representatives dedicated to supplying technical and training support. DURECT will be responsible for the manufacture of CHRONOGESIC. We and DURECT will share profits equally, based on projected financial performance of CHRONOGESIC. Further, this agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. This agreement generally lasts until the underlying patents on the product expire. With respect to termination rights, this agreement permits us to terminate our continued participation under a number of circumstances, one of which could require us to pay DURECT \$10.0 million.

*SkyePharma, Inc.*

On December 31, 2002, we entered into a Development and Marketing Strategic Alliance Agreement with SkyePharma, Inc. and SkyePharma Canada, Inc. relating to two of SkyePharma's patented development products, DepoDur, previously referred to as DepoMorphine and Propofol IDD-D (collectively, the Skye Products). Under the terms of the Agreement, we received an exclusive license to the U.S. and Canadian marketing and distribution rights for the Skye Products, with options for certain other development products. In return, SkyePharma received a \$25 million upfront payment from us, which we capitalized as an intangible asset representing the fair value of the exclusive license of these distribution and marketing rights. We are amortizing this intangible asset over its useful life of 17 years. In addition, SkyePharma may receive milestone payments in addition to the \$25 million upfront payment of up to \$95 million, which include total milestones of \$10 million for DepoDur through FDA approval. During 2003, we paid and expensed \$5 million to SkyePharma upon the acceptance by the FDA of the NDA for DepoDur. In May 2004, we accrued and expensed a \$5 million milestone payment due to SkyePharma upon the approval of the NDA for DepoDur by the FDA. The milestone payments also include \$50 million for Propofol IDD-D, payable when the product successfully achieves certain regulatory milestones, including FDA approval. In April 2004, we paid and expensed \$5 million to SkyePharma upon the advancement of Propofol IDD-D into Phase III. The total further includes a \$15 million milestone payable when net sales of DepoDur exceed \$125 million in a calendar year and a \$20 million milestone payable when net sales of DepoDur exceed \$175 million in a calendar year. SkyePharma will also receive a share of each product's sales revenue that will increase from 20% initially, to a maximum of 60%, of net

sales as the Skye Products combined net sales achieve certain thresholds. This agreement provides for the parties to work together to complete the necessary clinical, regulatory and manufacturing work for North American regulatory approval of the Skye Products. SkyePharma will be primarily responsible for clinical development up to final FDA approval, and for the manufacture of the Skye Products, including all associated costs. Upon approval, we will market each Skye Product in the U.S. and Canada, with SkyePharma as the supplier. We will be responsible for funding and conducting any post-marketing studies and for all selling and marketing expenses. Under this agreement, we also obtained options on other SkyePharma development products, including DepoBupivacaine, a long-acting, sustained release formulation of the local anesthetic bupivacaine. We have the option to obtain commercialization rights for this product when SkyePharma successfully completes its Phase II trials, as well as any further SkyePharma products formulated using the DepoFoam technology successfully developed for the prophylaxis or treatment of pain. In addition, this agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. This agreement generally lasts until the underlying patents on the product expire. With respect to termination rights, this agreement permits us to terminate our continued participation under a number of circumstances, one

**Table of Contents**

of which could require us to pay SkyePharma \$5.0 million.

*Noven Pharmaceuticals, Inc.*

On February 25, 2004, we entered into a License Agreement and a Supply Agreement with Noven Pharmaceuticals, Inc., under which Noven exclusively licensed to us the U.S. and Canadian rights to its developmental transdermal fentanyl patch, which is intended to be the generic equivalent of Johnson & Johnson's Duragesic (fentanyl transdermal system). Under this agreement, we made an upfront payment to Noven of \$8.0 million, \$6.5 million of which we capitalized as an intangible asset representing the fair value of the exclusive license of these distribution and marketing rights. We are amortizing this intangible asset over its useful life of 11 years. Upon our first commercial sale of the fentanyl patch, Noven is entitled to receive an additional payment ranging from \$5.0 million to \$10.0 million, depending on the timing of launch and the number of generic competitors on the market. Noven will manufacture and supply the product at its cost, and the two companies will share profits on undisclosed terms. The License Agreement also establishes an ongoing collaboration between the two companies to identify and develop additional new transdermal therapies. As part of this effort, Noven will undertake feasibility studies to determine whether certain compounds identified by the parties can be delivered through Noven's transdermal patch technology. We are expected to fund and manage clinical development of those compounds proceeding into clinical trials. In addition, this agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. This agreement generally lasts for a term of ten years from the first commercial sale of the developmental transdermal fentanyl patch product. With respect to termination rights, this agreement permits us to terminate our continued participation under a number of circumstances.

*EpiCept Corp.*

On December 19, 2003, we entered into a license granting us exclusive, worldwide rights to certain patents of EpiCept Corp. as well as exclusive, worldwide commercialization rights to EpiCept's LidoPAIN<sup>®</sup> BP product. The license agreement provides for Endo to pay EpiCept milestones as well as royalties on the net sales of EpiCept's LidoPAIN<sup>®</sup> BP product. EpiCept has also retained an option to co-promote the LidoPAIN<sup>®</sup> BP product. Under this agreement, we made an upfront payment to EpiCept of \$7.5 million which we capitalized as an intangible asset representing the fair value of the exclusive right and the patents. We are amortizing this intangible asset over its useful life of 13 years. Future payments made by us under this agreement, including regulatory milestones and sales thresholds but excluding royalties, could total up to \$82.5 million. In addition, this agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. This agreement generally lasts until the underlying patents expire.

*Hind Healthcare Inc.*

In November 1998, we entered into a license agreement with Hind Healthcare Inc. for the sole and exclusive right to develop, use, market, promote and sell Lidoderm<sup>®</sup> in the United States. We paid Hind up-front fees and milestone payments on the occurrence of certain events. From now until the shorter of (1) the life of the last-to-expire patent licensed pursuant to this license agreement and (2) November 20, 2011, we will pay Hind non-refundable royalties of 10% of net sales of the product, including a minimum annual royalty of at least \$500,000 per year. Because these royalty payments are based on the net sales of the product, the maximum cost of these royalty payments is uncertain at this time. During the three months ended June 30, 2004 and 2003, we accrued \$6.5 million and \$5.7 million, respectively, for this royalty. During the six months ended June 30, 2004 and 2003, we accrued \$13.8 million and \$10.3 million, respectively, for this royalty. This royalty is recorded as a reduction of net sales due to the unique nature of the license agreement and the characteristics of the involvement by Hind in Lidoderm<sup>®</sup>. Either party may terminate this agreement for material breach, or we may terminate it immediately upon termination of our supply

agreement with Teikoku. In September 1999, we launched Lidoderm<sup>®</sup>, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia. In March 2002, we extended this license with Hind to cover Lidoderm<sup>®</sup> in Canada and Mexico.

*Lavipharm*

In November 1999, Endo entered into a collaboration agreement with Lavipharm Laboratories, Inc. pursuant to which Endo obtained exclusive worldwide rights to Lavipharm's existing drug delivery technology platforms. Under the terms of this collaboration agreement, Endo paid an upfront license fee of \$1 million. In September 2001, we amended this agreement to limit its scope to one of Lavipharm's existing drug delivery technologies in combination with two specific active drug substances. In January 2004, we terminated this agreement and made a termination payment to Lavipharm of \$3 million plus the potential for up to an additional \$5 million upon the occurrence of future events. We wrote-off the unamortized portion of the upfront license fee and expensed the termination payment of \$3 million during the six months ended June 30, 2004.

**Table of Contents***Life Sciences Opportunities Fund (Institutional) II, L.P.*

On December 12, 2003, we entered into a subscription agreement to invest up to \$10 million into Life Sciences Opportunities Fund (Institutional) II, L.P.; a Delaware limited partnership formed to carry out investments in life science companies. As part of this investment, we are able to capitalize on the knowledge of LOF Partners, LLC, the general partner, and its access to, life sciences entities with promising pharmaceutical assets, technologies and management talent and on the general partner's wide range of industry contacts and resources.

**Employment Agreements**

We have entered into employment agreements with certain members of management.

**Research Contracts**

We routinely contract with universities, medical centers, contract research organizations and other institutions for the conduct of research and clinical studies on our behalf. These agreements are generally for the duration of the contracted study and contain provisions that allow us to terminate prior to completion.

**Collaboration Agreements**

We have entered into certain collaboration agreements with third parties for the development of pain management products. These agreements require us to share in the development costs of such products and grant marketing rights to us for such products. If our third party partners are unable or unwilling to fund their portion of the collaboration project with us, this may adversely affect our results of operations and cash flows in the foreseeable future.

**Contingencies**

We are, and may in the future be, subject to various claims or legal proceedings arising out of the normal course of business with respect to commercial matters, including product liabilities, patent infringement matters, governmental regulation and other actions. We cannot predict the timing or outcome of these claims or proceedings. Currently, the Company is not involved in any claim and/or legal proceeding with respect to which the amount of ultimate liability will, in the opinion of management, materially affect our financial position, results of operations or liquidity.

**10. Earnings Per Share**

The following is a reconciliation of the numerator and denominator of basic and diluted earnings per share (in thousands, except per share data):

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2004</b>	<b>2003</b>	<b>2004</b>	<b>2003</b>
Numerator:				
Net income available to common stockholders	\$ 31,548	\$ 45,168	\$ 72,722	\$ 61,527
Denominator:				
	131,792	131,734	131,786	125,014

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-Q

For basic per share data	weighted				
average shares					
Effect of dilutive stock options		997	933	973	7,405
		<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
For diluted per share data		132,789	132,667	132,759	132,419
Basic income per share		\$ 0.24	\$ 0.34	\$ 0.55	\$ 0.49
		<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Diluted income per share		\$ 0.24	\$ 0.34	\$ 0.55	\$ 0.46
		<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>

During the three and six months ended June 30, 2004, employees exercised stock options to acquire 7,869 and 26,844 shares of common stock at exercise prices ranging from \$9.29 to \$9.40 and \$7.25 to \$9.40, respectively.

**Table of Contents**

**11. Subsequent Events**

On July 14, 2004, we entered into a license agreement and a loan agreement with Vernalis Development Limited, or Vernalis, under which Vernalis agreed to exclusively license to us rights to market Frova (frovatriptan) in North America. Launched in the U.S. in June 2002, Frova is indicated for the acute treatment of migraine headaches in adults. Net sales of Frova in the U.S. were \$37.5 million in 2003. Under the terms of the license agreement, we will pay Vernalis an upfront fee of \$30 million, anniversary payments for the first two years at \$15 million each year, and a \$40 million milestone payment upon U.S. Food and Drug Administration, FDA, approval for the menstrually associated migraine indication. In addition, Vernalis will receive one-time milestone payments for achieving defined annual net sales targets. These sales milestone payments increase based on increasing net sales targets ranging from a milestone of \$10 million on \$200 million in net sales to a milestone of \$75 million on \$1.2 billion in net sales. These sales milestones could total up to \$255 million if all of the defined net sales targets are achieved. We will also pay royalties to Vernalis based on the net sales of Frova. In addition, the license agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of the license agreement is for the shorter of the time (i) that there are valid claims on the Vernalis patents covering Frova or there is market exclusivity granted by a regulatory authority, whichever is longer, or (ii) until the date on which a generic version of Frova is first offered, but in no event longer than 20 years. We can terminate the license agreement under certain circumstances, including upon one years written notice. The license agreement is subject to a number of closing conditions, including obtaining clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended. Under the loan agreement, Endo will provide Vernalis with a loan of \$50 million at closing. The loan will primarily be used to make a payment in full and final settlement of the amounts currently due to Elan Corporation from Vernalis in connection with Vernalis reacquisition of the North American rights to Frova. The balance of the loan will be available for general corporate purposes. The loan will be secured against the revenues receivable by Vernalis under the license agreement. At Endo's election, Endo is able to offset \$20 million of the \$40 million MAM approval milestone and 50% of all royalties to be paid under the license agreement to Vernalis to repay the loan. To the extent not previously repaid, the loan is due in full after five years. Interest is at the rate of 5% per annum payable semi-annually. However, Vernalis has the option to defer payment of interest and increase the loan outstanding each time an interest payment becomes due.



**Table of Contents**

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

Except for the historical information contained in this Report, this Report, including the following discussion, contains forward-looking statements that involve risks and uncertainties. See *Forward-Looking Statements* on page 3 of this Report.

**Overview**

We, through our wholly owned subsidiary, Endo Pharmaceuticals Inc., are engaged in the research, development, sales and marketing of branded and generic prescription pharmaceuticals used primarily for the treatment and management of pain. Branded products comprised approximately 63%, 70% and 59% of net sales for the years ended December 31, 2002, 2003 and the six months ended June 30, 2004, respectively. On August 26, 1997, an affiliate of Kelso & Company and the then members of management entered into an asset purchase agreement with the then DuPont Merck Pharmaceutical Company to acquire certain branded and generic pharmaceutical products and exclusive worldwide rights to a number of new chemical entities in the DuPont research and development pipeline from DuPont Merck through the newly-formed Endo Pharmaceuticals Inc. The stock of Endo Pharmaceuticals Inc. is our only asset, and we have no other operations or business.

On March 23, 2004, the U.S. Food and Drug Administration (FDA) granted final approval of our abbreviated new drug application (ANDA) for oxycodone extended-release tablets, 10mg, 20mg and 40mg, and confirmed its tentative approval of our 80 mg dosage strength. Our oxycodone extended-release tablets are AB-rated bioequivalent versions of the 10mg, 20mg and 40mg strengths of OxyContin, a product of The Purdue Frederick Company that is indicated for the management of moderate-to-severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. OxyContin had combined 2003 U.S. branded sales of approximately \$1.9 billion. The 10mg, 20mg and 40mg strengths represent approximately 63% of the U.S. branded sales of OxyContin. As announced on May 17, 2004, we have decided to wait until appellate review of the district court's decision to launch our 10mg, 20mg and 40mg bioequivalent versions of generic OxyContin. However, if upon further examination we determine that is in our best interest to launch one or more of our bioequivalent versions of OxyContin in advance of the appellate court decision and the district court's ruling is overturned on appeal, we may be liable for lost profits and damages to Purdue and costs associated with the launching of our products. Any launch by us of one or more of our bioequivalent versions of OxyContin could significantly impact our future results.

On April 30, 2004, we filed a shelf registration statement on Form S-3, as amended on June 10, June 14, and June 25, 2004, providing for the sale by Endo Pharma LLC and certain other selling stockholders named therein, including certain of our directors and officers, from time to time, of up to 30 million currently issued and outstanding shares of our common stock. The shelf registration statement was declared effective by the Securities and Exchange Commission on June 28, 2004. After the closing of the August 9, 2004 offering of the 11 million shares (or 12.65 million shares if the over allotment option is exercised in full) discussed above, up to 19 million shares (or 17.35 million shares if over-allotment option is exercised in full) will remain eligible for sale by Endo Pharma LLC under this shelf registration statement. The shelf registration statement enables one or more offerings of common stock, subject to market conditions. The nature and terms of any offering will be established at the time of the offering and set forth in a prospectus supplement. Any offering will not increase the number of our outstanding shares of common stock, and we will not receive any proceeds from any offering covered by this shelf registration.

On May 19, 2004, we and SkyePharma, Inc., our collaboration partner, announced that the FDA had approved SkyePharma's NDA for DepoDur for the treatment of pain following major surgery. Previously referred to as DepoMorphine, DepoDur is a novel single dose sustained-release injectable formulation of morphine. We believe the approval of DepoDur is an important step in fulfilling our vision of building our franchise in pain management as well

as extending our reach into complementary therapeutic areas such as anesthesiology. We expect to be in a position to commercialize DepoDur by the end of 2004 provided SkyePharma is able to provide sufficient inventory to support the launch of the product. This launch could significantly impact our future results.

On July 7, 2004, we announced that we had reached agreement with the FDA as to the design of a new clinical trial to provide additional safety and efficacy data of oxymorphone ER in support of our NDA for this developmental product. We had submitted the trial protocol to the FDA under the Special Protocol Assessment (SPA) process. Under the terms of the SPA, we will initiate a 12-week, multicenter, double-blinded, placebo-controlled trial of oxymorphone ER. As previously disclosed on October 20, 2003, the FDA issued an approvable letter for our oxymorphone ER NDA but had requested that we address certain questions and provide additional clarification and information, including some form of additional clinical trial to further confirm the safety and efficacy of this product. Also as previously announced, the FDA, following a meeting with us in early May, indicated its concern that the outcome of two of the three Phase III efficacy trials submitted in the NDA that met their predefined primary end-points may have been

## **Table of Contents**

favorably biased by the statistical handling of data from patients who did not complete the trials. The design of this additional clinical trial is intended to address this issue. Based on the duration of the trial and the number of patients to be enrolled, we believe that, assuming the data are favorable, we will be in a position to finish the study and submit the complete response to the FDA in the late third quarter or early fourth quarter of 2005. At that point, the FDA will have six months to act on this complete response to its October 2003 approvable letter.

On July 14, 2004, we entered into a license agreement and a loan agreement with Vernalis Development Limited, or Vernalis, under which Vernalis agreed to exclusively license to us rights to market Frova (frovatriptan) in North America. Launched in the U.S. in June 2002, Frova is indicated for the acute treatment of migraine headaches in adults. Net sales of Frova in the U.S. were \$37.5 million in 2003. Under the terms of the license agreement, we will pay Vernalis an upfront fee of \$30 million, anniversary payments for the first two years at \$15 million each year, and a \$40 million milestone payment upon U.S. Food and Drug Administration, FDA, approval for the menstrually associated migraine indication. In addition, Vernalis will receive one-time milestone payments for achieving defined annual net sales targets. These sales milestone payments increase based on increasing net sales targets ranging from a milestone of \$10 million on \$200 million in net sales to a milestone of \$75 million on \$1.2 billion in net sales. These sales milestones could total up to \$255 million if all of the defined net sales targets are achieved. We will also pay royalties to Vernalis based on the net sales of Frova. In addition, the license agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of the license agreement is for the shorter of the time (i) that there are valid claims on the Vernalis patents covering Frova or there is market exclusivity granted by a regulatory authority, whichever is longer, or (ii) until the date on which a generic version of Frova is first offered, but in no event longer than 20 years. We can terminate the license agreement under certain circumstances, including upon one years written notice. The license agreement is subject to a number of closing conditions, including obtaining clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended. Under the loan agreement, Endo will provide Vernalis with a loan of \$50 million at closing. The loan will primarily be used to pay in full the amounts currently due to Elan Corporation from Vernalis in connection with Vernalis reacquisition of the North American rights to Frova. The balance of the loan will be available for Vernalis general corporate purposes. The loan will be secured against the revenues receivable by Vernalis under the license agreement. At Endo's election, Endo is able to offset \$20 million of the \$40 million MAM approval milestone and 50% of all royalties to be paid under the license agreement to Vernalis to repay the loan. To the extent not previously repaid, the loan is due in full after five years. Interest is at the rate of 5% per annum payable semi-annually; however, Vernalis has the option to defer payment of interest and increase the loan outstanding each time an interest payment becomes due.

Our quarterly results have fluctuated in the past, and may continue to fluctuate. These fluctuations are primarily due to the timing of new product launches, purchasing patterns of our customers, market acceptance of our products, the impact of competitive products and pricing as well as charges incurred for compensation related to stock options and milestone payments.

## **Critical Accounting Policies and Estimates**

To understand our financial statements, it is important to understand our critical accounting policies and estimates. The preparation of our financial statements in conformity with accounting principles generally accepted in the United States requires us 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 revenues and expenses during the reporting period. Significant estimates and assumptions are required in the determination of sales deductions for estimated chargebacks, rebates, sales incentives and allowances, royalties and returns and losses. Significant estimates and assumptions are also required in the appropriateness of amortization periods for identifiable intangible assets, inventory reserves and the potential impairment of goodwill and other

intangible assets. Some of these judgments can be subjective and complex, and, consequently, actual results may differ from these estimates. For any given individual estimate or assumption made by us, there may also be other estimates or assumptions that are reasonable. We believe, however, that given current facts and circumstances, it is unlikely that applying any such other reasonable judgment would cause a material adverse effect on our consolidated results of operations, financial position or cash flows for the periods represented in this section. Our most critical accounting policies and estimates are described below:

***Sales Deductions***

When we recognize revenue from the sale of our products, we simultaneously record an adjustment to revenue for estimated chargebacks, rebates, sales incentives and allowances, royalties and returns and losses. These provisions are estimated based on historical experience, estimated future trends, estimated customer inventory levels, current contract sales terms with our wholesale and indirect customers and other competitive factors. If the assumptions we used to calculate these adjustments do not appropriately reflect future activity, our financial position, results of operations and cash flows could be impacted. The provision for chargebacks is the

**Table of Contents**

most significant and complex estimate used in the recognition of our revenue. We establish contract prices for indirect customers who are supplied by our wholesale customers. A chargeback represents the difference between our invoice price to the wholesaler and the indirect customer's contract price. Provisions for estimating chargebacks are calculated primarily using historical chargeback experience, estimated wholesaler inventory levels and estimated future trends. We establish contracts with wholesalers, chain stores and indirect customers that provide for rebates, sales incentives and other allowances. Some customers receive rebates upon attaining established sales volumes. We estimate rebates, sales incentives and other allowances based upon the terms of the contracts with our customers, historical experience, estimated inventory levels of our customers and estimated future trends. We estimate an accrual for Medicaid rebates as a reduction of revenue at the time product sales are recorded. The Medicaid rebate reserve is estimated based upon the historical payment experience, historical relationship to revenues and estimated future trends. Royalties represent amounts accrued pursuant to the license agreement with Hind Healthcare Inc. (Hind). Royalties are recorded as a reduction to net sales due to the nature of the license agreement and the characteristics of the license involvement by Hind in Lidoderm®. Royalties are paid to Hind at a rate of 10% of net sales of Lidoderm®. Our return policy allows customers to receive credit for expired products within three months prior to expiration and within one year after expiration. We estimate the provision for product returns based upon the historical experience of returns for each product, historical relationship to revenues, estimated future trends, estimated customer inventory levels and other competitive factors. We continually monitor the factors that influence each type of sales deduction and make adjustments as necessary.

***Inventories***

Inventories consist of finished goods held for distribution, raw materials and work in process. Our inventories are stated at the lower of cost or market. Cost is determined by the first-in, first-out method. We write down inventories to net realizable value based on forecasted demand and market conditions, which may differ from actual results.

***Amortizable Intangibles: Licenses***

Licenses are stated at cost, less accumulated amortization, and are amortized using the straight-line method over their estimated useful lives ranging from eleven to twenty years. We determine amortization periods for licenses based on our assessment of various factors impacting estimated useful lives and cash flows of the acquired rights. Such factors include the expected launch date of the product, the strength of the intellectual property protection of the product and various other competitive, developmental and regulatory issues, and contractual terms. Significant changes to any of these factors may result in a reduction in the useful life of the license and an acceleration of related amortization expense, which could cause our operating income, net income and earnings per share to decrease.

Licenses are assessed periodically for impairment in accordance with Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS No. 144). The impairment testing involves comparing the carrying amount of the asset to the forecasted undiscounted future cash flows of the product. In the event the carrying value of the asset exceeds the undiscounted future cash flows of the product and the carrying value is not considered recoverable, an impairment exists. An impairment loss is measured as the excess of the asset's carrying value over its fair value, calculated using a discounted future cash flow method. An impairment loss would be recognized in net income in the period that the impairment occurs.

***Goodwill and Other Intangibles***

Effective January 1, 2002, we adopted the provisions of SFAS No. 142, *Goodwill and Other Intangible Assets*, and no longer amortize goodwill and workforce in place. Goodwill and other intangibles represents a significant portion of our assets and stockholders' equity. As of June 30, 2004, goodwill and other intangibles comprised approximately 27% of our total assets and 36% of our stockholders' equity. SFAS No. 142 prescribes a two-step method for determining

goodwill impairment. In the first step, we determine the fair value of our one reporting unit. If the net book value of our reporting unit exceeds the fair value, we would then perform the second step of the impairment test which requires allocation of our reporting unit's fair value to all of its assets and liabilities in a manner similar to a purchase price allocation, with any residual fair value being allocated to goodwill. An impairment charge will be recognized only when the implied fair value of our reporting unit's goodwill is less than its carrying amount. As a result of the significance of goodwill, our results of operations and financial position in a future period could be negatively impacted should an impairment of goodwill occur.

We have one reportable segment, pharmaceutical products. Goodwill arose as a result of the August 26, 1997 acquisition of certain branded and generic pharmaceutical products, related rights and certain assets of the then DuPont Merck Pharmaceutical Company (n/k/a Bristol-Myers Squibb Pharma Company) and the July 17, 2000 acquisition of Algos. Although goodwill arose in two separate

**Table of Contents**

transactions, the components of our operating segment have been integrated and are managed as one reporting unit. Our components extensively share assets and other resources with the other components of our business and have similar economic characteristics. In addition, our components do not maintain discrete financial information. Accordingly, the components of our business have been aggregated into one reporting unit and are evaluated as such for goodwill impairment. Goodwill is evaluated for impairment on an annual basis on January 1st of each year unless events or circumstances indicate that an impairment may have occurred between annual dates. Goodwill was evaluated for impairment upon the adoption of SFAS No. 142 on January 1, 2002 and, based on the fair value of our reporting unit, no impairment was identified. On January 1, 2004 and 2003, our goodwill was evaluated for impairment and, based on the fair value of our reporting unit, no impairment was identified.

Our goodwill and other intangible assets consist of the following (in thousands):

	<b>June 30, 2004</b>	<b>December 31, 2003</b>
Goodwill	\$ 181,079	\$ 181,079
Amortizable Intangibles:		
Licenses	\$ 49,750	\$ 43,500
Patents	3,200	3,200
	52,950	46,700
Less accumulated amortization	(6,032)	(4,657)
Other Intangibles, net	\$ 46,918	\$ 42,043

Effective January 1, 2002, we reclassified the carrying amount of workforce-in-place as goodwill. The cost of license fees is capitalized and is being amortized using the straight-line method over the licenses' estimated useful lives ranging from eleven to twenty years. The cost of acquired patents is capitalized and is being amortized using the straight-line method over their estimated useful lives of seventeen years.

Estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2003 is as follows (in thousands):

2004	\$3,311
2005	3,366
2006	3,366
2007	3,366
2008	3,366

**Compensation Related to Stock Options    Endo Pharma LLC Stock Option Plans**

In our 2001 fiscal year we incurred a non-cash charge of \$37.3 million, in our 2002 fiscal year we recorded a non-cash charge of \$34.7 million and in our 2003 fiscal year we recorded non-cash charges of \$144.5 million, in each case for stock-based compensation relating to the vesting of options that were issued under the Endo Pharma LLC 1997 Amended and Restated Executive Stock Option Plan and the Endo Pharma LLC 1997 Amended and Restated Employee Stock Option Plan (together, the Endo Pharma LLC 1997 Stock Option Plans ) and the Endo Pharma LLC 2000 Supplemental Employee Stock Option Plan and the Endo Pharma LLC 2000 Supplemental Executive Stock Option Plan (collectively, the Endo Pharma LLC 2000 Supplemental Stock Option Plans ). Under the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans, tranches of options vested if we attained certain stock price targets. As each tranche vested, we incurred a non-cash charge representing the difference between the market price of the shares underlying the options and the exercise price of such options. Upon exercise, no additional shares of our common stock will be issued, however, because these stock options are exercisable only into shares of our common stock that are held by Endo Pharma LLC. Accordingly, these stock options do not dilute the public stockholders. In addition, Endo Pharma LLC, and not us, will receive the exercise price payable in connection with these options. Further, the shares of common stock that individuals receive upon exercise of stock options granted pursuant to the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans are currently subject to significant restrictions that are set forth in stockholders agreements.

For a discussion of the tax sharing agreement between the Company and Endo Pharma LLC relating to the Endo Pharma LLC Stock Options, see Liquidity and Capital Resources; Tax Sharing Agreement.



**Table of Contents****Compensation Related to Stock Options    Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan**

All the stock options we have granted pursuant to the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan have exercise prices equal to the market price of our stock on the date granted and, under accounting principles generally accepted in the United States of America, a measurement date occurs on the date of each grant. Consequently, we do not expect to incur a charge upon the vesting or exercise of those options.

**Compensation Related to Stock Options    Endo Pharmaceuticals Holdings Inc. 2004 Stock Incentive Plan**

In May 2004, our stockholders approved the Endo Pharmaceuticals Holdings Inc. 2004 Stock Incentive Plan. The maximum number of shares of Company stock reserved for issuance under the 2004 Plan is 4,000,000 shares. The 2004 Plan provides for the grant of stock options, stock appreciation rights, shares of restricted stock, performance shares, performance units or other share-based awards that may be granted to executive officers and other employees of the Company, including officers and directors who are employees, to non-employee directors and to consultants to the Company. No awards have been granted pursuant to this plan.

**Results of Operations***Net Sales*

Our net sales consist of revenues from sales of our pharmaceutical products, less estimates for certain chargebacks, rebates, sales incentives and allowances, royalties and returns and losses. We recognize revenue when products are shipped and title and risk of loss has passed to the customer, which is typically upon delivery to the customer. Our shipping terms are free on board customer's destination.

The following table presents our net sales by product category for the three months and six months ended June 30, 2004 and 2003.

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2004</b>	<b>2003</b>	<b>2004</b>	<b>2003</b>
	<b>(in thousands)</b>		<b>(in thousands)</b>	
Lidoderm®	\$ 58,235	\$ 50,617	\$ 123,591	\$ 92,107
Percocet®	13,624	52,434	44,368	107,893
Other brands	3,106	8,098	7,456	15,477
	<hr/>	<hr/>	<hr/>	<hr/>
Total brands	\$ 74,965	\$ 111,149	\$ 175,415	\$ 215,477
Total generics	\$ 69,003	\$ 40,878	\$ 122,042	\$ 88,824
	<hr/>	<hr/>	<hr/>	<hr/>
Total net sales	\$ 143,968	\$ 152,027	\$ 297,457	\$ 304,301
	<hr/>	<hr/>	<hr/>	<hr/>

The following table presents our net sales of select products as a percentage of total net sales for the three months and six months ended June 30, 2004 and 2003.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Lidoderm®	40%	33%	42%	30%
Percocet®	10%	35%	15%	36%
Other brands	2%	5%	2%	5%
	<hr/>	<hr/>	<hr/>	<hr/>
Total brands	52%	73%	59%	71%
Total generics	48%	27%	41%	29%
	<hr/>	<hr/>	<hr/>	<hr/>
Total net sales	100%	100%	100%	100%
	<hr/>	<hr/>	<hr/>	<hr/>

*Three Months Ended June 30, 2004 Compared to the Three Months Ended June 30, 2003*

**Net Sales.** Net sales for the three months ended June 30, 2004 decreased to \$144.0 million from \$152.0 million in the comparable 2003 period. This decrease in net sales was primarily due to the reduction in the net sales of Percocet® offset by the increase in the net sales of Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia, and certain generic

**Table of Contents**

products. Net sales of Lidoderm® increased to \$58.2 million from \$50.6 million in the comparable 2003 period. In September 1999, we launched Lidoderm®, which continues to gain market share due to our ongoing promotional and educational efforts. Net sales of our generic products increased 69% to \$69.0 million from \$40.9 million in the comparable 2003 period primarily due to the growth of Endocet®. We experienced a decrease in net sales of our morphine sulfate extended release tablets due to generic competition introduced in the third quarter of 2003; however, this was offset by our launch in the fourth quarter of 2003 of two new strengths of Endocet®. During the second quarter of 2004, another competitor announced that they had received approval to market two of the five strengths of morphine sulfate extended-release tablets. In addition, during the second quarter of 2004, another competitor received approval for a product that competes with Endocet® 7.5/325, 7.5/500, 10.0/325 and 10.0/650. We expect this additional competition to adversely impact our market share and price of both Endocet® and our morphine sulfate extended-release. Percocet® net sales decreased to \$13.6 million from \$52.4 million in the comparable 2003 period due to the introduction of generic versions of Percocet® 7.5/325 and 10/325 during the fourth quarter of 2003. Generic competition with our products may have a material impact on our results of operations and cash flows in the future. We are raising our financial guidance for 2004 and believe that we are currently well-positioned to achieve 2004 net sales of approximately \$590 to \$600 million. Further, we reaffirm our previous guidance for Lidoderm® net sales to be approximately \$300 million in 2004. In addition, we anticipate diluted earnings per share for the year ended December 31, 2004 to be approximately \$0.88 to \$0.90 per share. Our guidance includes the revenue and costs associated with the launch of DepoDur and Frova and factoring in the additional clinical trials for our immediate-release and extended-release oxymorphone. Of course, there can be no assurance of Endo achieving these results.

**Gross Profit.** Gross profit for the three months ended June 30, 2004 decreased by 9% to \$115.1 million from \$125.8 million in the comparable 2003 period. Gross profit margins decreased to 80% from 83% due to the shift in revenues from higher-margin Percocet® to generic Endocet® combined with the impact of pricing pressure on our generic morphine sulfate product and the introduction of child-resistant packaging for Lidoderm® during the second quarter of 2004. We expect gross profit margins to continue to decrease in 2004.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses for the three months ended June 30, 2004 increased by 3% to \$43.0 million from \$41.8 million in the comparable 2003 period. This increase was primarily due to the increase in educational and promotional efforts in 2004 over the comparable 2003 period to support our products, as well as support provided to our new product pipeline in anticipation of product launches.

**Research and Development Expenses.** Research and development expenses for the three months ended June 30, 2004 increased by \$9.8 million to \$19.2 million from \$9.4 million in the comparable 2003 period. This increase is primarily attributable to \$10 million in milestone payments, incurred in the second quarter of 2004, to SkyePharma related to the FDA approval of DepoDur and the advance of Propofol IDD-D into Phase III clinical development.

**Depreciation and Amortization.** Depreciation and amortization for the three months ended June 30, 2004 increased to \$2.3 million from \$1.4 million in the comparable 2003 period primarily due to an increase in depreciation expense as a result of an increase in capital expenditures. We expect depreciation and amortization to continue to increase as we increase our capital expenditures for new office and lab space and automobiles for our newly hired sales representatives, and as we continue to license in products and technologies.

**Interest (Income) Expense, Net.** Interest (income) expense, net for the three months ended June 30, 2004 was \$228,000 in interest income compared to \$22,000 in interest expense in the comparable 2003 period. This change is substantially due to the increased interest income earned as a result of higher cash balances during the second quarter of 2004.

**Income Tax.** Income tax for the three months ended June 30, 2004 decreased to \$19.2 million from \$28.0 million in the comparable 2003 period. This decrease is due to the decrease in income before income tax for the three months ended June 30, 2004.

*Six Months Ended June 30, 2004 Compared to the Six Months Ended June 30, 2003*

**Net Sales.** Net sales for the six months ended June 30, 2004 decreased to \$297.5 million from \$304.3 million in the comparable 2003 period. This decrease in net sales was primarily due to the reduction in the net sales of Percocet® offset by the increase in the net sales of Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia, and certain generic products. Net sales of Lidoderm® increased to \$123.6 million from \$92.1 million in the comparable 2003 period. In September 1999, we launched Lidoderm®, which continues to gain market share due to our ongoing promotional and educational efforts. Net sales of our generic products increased 37% to \$122.0 million from \$88.8 million in the comparable 2003 period primarily due to the growth of Endocet®. We experienced a decrease in net sales of our morphine sulfate extended release tablets due to generic competition

**Table of Contents**

introduced in the third quarter of 2003; however, this was offset by our launch in the fourth quarter of 2003 of two new strengths of Endocet®. During the second quarter of 2004, another competitor announced that they had received approval to market two of the five strengths of morphine sulfate extended-release tablets. In addition, during the second quarter of 2004, another competitor received approval for a product that competes with Endocet® 7.5/325, 7.5/500, 10.0/325 and 10.0/650. We expect this additional competition to adversely impact our market share and price of both Endocet® and our morphine sulfate extended-release. Percocet® net sales decreased to \$44.4 million from \$107.9 million in the comparable 2003 period due to the introduction of generic versions of Percocet® 7.5/325 and 10/325 during the fourth quarter of 2003. Generic competition with our products may have a material impact on our results of operations and cash flows in the future. We are raising our financial guidance for 2004 and believe that we are currently well-positioned to achieve 2004 net sales of approximately \$590 to \$600 million. Further, we reaffirm our previous guidance for Lidoderm® net sales to be approximately \$300 million in 2004. In addition, we anticipate diluted earnings per share for the year ended December 31, 2004 to be approximately \$0.88 to \$0.90 per share. Our guidance includes the revenue and costs associated with the launch of DepoDur and Frova and factoring in the additional clinical trials for our immediate-release and extended-release oxymorphone. Of course, there can be no assurance of Endo achieving these results.

**Gross Profit.** Gross profit for the six months ended June 30, 2004 decreased by 6% to \$235.7 million from \$250.5 million in the comparable 2003 period. Gross profit margins decreased to 79% from 82% due to the shift in revenues from higher-margin Percocet® to generic Endocet® combined with the impact of pricing pressure on our generic morphine sulfate product and the introduction of child-resistant packaging for Lidoderm® during the second quarter of 2004. We expect gross profit margins to continue to decrease in 2004.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses for the six months ended June 30, 2004 increased by 5% to \$81.8 million from \$77.9 million in the comparable 2003 period. This increase was primarily due to the increase in educational and promotional efforts in 2004 over the comparable 2003 period to support our products, as well as support provided to our new product pipeline in anticipation of product launches.

**Research and Development Expenses.** Research and development expenses for the six months ended June 30, 2004 increased by 35% to \$29.0 million from \$21.5 million in the comparable 2003 period. This increase is primarily attributable to \$10 million in milestone payments, incurred in the second quarter of 2004, to SkyePharma related to the FDA approval of DepoDur and the advance of Propofol IDD-D into Phase III clinical development.

**Depreciation and Amortization.** Depreciation and amortization for the six months ended June 30, 2004 increased to \$4.1 million from \$2.7 million in the comparable 2003 period primarily due to an increase in depreciation expense as a result of an increase in capital expenditures. We expect depreciation and amortization to continue to increase as we increase our capital expenditures for new office and lab space and automobiles for our newly hired sales representatives, and as we continue to license in products and technologies.

**Loss on Disposal of Other Intangible.** The loss on disposal of other intangible is due to the termination of our collaboration agreement with Lavipharm and the resulting write-off of the unamortized portion of the upfront license fee of \$0.8 million. The loss also includes a \$3 million termination payment made by us to Lavipharm.

**Compensation Related to Stock Options.** Compensation related to stock options decreased to \$0 during the six months ended June 30, 2004 from \$48.5 million during the six months ended June 30, 2003. Effective January 1, 2003, the Endo Pharma LLC 2000 Supplemental Stock Option Plans became effective resulting in the issuance of approximately 10.7 million stock options to certain employees and members of management. Because approximately 9.2 million of these stock options were immediately vested upon their issuance, we recorded a non-cash compensation charge of approximately \$48.5 million in the first quarter of 2003 representing the difference between the market price

of the common stock of \$7.70 and the exercise price of these stock options of \$2.42. No additional shares of Company common stock will be issued, however, because these stock options are exercisable only into shares of Company common stock that are held by Endo Pharma LLC. Accordingly, these stock options do not dilute the ownership of our other public stockholders.

**Interest (Income) Expense, Net.** Interest (income) expense, net for the three months ended June 30, 2004 was \$218,000 in interest income compared to \$153,000 in interest expense in the comparable 2003 period. This change is substantially due to the increased interest income earned as a result of higher cash balances during the first half of 2004.

**Income Tax.** Income tax for the six months ended June 30, 2004 increased to \$44.5 million from \$38.1 million in the comparable 2003 period. This increase is due to the increase in income before income tax for the six months ended June 30, 2004.

**Table of Contents***Liquidity and Capital Resources*

Our principal source of liquidity is cash generated from operations. Under our credit facility, we may borrow up to \$75.0 million on a revolving basis for certain purposes as described below. Our principal liquidity requirements are for working capital for operations, acquisitions, licenses and capital expenditures.

***Net Cash Provided by Operating Activities.*** Net cash provided by operating activities decreased to \$15.1 million for the six months ended June 30, 2004 from \$139.1 million for the six months ended June 30, 2003. This decrease primarily reflects an increase in accounts receivable and an increase in our inventory levels. The increase in accounts receivable is substantially attributable to an increase in the proportion of revenues of our generic products, which have payment terms of 60 days, compared to our branded products, which have payment terms of 30 days, as well as the timing of purchases by our customers. The increase in our inventory levels is substantially due to an increase in our inventory of Lidoderm®. Historically, we have carried low inventory levels of Lidoderm® due to our manufacturing not being able to keep up with demand. This year, additional capacity has been added and our manufacturing of Lidoderm® and we have built up a safety stock of Lidoderm® inventory. We are at this time, however, carrying more Lidoderm® inventory than we would like to. Although we do not believe that there is a risk of obsolescence with this inventory, we and our manufacturer will be working together over the remainder of 2004 to bring the Lidoderm® inventory to more appropriate levels. In addition, during the second quarter of 2004, we made the decision to manufacture an additional \$4.5 million of our generic oxycodone extended-release tablets. We did not reserve for this inventory and, although there can be no assurance, we remain confident that the decision of the U.S. District Court for the Southern District of New York declaring Purdue's OxyContin patents unenforceable will be affirmed by the U.S. Court of Appeals for the Federal Circuit.

***Net Cash Utilized in Investing Activities.*** Net cash utilized in investing activities decreased by \$14.6 million to \$12.7 million for the six months ended June 30, 2004 from \$27.3 million for the six months ended June 30, 2003. During the six months ended June 30, 2004, the Company paid \$7.3 million in license fees, a termination penalty of \$3 million to Lavipharm and had capital expenditures of \$2.6 million primarily related to our new research and development facility in Long Island, NY compared to a \$25.0 million license fee to SkyePharma, Inc. for the marketing rights to DepoDur and Propofol IDD-D and \$2.3 million in capital expenditures during the six months ended June 30, 2003.

***Net Cash Utilized in Financing Activities.*** Net cash utilized in financing activities increased to \$0.4 million for the six months ended June 30, 2004 from \$0.2 million for the six months ended June 30, 2003 primarily due an increase in capital lease obligations repayments made during the first half of 2004 compared to 2003 partially offset by an increase in the proceeds received from the exercise of stock options.

***Credit Facility.*** In December 2001, we amended and restated our senior secured credit facility with a number of lenders. This amended and restated credit facility provides us with a line of credit of \$75.0 million. The line of credit matures on December 21, 2006. Any loans outstanding under the amended and restated credit facility are secured by a first priority security interest in substantially all of our assets. The credit facility contains representations and warranties, covenants, including a covenant requiring us to maintain minimum EBITDA of \$50 million over the prior four-quarter period, events of default and other provisions customarily found in similar agreements. Our ability to borrow under the credit facility is dependent, among other things, on our compliance with those provisions. On April 30, 2004, we amended our credit facility to allow us to file a shelf registration statement on Form S-3, which we initially filed on April 30, 2004, providing for the sale by Endo Pharma LLC and certain other selling stockholders to be named therein, including certain of our directors and officers, from time to time, of up to 30 million currently issued and outstanding shares of our common stock. On July 13, 2004, we amended our credit facility to allow us to enter in the transaction with Vernalis. As of June 30, 2004, we have not borrowed any amounts under our credit facility.

***Tax Sharing Agreement.*** On July 14, 2000, Endo Pharma LLC was formed in connection with the Algos merger to ensure that the stock options granted pursuant to the Endo Pharma LLC Stock Option Plans diluted only the Endo common stock held by persons and entities that held such shares prior to our merger with Algos. Upon the exercise of these stock options, only currently outstanding shares of our common stock held by Endo Pharma LLC will be delivered. Because Endo Pharma LLC, and not us, will provide the shares upon the exercise of these options, we have entered into a tax sharing agreement with Endo Pharma LLC under which we will be required to pay to Endo Pharma LLC upon the occurrence of a liquidity event, as described further below, the amount of the tax benefits usable by us as a result of the exercise of these stock options into shares of our common stock held by Endo Pharma LLC. As of June 30, 2004, approximately 3.8 million of these stock options had been exercised into shares of our common stock held by Endo Pharma LLC. Upon exercise of any of these Endo Pharma LLC stock options, we generally will be permitted to deduct as a compensation charge, for federal income tax purposes, an amount equal to the difference between the market price of our common



**Table of Contents**

stock and the exercise price paid upon exercise of these options (as of June 30, 2004, approximately \$38 million), which is estimated to result in a tax benefit amount of approximately \$15 million. Under the tax sharing agreement, we are required to pay this \$15 million to Endo Pharma LLC upon the occurrence of a liquidity event, as described further below, to the extent that a compensation charge deduction is usable by us to reduce our taxes and based upon the assumption that all other deductions of Endo are used prior thereto. If payments are made pursuant to the tax sharing agreement, they will be reflected as a reduction of stockholders' equity in the accompanying financial statements.

Using a weighted average exercise price of \$2.60 per share and an assumed effective tax rate of 38.3%, if all 36.3 million stock options under the Endo Pharma LLC Stock Option Plans were vested and exercised (including the 3.8 million stock options already exercised as discussed above):

upon exercise, assuming the market price of our common stock is then \$20.00 per share, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$632 million, which could result in a tax benefit amount of approximately \$242 million payable to Endo Pharma LLC.

upon exercise, assuming the market price of our common stock is then \$25.00 per share, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$813 million, which could result in a tax benefit amount of approximately \$311 million payable to Endo Pharma LLC.

upon exercise, assuming the market price of our common stock is then \$30.00 per share, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$994 million, which could result in a tax benefit amount of approximately \$381 million payable to Endo Pharma LLC.

Under the terms of the tax sharing agreement, we must pay all such tax benefit amounts to Endo Pharma LLC to the extent these tax benefits are usable by us, as described above. However, these payments need only be made to Endo Pharma LLC upon the occurrence of a liquidity event, which is generally defined as a transaction or series of transactions resulting in (a) a sale of greater than 20% on a fully diluted basis of our common equity (either through (i) a primary offering by us, (ii) a secondary sale by Endo Pharma LLC or other holders of common stock pursuant to a registration rights agreement or (iii) a combination of both such primary and secondary offerings), (b) a change in control of Endo or (c) a sale of all or substantially all of our assets. In accordance with the tax sharing agreement, no payments have been made or accrued to date. On July 8, 2003, a secondary sale by Endo Pharma LLC was closed which represented a sale of, on a fully diluted basis, approximately 12% of our common equity which did not, by itself, trigger a payment under the tax sharing agreement, and was not a liquidity event. That offering may, however, be combined with future offerings to result in a series of transactions that will trigger a payment obligation pursuant to the tax sharing agreement. A secondary sale of 11 million shares by Endo Pharma LLC is expected to close on August 9, 2004 with an over-allotment option for an additional 1.65 million shares. This offering, when combined with the 16.6 million shares sold in July 2003, will constitute a liquidity event and thus will trigger a payment obligation as discussed below. Endo Pharma LLC has informed us that, subject to a variety of factors, including market conditions and stock price levels, it may initiate additional secondary offerings of our common stock in the future.

On April 30, 2004 the tax sharing agreement was amended to provide for a specific schedule upon which payments currently contemplated by the tax sharing agreement would be made once a liquidity event has occurred. The amendment provides that upon the occurrence of a liquidity event, we will pay to Endo Pharma LLC, within 30 business days, the amount of the tax benefits usable by us in each of the previous taxable years for which we have filed a federal income tax return. In addition, the amended tax sharing agreement provides that with respect to all taxable years following the occurrence of a liquidity event, the amount of the tax benefits usable by us in each such year will be paid to Endo Pharma LLC in two installments: (i) 50% of the estimated amount shall be paid within 15 business days of our receipt from our independent auditors of an opinion on our final audited financial statements, and

(ii) the remaining amount shall be paid within 30 business days of the filing of our federal income tax return. Finally, the amendment also clarifies two matters related to determining the occurrence of when a liquidity event has occurred: (i) the amendment establishes a formula for calculating when a sale of 20% of the common equity of Endo has occurred, and (ii) the amendment specifies that secondary sales of Endo common stock include sales pursuant to a shelf registration statement.

Under the amended tax sharing agreement, the sale of the 11 million shares of our common stock expected to close on August 9, 2004 when added to the 16.6 million shares sold in July 2003 will cause a liquidity event to occur, and we will be obligated to pay to Endo Pharma LLC, within 30 business days, the tax benefit amounts attributable to 2001 and 2002 of approximately \$2 million and \$1 million, respectively. We will also be obligated to pay to Endo Pharma LLC, 50% of the estimated tax benefit amount of approximately \$9 million attributable to 2003 within 30 business days, and the remaining 50% of the tax benefit amount attributable to 2003 within 30 business days of the date on which we file our 2003 tax return with the Internal Revenue Service (which we estimate

**Table of Contents**

will occur in September 2004). In addition, since 3.8 million shares underlying stock options granted under the Endo Pharma LLC stock option plans will be exercised into common stock and sold in the offering expected to close on August 9, 2004, at a price of \$17.46, with a weighted average exercise price of \$2.44, an assumed tax rate of 38.3% and assuming the attributable compensation charge deductions are usable to reduce our taxes in 2004, we will be obligated to pay Endo Pharma LLC a tax benefit of approximately \$22 million. If the over-allotment option is exercised, resulting in the exercise of 0.6 million additional options at an average exercise price of \$2.44, and assuming a tax rate of 38.3% and that the attributable compensation charge deductions are useable to reduce our taxes in 2004, we will be obligated to pay to Endo Pharma LLC an additional tax benefit of approximately \$3 million. Fifty percent of the tax benefit amount attributable to this offering and any additional offering in 2004 will be due within 15 business days of the date we receive an opinion on our audited 2004 financial statements from our independent registered public accounting firm (which we estimate will occur within 60 days of our fiscal year-end of December 31, 2004) and the remaining fifty percent of the tax benefit amount attributable to 2004 is due within 30 business days of the date on which we file our 2004 tax return with the Internal Revenue Service (which we estimate will occur in September 2005). This estimated tax benefit amount payment to Endo Pharma LLC attributable to Endo Pharma LLC stock options exercised in 2004 may increase if certain holders of Endo Pharma LLC stock options exercise additional stock options in 2004.

On April 30, 2004, we filed a shelf registration statement on Form S-3, as amended on June 10, June 14, and June 25, 2004, providing for the sale by Endo Pharma LLC and certain other selling stockholders to be named therein, including certain of our directors and officers, from time to time, of up to 30 million currently issued and outstanding shares of our common stock. The shelf registration statement was declared effective by the Securities and Exchange Commission on June 28, 2004. After the closing of the August 9, 2004 offering of the 11 million shares (or 12.65 million shares if the over allotment option is exercised in full) discussed above, up to 19 million shares (or 17.35 million shares if over-allotment option is exercised in full) will remain eligible for sale by Endo Pharma LLC under this shelf registration statement. The shelf registration statement enables one or more offerings of common stock, subject to market conditions. The nature and terms of any offering will be established at the time of the offering and set forth in a prospectus supplement. Any offering would not increase the number of our outstanding shares of common stock and we would not receive any proceeds from any offering covered by this shelf registration.

***Licenses and Collaboration Agreements.*** We enter into licenses and collaboration agreements to develop, use, market and promote certain of our products from or with other pharmaceutical companies and universities. A description of the material developments with respect to our significant third party license and collaboration agreements that have taken place since December 31, 2003 is as follows:

*Lavipharm*

In November 1999, Endo entered into a collaboration agreement with Lavipharm Laboratories, Inc. pursuant to which Endo obtained exclusive worldwide rights to Lavipharm's existing drug delivery technology platforms. Under the terms of this collaboration agreement, Endo paid an upfront license fee of \$1 million. In September 2001, we amended this agreement to limit its scope to one of Lavipharm's existing drug delivery technologies in combination with two specific active drug substances. In January 2004, we terminated this agreement and made a termination payment to Lavipharm of \$3 million plus the potential for up to an additional \$5 million upon the occurrence of future events. We wrote-off the unamortized portion of the upfront license fee and expensed the termination payment of \$3 million during the six months ended June 30, 2004.

*DURECT Corporation*

On November 8, 2002, we entered into a Development, Commercialization and Supply License Agreement with DURECT Corporation, which relates to DURECT's development product, CHRONOGESIC. On January 28, 2004, we

amended the Agreement with DURECT, essentially modifying our funding obligations of the ongoing development costs of CHRONOGESIC to take into account the program delay. The clinical development program of CHRONOGESIC is on temporary hold pending DURECT's implementation of some necessary design and manufacturing enhancements to CHRONOGESIC. DURECT has informed us that it anticipates that the implementation of these design and manufacturing enhancements will delay the restart of the clinical development program. On July 21, 2004, DURECT announced that it would not be resuming human clinical trials of the CHRONOGESIC product in 2004. DURECT had initiated the process of clinical manufacturing of CHRONOGESIC following a series of promising results of in vitro studies and in vivo animal studies of the most recent CHRONOGESIC system design. However, they learned recently from a further animal study that they have not yet solved the pre-mature shutdown problem (a stoppage in the delivery of drug before the intended full duration of delivery). DURECT continues to work to address this issue in order to bring this product to market.

**Table of Contents**

Under the terms of this agreement, as amended, for the period commencing January 1, 2004 until the earlier of January 1, 2005 or the commencement of a specified clinical trial, we will fund 25% of the ongoing development costs for the CHRONOGESIC product in the U.S. and Canada excluding system redesign costs and pharmacokinetic trials necessitated by any system redesign up to an aggregate amount of \$250,000 for the period. Once a specified clinical trial of CHRONOGESIC is started or beginning on January 1, 2005 (whichever is earlier), unless the agreement is earlier terminated, we will be obligated to fund 50% of the ongoing development costs of CHRONOGESIC. We will also reimburse DURECT for a portion of its prior development costs upon the achievement of certain milestones. Milestone payments made by Endo under this agreement could total up to \$52.0 million. In addition, under this agreement, DURECT licensed to us the exclusive promotional rights to CHRONOGESIC in the U.S. and Canada. We will be responsible for marketing, sales and distribution, including providing technical support representatives dedicated to supplying technical and training support. DURECT will be responsible for the manufacture of CHRONOGESIC. We and DURECT will share profits equally, based on projected financial performance of CHRONOGESIC. Further, this agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. This agreement generally lasts until the underlying patents on the product expire. With respect to termination rights, this agreement permits us to terminate our continued participation under a number of circumstances, one of which could require us to pay DURECT \$10.0 million.

*Noven Pharmaceuticals, Inc.*

On February 25, 2004, we entered into a License Agreement and a Supply Agreement with Noven Pharmaceuticals, Inc., under which Noven exclusively licensed to us the U.S. and Canadian rights to its developmental transdermal fentanyl patch, which is intended to be the generic equivalent of Johnson & Johnson's Duragesic (fentanyl transdermal system). Under this agreement, we made an upfront payment to Noven of \$8.0 million, \$6.5 million of which we capitalized as an intangible asset representing the fair value of the exclusive license of these distribution and marketing rights. We are amortizing this intangible asset over its useful life of 11 years. Upon our first commercial sale of the fentanyl patch, Noven is entitled to receive an additional payment ranging from \$5.0 million to \$10.0 million, depending on the timing of launch and the number of generic competitors on the market. Noven will manufacture and supply the product at its cost, and the two companies will share profits on undisclosed terms. The License Agreement also establishes an ongoing collaboration between the two companies to identify and develop additional new transdermal therapies. As part of this effort, Noven will undertake feasibility studies to determine whether certain compounds identified by the parties can be delivered through Noven's transdermal patch technology. We are expected to fund and manage clinical development of those compounds proceeding into clinical trials. In addition, this agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. This agreement generally lasts for a term of ten years from the first commercial sale of the developmental transdermal fentanyl patch product. With respect to termination rights, this agreement permits us to terminate our continued participation under a number of circumstances.

*SkyePharma, Inc.*

In April 2004, we paid and expensed \$5 million to SkyePharma upon the advancement of Propofol IDD-D into Phase III. If the Phase III clinical trial results are positive, we currently expect that SkyePharma will submit an NDA for Propofol IDD-D to the FDA in the second half of 2006. In May 2004, we accrued and expensed a \$5 million milestone payment due to SkyePharma upon the approval of the NDA for DepoDur by the FDA. Both of these amounts, totaling \$10 million, are included in research and development for the three months and six months ended June 30, 2004.

*Penwest Pharmaceuticals*

In September 1997, we entered into a collaboration agreement with Penwest Pharmaceuticals to exclusively co-develop opioid analgesic products for pain management, using Penwest's patent-protected proprietary technology, for commercial sale worldwide. On April 2, 2002, we amended and restated this agreement to provide, among other things, that this collaboration would cover only that opioid analgesic product currently under development by the parties, namely, oxymorphone ER. We have historically shared on an equal basis the costs of products developed under this agreement and will, in the future, share costs and profits on an equal basis (subject to the recoupment discussed below). On March 18, 2003, we received notice from Penwest that it was exercising its right under the agreement to cease funding its share of the development and pre-launch marketing costs of oxymorphone ER on account of their concern about their ability to access external capital funding opportunities in the future. Accordingly, we are now responsible for funding 100% of these remaining costs until oxymorphone ER is approved by the FDA, at which time we will recoup from the royalties due to Penwest the full amount of what Penwest should have contributed had it not exercised such right. On May 7, 2004, we announced that the FDA is requiring us to initiate a new clinical trial to provide additional safety and efficacy data of oxymorphone ER in support of our New Drug Application (NDA) for this developmental product. On July 7, 2004, we announced

**Table of Contents**

that we had reached agreement with the FDA as to the design of a new clinical trial to provide additional safety and efficacy data of oxymorphone ER in support of our NDA for this developmental product. We had submitted the trial protocol to FDA under the Special Protocol Assessment (SPA) process. Under the terms of the SPA, we will initiate a 12-week, multicenter, double-blinded, placebo-controlled trial of oxymorphone ER. We have exclusive U.S. marketing rights with respect to oxymorphone ER, subject to the terms and conditions contained in this agreement.

*Vernalis*

On July 14, 2004, we entered into a license agreement and a loan agreement with Vernalis Development Limited, or Vernalis, under which Vernalis agreed to exclusively license to us rights to market Frova (frovatriptan) in North America. Launched in the U.S. in June 2002, Frova is indicated for the acute treatment of migraine headaches in adults. Net sales of Frova in the U.S. were \$37.5 million in 2003. Under the terms of the license agreement, we will pay Vernalis an upfront fee of \$30 million, anniversary payments for the first two years at \$15 million each year, and a \$40 million milestone payment upon U.S. Food and Drug Administration, FDA, approval for the menstrually associated migraine indication. In addition, Vernalis will receive one-time milestone payments for achieving defined annual net sales targets. These sales milestone payments increase based on increasing net sales targets ranging from a milestone of \$10 million on \$200 million in net sales to a milestone of \$75 million on \$1.2 billion in net sales. These sales milestones could total up to \$255 million if all of the defined net sales targets are achieved. We will also pay royalties to Vernalis based on the net sales of Frova. In addition, the license agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of the license agreement is for the shorter of the time (i) that there are valid claims on the Vernalis patents covering Frova or there is market exclusivity granted by a regulatory authority, whichever is longer, or (ii) until the date on which a generic version of Frova is first offered, but in no event longer than 20 years. We can terminate the license agreement under certain circumstances, including upon one year's written notice. The license agreement is subject to a number of closing conditions, including obtaining clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended. Under the loan agreement, Endo will provide Vernalis with a loan of \$50 million at closing. The loan will primarily be used to pay in full the amounts currently due to Elan Corporation from Vernalis in connection with Vernalis' reacquisition of the North American rights to Frova. The balance of the loan will be available for Vernalis' general corporate purposes. The loan will be secured against the revenues receivable by Vernalis under the license agreement. At Endo's election, Endo is able to offset \$20 million of the \$40 million MAM approval milestone and 50% of all royalties to be paid under the license agreement to Vernalis to repay the loan. To the extent not previously repaid, the loan is due in full after five years. Interest is at the rate of 5% per annum payable semi-annually; however, Vernalis has the option to defer payment of interest and increase the loan outstanding each time an interest payment becomes due.

***Fluctuations.*** Our quarterly results have fluctuated in the past, and may continue to fluctuate. These fluctuations are primarily due to the timing of new product launches, purchasing patterns of our customers, market acceptance of our products and the impact of competitive products and pricing. Further, a substantial portion of our net sales are through wholesale drug distributors who in turn supply our products to pharmacies, hospitals and physicians. Accordingly, we are potentially subject to a concentration of credit risk with respect to our trade receivables.

***Growth Opportunities.*** We continue to evaluate growth opportunities including strategic investments, licensing arrangements and acquisitions of product rights or technologies, which could require significant capital resources.

***Non-U.S. Operations.*** We currently have no operations outside of the United States. As a result, fluctuations in foreign currency exchange rates do not have a material effect on our financial statements.

***Inflation.*** We do not believe that inflation had a material adverse effect on our financial statements for the periods presented.

### **Recent Accounting Pronouncements**

In December 2003, the Financial Accounting Standards Board issued FASB Interpretation No. 46R (FIN 46R), *Consolidation of Variable Interest Entities*. FIN 46R replaces the same titled FIN 46 that was issued in January 2003. FIN 46R identifies when entities must be consolidated with the financial statements of a company where the investors in an entity do not have the characteristics of a controlling financial interest or the entity does not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support. The adoption, on March 31, 2004, of FIN 46R did not have a material impact on our financial position, results of operations or liquidity.



**Table of Contents**

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

On December 21, 2001, we entered into a new credit facility that provides for a line of credit of \$75.0 million. On April 30, 2004, we amended our credit facility to allow us to file a shelf registration statement on Form S-3, which we initially filed on April 30, 2004. On July 13, 2004, we amended our credit facility to allow us to enter in the transaction with Vernalis. Borrowings under the new credit facility are variable rate borrowings. There are no amounts outstanding under the new credit facility. We do not utilize financial instruments for trading purposes and hold no derivative financial instruments that could expose us to significant market risk. We monitor interest rates and enter into interest rate agreements as considered appropriate.

As of June 30, 2004 and December 31, 2003, we had no assets or liabilities that have significant interest rate sensitivity.

At June 30, 2004, we had publicly traded equity securities comprised of DURECT Corporation common stock at fair value totaling \$5.3 million in Other assets. The fair value of this investment is subject to significant fluctuations due to volatility of the stock market and changes in general economic conditions. Based on the fair value of the publicly traded equity securities we held at June 30, 2004, an assumed 25%, 40% and 50% adverse change in the market prices of this security would result in a corresponding decline in total fair value of approximately \$1.3 million, \$2.1 million and \$2.7 million, respectively. As of August 4, 2004, the fair market value of this investment was \$2.0 million and this impairment in value is not deemed to be other than temporary. On an ongoing basis, we will continue to evaluate this investment to determine if a decline in fair value is other than temporary. When a decline in fair value is determined to be other than temporary, an impairment charge would be recorded in operations and a new cost basis in the investment would be established.

**Item 4. *Controls and Procedures.***

Our management, including our Chief Executive Officer and Chief Financial Officer, has conducted an evaluation of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective for timely gathering, analyzing and disclosing the information we are required to disclose in our reports filed with the SEC under the Securities Exchange Act of 1934, as amended.

In addition, we evaluated our internal control over financial reporting, and there have been no changes in our internal control over financial reporting that occurred during the quarter covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Table of Contents**

**PART II**

**OTHER INFORMATION**

**Item 1. *Legal Proceedings.***

*Purdue Pharma L.P., et al. v. Endo Pharmaceuticals Inc., et al., Index No. 00 Civ. 8029 (SHS) (S.D.N.Y.); Purdue Pharma L.P., et al. v. Endo Pharmaceuticals Inc., et al., Index No. 01 Civ. 2109 (SHS) (S.D.N.Y.); Purdue Pharma L.P., et al. v. Endo Pharmaceuticals Inc., et al., Index No. 01 Civ. 8177 (SHS) (S.D.N.Y.)*

On October 20, 2000, The Purdue Frederick Company and related companies (Purdue Frederick) filed suit against us and our subsidiary, Endo Pharmaceuticals Inc. (EPI), in the U.S. District Court for the Southern District of New York alleging that EPI's bioequivalent version of Purdue Frederick's OxyContin (oxycodone hydrochloride extended-release tablets), 40mg strength, infringes three of its patents. This suit arose after EPI provided the plaintiffs with notice that its ANDA submission for a bioequivalent version of Purdue Frederick's OxyContin, 40mg strength, challenged the listed patents for OxyContin 40mg tablets. On March 13, 2001, Purdue Frederick filed a second suit against us and EPI in the U.S. District Court for the Southern District of New York alleging that EPI's bioequivalent versions of Purdue Frederick's OxyContin, 10mg and 20mg strengths, infringe the same three patents. This suit arose from EPI having amended its earlier ANDA on February 9, 2001 to add bioequivalent versions of the 10mg and 20mg strengths of OxyContin. On August 30, 2001, Purdue Frederick filed a third suit against us and EPI in the U.S. District Court for the Southern District of New York alleging that EPI's bioequivalent version of Purdue Frederick's OxyContin, 80mg strength, infringes the same three patents. This suit arose from EPI having amended its earlier ANDA on July 30, 2001 to add the bioequivalent version of the 80mg strength of OxyContin.

For each of the 10mg, 20mg, 40mg and 80mg strengths of this product, EPI made the required Paragraph IV certification against the patents listed in the FDA's Orange Book as covering these strengths of OxyContin. EPI pleaded counterclaims that the patents asserted by Purdue Frederick are invalid, unenforceable and/or not infringed by EPI's formulation of oxycodone hydrochloride extended-release tablets, 10mg, 20mg, 40mg and 80mg strengths. EPI also counterclaimed for antitrust damages based on allegations that Purdue Frederick obtained the patents through fraud on the United States Patent and Trademark Office and is asserting them while aware of their invalidity and unenforceability.

The trial of the patent claims in all three of the suits against us and EPI concluded on June 23, 2003. On January 5, 2004, the district court issued an opinion and order holding that, while Endo infringes the three Purdue patents, the patents are unenforceable due to inequitable conduct. The district court, therefore, dismissed the patent claims against us and EPI, declared the patents invalid, and enjoined Purdue from further enforcement of the patents. Purdue filed an appeal, as well as motions to expedite the appeal and to stay the injunction against enforcement of the patents until the appeal is resolved. Both motions were denied on March 18, 2004. In turn, we have cross-appealed the district court's infringement ruling. Briefing on the appeal and cross-appeal concluded in July 2004, and oral argument is expected to take place by the end of 2004. By an earlier order, the judge bifurcated the antitrust counterclaims for a separate and subsequent trial.

At this time we have decided to launch our bioequivalent versions of OxyContin after appellate review of the district court's decision. We will continue to monitor the situation and may in the future decide to launch our bioequivalent versions of OxyContin in advance of the appellate decision. If we do launch our bioequivalent versions of OxyContin in advance of the appellate decision and the district court's ruling is overturned, we may be liable for lost profits and damages to Purdue and costs associated with the launching of our products. Our payment of those amounts may materially adversely affect our business, financial condition and cash flows. Whether or not we have launched

our bioequivalent versions of OxyContin, if we receive an unfavorable ruling from the appeals court, we may be unable to sell our generic OxyContin.

Litigation similar to that described above may also result from products we currently have in development, as well as those that we may develop in the future. We, however, cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against us.

*Rowe, et al. v. Bayer Corp., et al., No. 02-1833 (E.D. La.); In Re: PPA Products Liability Litigation, MDL No. 1407 (W.D. Wash.); Landry, et al. v. Bayer Corp., et al., No. 02-1835, (E.D. La.); In Re: PPA Products Liability Litigation, MDL No. 1407 (W.D. Wash.); Everidge, et al. v. Bayer Corp., et al., No. 02-1834 (E.D. La.); In Re: PPA Products Liability Litigation, MDL No. 1407 (W.D. Wash.); Ackel, et al. v. Bayer Corp., et al., No. 02-1831 (E.D. La.); In Re: PPA Products Liability Litigation, MDL No. 1407 (W.D. Wash.); Ashton, et al. v. Bayer Corp., et al., No. 02-598 (M.D. La.); In Re: PPA Products Liability Litigation, MDL No. 1407 (W.D. Wash.);*

**Table of Contents**

*McCullough, et al. v. American Home Products Corp., et al., No. CV02-1295-S (W.D. La.); In Re: PPA Products Liability Litigation, MDL No. 1407 (W.D. Wash.)*

On June 17, 2002, EPI was named, along with ten other pharmaceutical companies, as a defendant in four lawsuits filed by groups of 28, 34, 37, and 43 individual plaintiffs, respectively, in the United States District Court for the Eastern District of Louisiana. On June 18, 2002, EPI was named, along with ten other pharmaceutical companies, as a defendant in a lawsuit filed by Ellen McCullough and Brenda Businelle in the United States District Court for the Western District of Louisiana. On June 21, 2002, EPI was named, along with ten other pharmaceutical companies, as a defendant in a lawsuit filed by Joyce Ashton and Bernadine Johnson in the United States District Court for the Middle District of Louisiana. According to each of these six complaints, each of the defendant pharmaceutical companies allegedly manufactured and sold products containing phenylpropanolamine (PPA). Each complaint alleges that the defendants failed to adequately warn plaintiff of the hazards of the use of the subject products containing PPA and that as a result of this failure to warn, plaintiffs suffered injury. Each of these six cases was transferred to the United States District Court for the Western District of Washington by order of the United States Judicial Panel on Multidistrict Litigation. Each plaintiff in the above-referenced cases was directed by the presiding judge to file, not later than June 29, 2003, a separate, single-plaintiff action identifying particular defendant manufacturers whose products allegedly harmed each plaintiff. EPI neither has been named, nor served with process in any single-plaintiff case filed by any of the foregoing plaintiffs pursuant to the Court's prior order. On October 14, 2003, the Court granted EPI's motions to dismiss with prejudice the claims of 113 individual plaintiffs from the *Rowe, Landry, Everidge, Ackel* and *Ashton* cases on the grounds that those plaintiffs had failed to specifically allege use of an EPI product containing PPA. On October 24, 2003, the Court granted a co-defendant's motion to dismiss with prejudice, as to all defendants including EPI, the claims of 69 individual plaintiffs in the *Rowe, Landry, Everidge, Ackel, Ashton* and *McCullough* cases on the grounds that those plaintiffs failed to comply with Court-ordered discovery. One or more of the foregoing orders of dismissal with prejudice applies to every plaintiff in the *Rowe, Landry, Everidge, Ackel, Ashton* and *McCullough* cases. Moreover, on August 25, 2003, after providing plaintiffs with the opportunity to file separate single-plaintiff actions, the Court dismissed the *Rowe, Landry, Everidge, Ackel, Ashton* and *McCullough* multi-plaintiff cases with prejudice. Certain plaintiffs moved the District Court for reconsideration of and for relief from the August 25, 2003 and October 24, 2003 orders, and the District Court denied those motions for reconsideration in orders dated May 7, 2004 and March 30, 2004, respectively. On July 7, 2004, certain plaintiffs appealed from the foregoing May 7, 2004 Order; however, it appears that the appeal concerns other rulings included in the Order, and does not concern the August 25, 2003 dismissal of the multi-plaintiff cases. Further, no plaintiff has appealed the October 14, 2003 and October 24, 2003 orders dismissing the claims of various plaintiffs against EPI. Consequently, EPI is no longer a party defendant in any multidistrict litigation proceedings concerning alleged harm from PPA, and EPI's dismissal from the foregoing cases should be final.

*Linda Serafin, et al. v. Purdue Pharma L.P., et al., No. 103031/04 (Supreme Court of the State of New York, County of New York)*

On February 27, 2004, EPI was named, along with three other pharmaceutical companies, a hospital, and a doctor, as a defendant in a lawsuit filed by Linda Serafin and Michael Serafin in the Supreme Court of the State of New York, County of New York. According to the complaint, each of the pharmaceutical companies manufactured or distributed the drugs oxycodone and OxyContin. The complaint alleges that EPI and another defendant manufactured oxycodone, OxyContin and/or Percocet®. The complaint alleges that the defendants failed to adequately warn about the dangers involved with these drugs and that as a result of this failure to warn, plaintiffs sustained injury. EPI intends to defend itself vigorously in this case.

*General*

In addition to the above, we are involved in, or have been involved in, arbitrations or legal proceedings that arise from the normal course of our business. We cannot predict the timing or outcome of these claims and proceedings. Currently, we are not involved in any arbitration and/or legal proceeding that we expect to have a material effect on our business, financial condition, results of operations or cash flows.

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

None.

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

None.

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

- (a) The annual meeting of the stockholders of the Company was held on May 26, 2004.
- (b) The stockholders elected all of the Company's nominees for director. The stockholders also approved the appointment of Deloitte & Touche LLP as the Company's independent auditors for 2004 and the Company's 2004 Stock Incentive Plan.

*(1) Election of Directors:*

	<u>For</u>	<u>Against</u>
Carol A. Ammon	82,219,380	0
Brian T. Clingen	82,219,380	0
Michael B. Goldberg	82,219,380	0
Michael Hyatt	82,219,380	0
Roger H. Kimmel	82,219,380	0
Frank J. Loverro	82,219,380	0
Clive A. Meanwell, M.D., Ph.D.	82,219,380	0
Michael W. Mitchell	82,219,380	0
Joseph T. O'Donnell, Jr.	82,219,380	0
David I. Wahrhaftig	82,219,380	0

*(2) Approval of Appointment of Deloitte & Touche LLP*

For	82,219,380
Against	0

*(3) Approval of 2004 Stock Incentive Plan*

For	82,219,380
Against	0

The foregoing matters are described in detail in the Company's information statement dated April 28, 2004, relating to the Annual Meeting of Stockholders held on May 26, 2004.

**Item 5. Other Information.**

None.

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

The information called for by this item is incorporated by reference to the Exhibit Index of this Report.

*(b) Reports on Form 8-K.*



**Table of Contents**

We filed no Form 8-Ks in the quarter ended June 30, 2004.



**Table of Contents**

**SIGNATURES**

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

ENDO PHARMACEUTICALS HOLDINGS INC.  
(Registrant)

/s/Carol A. Ammon

Name: Carol A. Ammon

Title: *Chairman and Chief Executive Officer*

/s/Jeffrey R. Black

Name: Jeffrey R. Black

Title: *Executive Vice President and Chief Financial Officer*

Date: August 9, 2004

**Table of Contents****Exhibit Index**

<b>Exhibit No.</b>	<b>Title</b>
3.1	Amended and Restated Certificate of Incorporation of Endo Pharmaceuticals Holdings Inc. ( Endo ) (incorporated herein by reference to Exhibit 3.1 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
3.2	Amended and Restated By-laws of Endo (incorporated herein by reference to Exhibit 3.2 of the Form 10-Q for the Quarter ended March 31, 2003 filed with the Commission on May 14, 2003)
4.1	Amended and Restated Executive Stockholders Agreement, dated as of July 7, 2003, by and among Endo, Endo Pharma LLC ( Endo LLC ), Kelso Investment Associates V, L.P. ( KIA V ), Kelso Equity Partners V, L.P. ( KEP V ) and the Management Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.1 of the Form 10-Q for the Quarter ended June 30, 2003 filed with the Commission on August 14, 2003)
4.2	Amended and Restated Employee Stockholders Agreement, dated as of June 5, 2003, by and among Endo, Endo LLC, KIA V, KEP V and the Employee Stockholders (as defined therein) (incorporated herein by reference to Exhibit 10.2 of Amendment No. 2 to the Form S-3 Registration Statement (Registration No. 333-105338) filed with the Commission on July 1, 2003)
4.3	[Intentionally Omitted.]
4.4	Registration Rights Agreement, dated as of July 17, 2000, by and between Endo and Endo LLC (incorporated herein by reference to Exhibit 4.4 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
4.5	Amendment to Registration Rights Agreement, dated as of June 30, 2003, by and between Endo and Endo LLC (incorporated herein by reference to Exhibit 10.1 of Amendment No. 2 to the Form S-3 Registration Statement (Registration No. 333-105338) filed with the Commission on July 1, 2003)
10.1	Shelf Registration Agreement, dated April 30, 2004, between Endo Pharmaceuticals Holdings Inc. and Endo Pharma LLC (incorporated herein by reference to Exhibit 10.2 of Amendment No. 1 to the Form S-3 Registration Statement (Registration No. 333-115032) filed with the Commission on June 10, 2004)
10.2	Amendment to Shelf Registration Agreement, dated June 10, 2004 between Endo Pharmaceuticals Holdings Inc. and Endo Pharma LLC (incorporated herein by reference to Exhibit 10.3 of Amendment No. 1 to the Form S-3 Registration Statement (Registration No. 333-115032) filed with the Commission on June 10, 2004)
10.3	[Intentionally Omitted.]
10.4	[Intentionally Omitted.]
10.5	

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-Q

Tax Sharing Agreement, dated as of July 17, 2000, by and among Endo, Endo Inc. and Endo LLC (incorporated herein by reference to Exhibit 10.5 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)

- 10.6 Amended and Restated Tax Sharing Agreement, dated as of April 30, 2004 by and among Endo, Endo Inc. and Endo LLC (incorporated herein by reference to Exhibit 10.6 of the Form 10-Q for the Quarter ended March 31, 2004 filed with the Commission on May 10, 2004)
- 10.7 Amended and Restated Credit Agreement, dated as of December 21, 2001, by and between Endo, Endo Pharmaceuticals,

**Table of Contents**

<b>Exhibit No.</b>	<b>Title</b>
	the Lenders Party Thereto and JPMorgan Chase Bank (incorporated by reference to Exhibit 10.7 of the Annual Report on Form 10-K for the Year Ended December 31, 2001 filed with the Commission on March 29, 2002)
10.8	Amendment No.1, dated as of April 30, 2004, to the Amended and Restated Credit Agreement dated as of December 21, 2001, among Endo, Endo Pharmaceuticals Inc., the Lenders thereto and JP Morgan Chase. (incorporated herein by reference to Exhibit 10.8 of the Form 10-Q for the Quarter ended March 31, 2004 filed with the Commission on May 10, 2004)
10.9	Amendment No.2, dated as of July 13, 2004, to the Amended and Restated Credit Agreement dated as of December 21, 2001, among Endo, Endo Pharmaceuticals Inc., the Lenders thereto and JP Morgan Chase.
10.10	Sole and Exclusive License Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals Inc. ( Endo Pharmaceuticals ) and Hind Health Care, Inc. (incorporated herein by reference to Exhibit 10.10 of the Registration Statement filed with the Commission on June 9, 2000)
10.11	Analgesic License Agreement, dated as of October 27, 1997, by and among Endo Pharmaceuticals, Endo Laboratories, LLC and DuPont Merck Pharmaceutical (incorporated herein by reference to Exhibit 10.11 of the Registration Statement filed with the Commission on June 9, 2000)
10.12	Anti-Epileptic License Agreement, dated as of October 27, 1997, by and among Endo Pharmaceuticals, Endo Laboratories, LLC and DuPont Merck Pharmaceutical (incorporated herein by reference to Exhibit 10.12 of the Registration Statement filed with the Commission on June 9, 2000)
10.13	[Intentionally Omitted.]
10.14	Supply and Manufacturing Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals and Teikoku Seiyaku Co., Ltd (incorporated herein by reference to Exhibit 10.14 of the Registration Statement filed with the Commission on June 9, 2000)
10.15	Supply Agreement, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt Inc. ( Mallinckrodt ) (incorporated herein by reference to Exhibit 10.15 of the Registration Statement filed with the Commission on June 9, 2000)
10.16	Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt (incorporated herein by reference to Exhibit 10.16 of the Registration Statement filed with the Commission on June 9, 2000)
10.17	Manufacture and Supply Agreement, dated as of August 26, 1997, by and among Endo Pharmaceuticals, DuPont Merck Pharmaceutical and DuPont Merck Pharma (n/k/a Bristol-Myers Squibb Pharma Company) (incorporated herein by reference to Exhibit 10.17 of the Registration Statement filed with the Commission on June 9, 2000)



**Table of Contents**

<b>Exhibit No.</b>	<b>Title</b>
10.17.2	Amendment Agreement effective August 27, 2002 by and between Endo Pharmaceuticals and Bristol-Myers Squibb Pharma Company as successor-in-interest to DuPont Pharmaceuticals Company formerly known as The DuPont Merck Pharmaceutical Company (incorporated herein by reference to Exhibit 10.17.2 of the Current Report on Form 8-K dated August 27, 2002)
10.18	Amended and Restated Strategic Alliance Agreement, dated as of April 2, 2002, by and between Endo Pharmaceuticals and Penwest Pharmaceuticals Co. (incorporated herein by reference to Exhibit 10.18 of the Quarterly Report on Form 10-Q for the Quarter Ended March 31, 2002 filed with the Commission on May 14, 2002)
10.19	Agreement, dated as of February 1, 2000, by and between Endo Pharmaceuticals and UPS Supply Chain Management, Inc. (f/d/b/a Livingston Healthcare Services Inc.) (incorporated herein by reference to Exhibit 10.19 of the Registration Statement filed with the Commission on June 9, 2000)
10.20	Medical Affairs Support Services Agreement, dated as of June 1, 1999, by and between Endo Pharmaceuticals and Kunitz and Associates, Inc. (incorporated herein by reference to Exhibit 10.20 of the Registration Statement filed with the Commission on June 9, 2000)
10.21	Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.21 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.22	Endo LLC Amended and Restated 1997 Employee Stock Option Plan (incorporated herein by reference to Exhibit 10.22 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.23	Endo LLC Amended and Restated 1997 Executive Stock Option Plan (incorporated herein by reference to Exhibit 10.23 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.24	Endo LLC 2000 Amended and Restated Supplemental Employee Stock Option Plan (incorporated herein by reference to Exhibit 10.24 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.25	Endo LLC 2000 Amended and Restated Supplemental Executive Stock Option Plan (incorporated herein by reference to Exhibit 10.25 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.26	Employment Agreement, dated as of July 17, 2000, by and between Endo and John W. Lyle (incorporated herein by reference to Exhibit 10.26 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 14, 2000)

**Table of Contents**

<b>Exhibit No.</b>	<b>Title</b>
10.27	Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo Pharmaceuticals and Carol A. Ammon (incorporated herein by reference to Exhibit 10.27 of the Current Report on Form 8-K dated August 31, 2001)
10.28	Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo Pharmaceuticals and Jeffrey R. Black (incorporated herein by reference to Exhibit 10.28 of the Current Report on Form 8-K dated August 31, 2001)
10.29	Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo Pharmaceuticals and David Allen Harvey Lee, MD, Ph.D. (incorporated herein by reference to Exhibit 10.29 of the Current Report on Form 8-K dated August 31, 2001)
10.30	Amended and Restated Employment Agreement, dated as September 1, 2001, by and between Endo Pharmaceuticals and Mariann T. MacDonald (incorporated herein by reference to Exhibit 10.30 of the Current Report on Form 8-K dated August 31, 2001)
10.31	Separation and Release Agreement, dated as of March 22, 2000, by and between Endo Pharmaceuticals, Endo and Osagie O. Imasogie (incorporated herein by reference to Exhibit 10.31 of the Registration Statement filed with the Commission on June 9, 2000)
10.32	Separation and Release Agreement, dated as of April 20, 2000, by and between Endo Pharmaceuticals, Endo and Louis J. Vollmer (incorporated herein by reference to Exhibit 10.32 of the Registration Statement filed with the Commission on June 9, 2000)
10.33	[Intentionally Omitted.]
10.34	Lease Agreement, dated as of May 5, 2000, by and between Endo Pharmaceuticals and Painters Crossing One Associates, L.P. (incorporated herein by reference to Exhibit 10.34 of the Registration Statement filed with the Commission on June 9, 2000)
10.35	Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo and Caroline B. Manogue (formerly Berry) (incorporated herein by reference to Exhibit 10.35 of the Current Report on Form 8-K dated August 31, 2001)
10.36	Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo and Peter A. Lankau (incorporated herein by reference to Exhibit 10.36 of the Current Report on Form 8-K dated August 31, 2001)
10.37	Endo Pharmaceuticals Holdings Inc. 2004 Stock Incentive Plan
10.38	[Intentionally Omitted.]
10.39	Master Development and Toll Manufacturing Agreement, dated as of

**Table of Contents**

<b>Exhibit No.</b>	<b>Title</b>
	May 3, 2001, by and between Novartis Consumer Health, Inc. and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.39 of the Form 10-Q for the Quarter Ended June 30, 2001 filed with the Commission on August 14, 2001)
10.40	[Intentionally Omitted.]
10.41	[Intentionally Omitted.]
10.42	Development, Commercialization and Supply License Agreement, dated as of November 8, 2002, by and between DURECT Corporation and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.42 of the Current Report on Form 8-K dated November 14, 2002)
10.42.2	Amendment to Development, Commercialization and Supply License Agreement, dated January 28, 2004, between DURECT Corporation and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.42.2 of the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on March 15, 2004)
10.43	Development and Marketing Strategic Alliance Agreement, dated as of December 31, 2002, by and among Endo Pharmaceuticals, SkyePharma, Inc. and SkyePharma Canada, Inc. (incorporated herein by reference to Exhibit 10.43 of the Current Report on Form 8-K dated January 8, 2003)
10.43.2	Amendment to Development and Marketing Strategic Alliance Agreement, dated March 2, 2004, between Endo Pharmaceuticals, SkyePharma, Inc. and SkyePharma Canada, Inc. (incorporated herein by reference to Exhibit 10.43.2 of the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on March 15, 2004)
10.44	Lease Agreement, dated as of January 6, 2003, by and between Endo Pharmaceuticals and Dawson Holding Company (incorporated by reference to Exhibit 10.44 of the Annual Report on Form 10-K for the Year Ended December 31, 2002 filed with the Commission on March 27, 2003)
10.45	Lease Agreement, dated as of November 13, 2003, by and between Endo Pharmaceuticals and Painters Crossing Two Associates, L.P. (incorporated herein by reference to Exhibit 10.45 of the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on March 15, 2004)
10.46	License Agreement, dated as of February 25, 2004, by and between Endo Pharmaceuticals and Noven Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.46 of Amendment No. 2 to the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on June 25, 2004)
10.47	Supply Agreement, dated as of February 25, 2004, by and between Endo Pharmaceuticals and Noven Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.47 of Amendment No. 2 to the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on June 25, 2004)



- 10.48 License and Co-Promotion Rights Agreement, dated as of July 14, 2004, by and between Endo Pharmaceuticals and Vernalis Development Limited (incorporated herein by reference to Exhibit 10.48 of the Current Report on Form 8-K dated July 19, 2004)
- 10.49 Loan Agreement, dated as of July 14, 2004, by and between Endo Pharmaceuticals and Vernalis Development Limited (incorporated herein by reference to Exhibit 10.49 of the Current Report on Form 8-K dated July 19, 2004)

**Table of Contents**

<b>Exhibit No.</b>	<b>Title</b>
31.1	Certification of the Chairman and Chief Executive Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Chief Financial Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certificate of the Chairman and Chief Executive Officer of Endo pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certificate of the Chief Financial Officer of Endo pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002