ENDO PHARMACEUTICALS HOLDINGS INC
Form 10-Q
November 05, 2004

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

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

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE TRANSITION PERIOD FROM_____ TO _____.

Commission file number: 001-15989

ENDO PHARMACEUTICALS HOLDINGS INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**13-4022871**
(State or other jurisdiction of incorporation or organization)	(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 þ NO o

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

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: 131,848,948 shares as of November 2, 2004.

ENDO PHARMACEUTICALS HOLDINGS INC.

INDEX

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;

the outcome of any pending litigation; 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)

	September 30, 2004	December 31, 2003
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$184,980	$ 229,573
Accounts receivable, net	156,802	101,284
Inventories	91,926	50,450
Prepaid expenses	11,643	7,145
Deferred income taxes	73,639	85,144
Total current assets	518,990	473,596
PROPERTY AND EQUIPMENT, Net	23,959	20,246
GOODWILL	181,079	181,079
OTHER INTANGIBLES, Net	120,790	42,043
DEFERRED INCOME TAXES	12,280	31,045
NOTE RECEIVABLE	43,903	
OTHER ASSETS	4,300	5,871
TOTAL ASSETS	$905,301	$ 753,880
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 62,052	$ 65,071
Accrued expenses	165,679	106,309
Income taxes payable	5,999	14,294
Total current liabilities	233,730	185,674
OTHER LIABILITIES	27,547	589
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS EQUITY		

Preferred Stock, $.01 par value; 40,000,000 shares authorized; none issued		
Common Stock, $.01 par value; 175,000,000 shares authorized; 131,813,060 and 131,769,766 issued and outstanding at September 30, 2004 and December 31, 2003, respectively	1,318	1,318
Additional paid-in capital	654,981	691,631
Accumulated deficit	(10,513)	(124,612)
Accumulated other comprehensive loss	(1,762)	(720)
Total stockholders equity	644,024	567,617
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$905,301	$ 753,880

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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
NET SALES	$160,349	$149,355	$457,806	$453,656
COST OF SALES	38,203	27,050	99,991	80,885
GROSS PROFIT	122,146	122,305	357,815	372,771
COSTS AND EXPENSES:				
Selling, general and administrative	43,512	35,764	125,271	113,681
Research and development	9,501	20,651	38,502	42,153
Depreciation and amortization	2,985	1,578	7,074	4,295
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	66,148	64,312	183,168	164,128
INTEREST (INCOME) EXPENSE, Net of interest (expense) income of $(290), $209, $(740) and $496, respectively	(578)	12	(796)	165
INCOME BEFORE INCOME TAX	66,726	64,300	183,964	163,963
INCOME TAX	25,349	24,376	69,865	62,512
NET INCOME	$ 41,377	$ 39,924	$114,099	$101,451
NET INCOME PER SHARE:				
Basic	$ 0.31	$ 0.30	$ 0.87	$ 0.80
Diluted	$ 0.31	$ 0.30	$ 0.86	$ 0.77
WEIGHTED AVERAGE SHARES:				
Basic	131,804	131,761	131,792	127,288
Diluted	132,460	132,636	132,688	132,510

See notes to condensed consolidated financial statements.

Table of Contents

ENDO PHARMACEUTICALS HOLDINGS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)
(In thousands)

	Nine Months Ended September 30,	
	2004	**2003**
OPERATING ACTIVITIES:		
Net income	$ 114,099	$101,451
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	7,074	4,295
Amortization of deferred financing costs	299	298
Accretion of interest on note receivable	(103)	
Deferred income taxes	30,916	(16,315)
Compensation related to stock options		48,514
Loss on disposal of other intangible	3,800	
Loss on disposal of property and equipment	28	
Changes in assets and liabilities which provided (used) cash:		
Accounts receivable	(55,518)	(6,758)
Inventories	(41,476)	(10,488)
Other assets	(4,414)	(7,557)
Accounts payable	(8,220)	5,639
Accrued expenses	31,421	53,482
Income taxes payable	(8,295)	(4,552)
Net cash provided by operating activities	69,611	168,009
INVESTING ACTIVITIES:		
Purchase of property and equipment	(4,699)	(4,182)
Proceeds from the sale of property and equipment	246	
Payment of license termination fee	(3,000)	
Loan made to third party	(50,000)	
Other investments	(500)	
License fees	(47,250)	(25,000)
Net cash used in investing activities	(105,203)	(29,182)
FINANCING ACTIVITIES:		
Capital lease obligations repayments	(1,028)	(428)
Exercise of pre-merger Endo warrants		2
Tax sharing payment to Endo Pharma LLC	(8,348)	

Exercise of Endo Pharmaceutical Holdings Inc. Stock Options	375	127
Net cash used in financing activities	(9,001)	(299)
NET (DECREASE)INCREASE IN CASH AND CASH EQUIVALENTS	(44,593)	138,528
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	229,573	56,902
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 184,980	$ 195,430
SUPPLEMENTAL INFORMATION:		
Interest paid	$ 321	$ 287
Income taxes paid	$ 47,006	$ 82,891
SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES		
Purchase of property and equipment financed by capital leases	$ 3,359	$ 279

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 NINE MONTHS ENDED SEPTEMBER 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 September 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 September 30, 2004 and December 31, 2003, respectively (in thousands):

	September 30, 2004	December 31, 2003
Raw Materials	$13,914	$12,615
Work-in-Process	23,871	18,195
Finished Goods	54,141	19,640
Total	$91,926	$50,450

4. GOODWILL AND OTHER INTANGIBLES

Our goodwill and other intangible assets consist of the following at September 30, 2004 and December 31, 2003, respectively (in thousands):

	September 30, 2004	December 31, 2003
Goodwill	$181,079	$181,079
Amortizable Intangibles:		
Licenses	$125,050	$ 43,500
Patents	3,200	3,200
	128,250	46,700
Less accumulated amortization	(7,460)	(4,657)
Other Intangibles, net	$120,790	$ 42,043

Goodwill and other intangibles represent a significant portion of our assets and stockholders equity. As of September 30, 2004, goodwill and other intangibles comprised approximately 33% of our total assets and 47% 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

Table of Contents

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	$5,131
2005	8,220
2006	8,220
2007	8,220
2008	8,220

5. NOTE RECEIVABLE

As discussed further in Note 10, 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. Under the loan agreement, we provided Vernalis with a loan of $50 million in August 2004. The loan was primarily used to make a payment in full and final settlement of the amounts due to Elan Corporation from Vernalis in connection with Vernalis reacquisition of the North American rights to Frova®. The loan is secured against the revenues receivable by Vernalis under the license agreement. At our election, we are 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.

Endo has estimated that an approximate fair market rate of interest for this type of secured loan would be 8% per annum and therefore has recorded the note receivable at its present value at inception of $43.8 million. The note receivable will be accreted up to its face value at maturity using the effective interest method and thus the effective

interest rate over the five year term will be 8% per annum. The difference of $6.2 million between the face amount of the note and its present value at inception has been treated as additional consideration paid to acquire the license rights and has been included in Other Intangibles.

Table of Contents

6. COMPREHENSIVE INCOME

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net income	$41,377	$39,924	$114,099	$101,451
Other comprehensive income:				
Unrealized (losses) gains on securities, net of tax	(1,951)	764	(1,042)	1,126
Total comprehensive income	$39,426	$40,688	$113,057	$102,577

7. 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 25,615,339 shares of common stock of the Company held by Endo Pharma LLC for issuance. Endo Pharma LLC is a limited liability company that currently holds the majority of our common stock, in which affiliates of Kelso & Company and certain other members of management have an interest. 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:

Option Class	**Common Stock Closing Price Threshold**
C1A and C1B	$ 4.28
C2	$ 6.62
C3	$ 10.58
C4	$ 17.29

Table of Contents

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 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. During the three and nine months ended September 30, 2004, 692,387 and 826,723 stock options, respectively, were granted pursuant to this plan.

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. As of September 30, 2004, no awards have been granted pursuant to this plan.

Table of Contents

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.

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 62% and 60-70% in 2004 and 2003, respectively; risk-free interest rate of 3.2% and 3.2-4.0% 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 September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net income, as reported	$ 41,377	$ 39,924	$114,099	$101,451
APB 25 Compensation Expense				48,514
Tax effect of APB 25 compensation expense				(18,580)
SFAS 123 compensation expense	(1,619)	(1,077)	(4,132)	(67,219)
Tax effect of SFAS 123 compensation expense	615	408	1,572	25,739
Pro forma net income	$ 40,373	$ 39,255	$111,539	$ 89,905
Basic earnings per share, as reported	$ 0.31	$ 0.30	$ 0.87	$ 0.80
Basic earnings per share, pro forma	$ 0.31	$ 0.30	$ 0.85	$ 0.71
Diluted earnings per share, as reported	$ 0.31	$ 0.30	$ 0.86	$ 0.77
Diluted earnings per share, pro forma	$ 0.30	$ 0.30	$ 0.84	$ 0.68
Weighted average shares outstanding				
Basic	131,804	131,761	131,792	127,288
Diluted	132,460	132,636	132,688	132,510

8. 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.

Table of Contents

9. 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 are required to pay to Endo Pharma LLC upon the occurrence of a liquidity event, which occurred on August 9, 2004 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 September 30, 2004, approximately 7.6 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 September 30, 2004, approximately $96 million), which is estimated to result in a tax benefit amount of approximately $37 million. Under the tax sharing agreement, we are required to pay this $37 million to Endo Pharma LLC 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.

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 7.6 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 had been made or accrued prior to August 9, 2004. 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 could, 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 closed on August 9, 2004. This offering, when combined with the 16.6 million shares sold in July 2003, constituted a liquidity event and thus triggered a payment obligation. 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 (which occurred on August 9, 2004), we are required 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

Table of Contents

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 clarified 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 that closed on August 9, 2004 when added to the 16.6 million shares sold in July 2003 caused a liquidity event to occur, and we were obligated to pay to Endo Pharma LLC, within 30 business days, the tax benefit amounts attributable to 2001 and 2002 of approximately $2.0 million and $1.2 million, respectively. We were obligated to pay to Endo Pharma LLC, 50% of the estimated tax benefit amount of approximately $10.4 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 occurred in September 2004). Therefore, in September 2004, we paid $8.3 million to Endo Pharma LLC and, in October 2004, we paid $5.2 million to satisfy the tax sharing obligations attributable to 2001, 2002 and 2003. In addition, since 3.8 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised into common stock and sold in the offering 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 are obligated to pay Endo Pharma LLC a tax benefit of approximately $22 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 60-75 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). As of September 30, 2004, $5.2 million is included in accounts payable, $11.7 million is included in accrued expenses and $11.7 million is included in other liabilities related to tax sharing payments that we are obligated to pay which are attributable to 2003 and 2004. All payments made and accrued pursuant to the tax sharing agreement have been reflected as a reduction of stockholders equity in the accompanying financial statements. The 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 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 discussed above, up to 19 million shares 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.

10. 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

Table of Contents

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. On September 20, 2004, we announced that the FDA has asked us to clarify some aspects of the analysis of the study outcome prior to granting final approval of this protocol. This additional request does not affect the already agreed-upon design of the oxymorphone ER clinical trial, and we are in the process of complying with this request. 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 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 estimated 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. This amount was paid in October 2004. 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

Table of Contents

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 DepoBupivicaine™, 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 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® BP product. The license agreement provides for Endo to pay EpiCept milestones as well as royalties on the net sales of EpiCept s LidoPAIN® BP product. EpiCept has also retained an option to co-promote the LidoPAIN® 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® in the United States. We paid Hind a license fee of approximately $10 million based upon the achievement of certain milestones and capitalized this amount as an intangible asset representing the fair value of these exclusive rights. We are amortizing this intangible asset over its estimated useful life of 20 years. 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 September 30, 2004 and 2003, we accrued $9.4 million and $4.2 million, respectively, for this royalty. During the

Table of Contents

nine months ended September 30, 2004 and 2003, we accrued $23.2 million and $14.5 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®. 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®, 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® in Canada and Mexico.

Vernalis Development Limited

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 paid Vernalis an upfront fee of $30 million and we will make 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. We have capitalized the $30 million up-front payment, the present value of the two $15 million anniversary payments and the difference of $6.2 million between the face amount of the note and its present value at inception (See Note 5) as an intangible asset representing the fair value of the exclusive license to market Frova®. We are amortizing this intangible asset over its estimated useful life of 15 years. 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. Under the loan agreement, Endo provided Vernalis with a loan of $50 million in August 2004. The loan was primarily used to make a payment in full and final settlement of the amounts due to Elan Corporation from Vernalis in connection with Vernalis reacquisition of the North American rights to Frova®. The balance of the loan was available for general corporate purposes. The loan is 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.

Orexo AB

On August 18, 2004, we entered into an agreement granting us the exclusive rights to develop and market Orexo AB s (a privately held Swedish company) patented sublingual muco-adhesive fentanyl product (Rapinyl) in North America. Rapinyl is an oral, fast-dissolving tablet of fentanyl intended for the treatment of breakthrough cancer pain. Rapinyl is based on Orexo s unique patented technology for sublingual administration. The agreement provides for us to make an up-front license fee payment of $10 million, which we capitalized as an intangible asset representing the fair value of the exclusive right to market the product and are amortizing over its estimated useful life of 20 years, in addition to other license fees and payments based on development and regulatory milestones, which may total up to $22.1 million through FDA approval of Rapinyl s New Drug Application. The agreement also provides for double-digit royalties upon commercial sales and may include sales milestones if defined sales thresholds are

achieved. In addition, the license agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of the license agreement shall be until the later of (i) the expiration of the patents or (ii) the expiration of any market exclusivity right. We can terminate the license agreement under certain circumstances, including upon six months written notice, and we may be required to pay a termination fee of up to $1.5 million.

Lavipharm Laboratories, Inc.

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

Table of Contents

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 nine months ended September 30, 2004.

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. As of September 30, 2004, we have invested $1 million in this partnership and are accounting for this investment utilizing the equity method.

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.

11. 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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	**2003**	**2004**	**2003**

Numerator:				
Net income available to common stockholders	$ 41,377	$ 39,924	$114,099	$101,451
Denominator:				
For basic per share data weighted average shares	131,804	131,761	131,792	127,288
Effect of dilutive stock options	656	875	896	5,222
For diluted per share data weighted average shares	132,460	132,636	132,688	132,510
Basic earnings per share	$ 0.31	$ 0.30	$ 0.87	$ 0.80
Diluted earnings per share	$ 0.31	$ 0.30	$ 0.86	$ 0.77

During the three and nine months ended September 30, 2004, employees exercised stock options to acquire 16,450 and 43,294 shares of common stock at exercise prices ranging from $7.25 to $15.00.

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 64% of net sales for the years ended December 31, 2002, 2003 and the nine months ended September 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 80mg dosage strength. We have since received final FDA approval of our 80mg 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 November 3, 2004, the oral arguments relating to the appeal of this case were heard by the U.S. Court of Appeals for the Federal Circuit in Washington, D.C., at which hearing both sides presented their arguments before a three-judge panel. We are awaiting the outcome of this appeal.

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 discussed in the accompanying financial statements, up to 19 million shares remain eligible for sale 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. 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. On September 20, 2004, we announced that the FDA has asked us to clarify some aspects of the analysis of the study outcome prior to granting final approval of this protocol. This additional request does not affect the already agreed-upon design of the oxymorphone ER clinical trial and we are in the process of complying with this request. 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

Table of Contents

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 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 September 20, 2004, we announced that we had received final approval from the FDA of the clinical trial protocol relating to our developmental product, oxymorphone immediate-release tablets (oxymorphone IR). We had submitted the trial protocol to the FDA under the Special Protocol Assessment (SPA) process.

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 paid Vernalis an upfront fee of $30 million and we will make 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. Under the loan agreement, Endo provided Vernalis with a loan of $50 million at closing. The loan was primarily used to make a payment in full and final settlement of the amounts due to Elan Corporation from Vernalis in connection with Vernalis reacquisition of the North American rights to Frova®. The balance of the loan was available for general corporate purposes. The loan is 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.

On August 18, 2004, we announced that we had entered into an agreement granting us the exclusive rights to develop and market Orexo AB s (a privately held Swedish company) patented sublingual muco-adhesive fentanyl product (Rapinyl) in North America. Rapinyl is an oral, fast-dissolving tablet of fentanyl intended for the treatment of breakthrough cancer pain. The benefits of Rapinyl are believed to include both a fast onset of action and added convenience. Rapinyl is based on Orexo s unique patented technology for sublingual administration. This novel pharmaceutical preparation is believed to provide rapid absorption of the active substance and a fast onset of action. Currently in Phase II clinical development, this product has demonstrated enhanced absorption characteristics and is intended for the management of breakthrough pain in opioid-tolerant cancer patients. We anticipate that it will commence Phase III clinical trials in 2005. The agreement provides for us to make an up-front license fee payment of $10 million, in addition to other license fees and payments based on development and regulatory milestones, which

may total up to $22.1 million through FDA approval of Rapinyl s New Drug Application. The agreement also provides for double-digit royalties upon commercial sales and may include sales milestones if defined sales thresholds are achieved.

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

Table of Contents

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 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. As a result

Table of Contents

of the significance of our amortizable intangibles, any recognized impairment loss could have a material adverse impact on our financial position and results of operations.

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 September 30, 2004, goodwill and other intangibles comprised approximately 33% of our total assets and 47% 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 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):

	September 30, 2004	**December 31, 2003**
Goodwill	$181,079	$181,079
Amortizable Intangibles:		
Licenses	$125,050	$ 43,500
Patents	3,200	3,200
	128,250	46,700
Less accumulated amortization	(7,460)	(4,657)

Other Intangibles, net	$120,790	$ 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	$5,131
2005	8,220
2006	8,220
2007	8,220
2008	8,220

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

Table of Contents

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.

Compensation Related to Stock Options Endo Pharmaceuticals Holdings Inc. 2000 and 2004 Stock Incentive Plans

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. As of September 30, 2004, no options have been granted under 2004 Stock Incentive 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 nine months ended September 30, 2004 and 2003:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
	(in thousands)		(in thousands)	
Lidoderm®	$ 83,758	$ 37,451	$207,349	$129,558
Percocet®	26,044	58,972	70,412	166,865
Frova®	5,019		5,019	

Other brands	2,834	3,739	10,290	19,216
Total brands	$117,655	$100,162	$293,070	$315,639
Total generics	$ 42,694	$ 49,193	$164,736	$138,017
Total net sales	$160,349	$149,355	$457,806	$453,656

Table of Contents

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Lidoderm®	52%	25%	45%	29%
Percocet®	16%	39%	16%	37%
Frova®	3%		1%	
Other brands	2%	3%	2%	4%
Total brands	73%	67%	64%	70%
Total generics	27%	33%	36%	30%
Total net sales	100%	100%	100%	100%

Three Months Ended September 30, 2004 Compared to the Three Months Ended September 30, 2003

Net Sales. Net sales for the three months ended September 30, 2004 increased to $160.3 million from $149.4 million in the comparable 2003 period. This increase in net sales was primarily due to the increase in the net sales of Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia, offset by the reduction in the net sales of Percocet® and certain generic products. Net sales of Lidoderm® increased to $83.8 million from $37.5 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. Lidoderm® inventory levels at our customers remain at relatively low levels compared to historical levels. We expect our customers inventory levels of Lidoderm® to remain at these levels for the remainder of 2004. Percocet® net sales decreased to $26.0 million from $59.0 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. Due to the generic erosion of Percocet®, inventory levels at our customers increased above normal levels during the second quarter of 2004. We had expected that inventory levels of Percocet® at our customers would return to normal levels during the third quarter of 2004; however, they remain approximately 3-4 weeks higher than normal at the end of the third quarter of 2004. We anticipate that our customers will be back to normal inventory levels by the end of 2004. Net sales of Frova® were $5.0 million for the three months ended September 30, 2004. We began shipping Frova® upon closing of the license agreement in mid-August 2004 and initiated our promotional efforts in September 2004. Net sales of our generic products decreased to $42.7 million from $49.2 million in the comparable 2003 period primarily due to increased generic competition with Endocet® and our morphine sulfate extended release tablets. During the third quarter of 2004, we have begun to experience both pricing pressure as well as a reduction in our share for both Endocet® and our morphine sulfate extended-release tablets due to generic competition. We expect that competitors will continue to have an impact on our market share and price of both of these generic products, which will adversely affect the net sales and profitability of our generic products. We are raising our financial guidance for 2004 and believe that we will be able to achieve 2004 net sales of approximately $600 million. Further, we reaffirm our previous guidance for Lidoderm® net sales, which we continue to expect 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 $1.06 per share. Of course, there can be no assurance of Endo achieving these results.

Gross Profit. Gross profit for the three months ended September 30, 2004 decreased slightly to $122.1 million from $122.3 million in the comparable 2003 period. Gross profit margins decreased to 76% from 82% due to the shift in revenues from higher-margin Percocet® to generic Endocet® combined with the impact of pricing pressures on our generic morphine sulfate product and our generic Endocet® and the introduction of child-resistant packaging for Lidoderm® during the second quarter of 2004.

Selling, General and Administrative Expenses. Selling, general and administrative expenses for the three months ended September 30, 2004 increased by 22% to $43.5 million from $35.8 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 for our growing business including our products Lidoderm®, Frova® and DepoDur.

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2004 decreased by $11.2 million to $9.5 million from $20.7 million in the comparable 2003 period. This decrease is primarily attributable to a $5 million milestone payment paid in the third quarter of 2003 to SkyePharma related to DepoDurTM and the overall stage of development of our development portfolio. During 2003, our development efforts were focused on our since-discontinued oral mucositis product which was in Phase III clinical trials.

Table of Contents

Depreciation and Amortization. Depreciation and amortization for the three months ended September 30, 2004 increased to $3.0 million from $1.6 million in the comparable 2003 period primarily due to an increase in depreciation expense as a result of an increase in capital expenditures and an increase in amortization expense as a result of new license rights acquired during 2004. 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 September 30, 2004 was $578,000 in interest income compared to $12,000 in interest expense in the comparable 2003 period. This change is substantially due to the increased interest income earned as a result of higher average cash balances during the third quarter of 2004 and interest income earned on our note receivable from Vernalis.

Income Tax. Income tax for the three months ended September 30, 2004 increased to $25.3 million from $24.4 million in the comparable 2003 period. This increase is due to the increase in income before income tax for the three months ended September 30, 2004.

Nine Months Ended September 30, 2004 Compared to the Nine Months Ended September 30, 2003

Net Sales. Net sales for the nine months ended September 30, 2004 increased to $457.8 million from $453.7 million in the comparable 2003 period. This increase in net sales was primarily due to the increase in the net sales of Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia, and an increase in the net sales of our generic products offset by the reduction in the net sales of Percocet®. Net sales of Lidoderm® increased to $207.3 million from $129.6 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. Lidoderm® levels at our customers remain at relatively low levels compared to historical levels. We expect our customers inventory levels of Lidoderm® to remain at these levels for the remainder of 2004. Percocet® net sales decreased to $70.4 million from $166.9 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. Due to the generic erosion of Percocet®, inventory levels at our customers increased above normal levels during the second quarter of 2004. We had expected that inventory levels of Percocet® at our customers would return to normal levels during the third quarter of 2004; however, they remain approximately 3-4 weeks higher than normal at the end of the third quarter of 2004. We anticipate that our customers will be back to normal inventory levels by the end of 2004. Net sales of Frova® were $5.0 million for the nine months ended September 30, 2004. We began shipping Frova® upon closing of the license agreement in mid-August 2004 and initiated our promotional efforts in September 2004. Net sales of our generic products increased to $164.7 million from $138.0 million in the comparable 2003 period primarily due to the growth of Endocet®. During the first nine months of 2004, Endo has experienced a decrease in net sales of its morphine sulfate extended-release tablets due to generic competition introduced in the third quarter of 2003; however, this has been offset by our launch in the fourth quarter of 2003 of two new strengths of Endocet®. During the third quarter of 2004, we have begun to experience both pricing pressure as well as a reduction in our share for both Endocet® and our morphine sulfate extended-release tablets. We expect that competitors will continue to have an impact on our market share and price of both of these generic products, which will adversely affect the net sales and profitability of our generic products. We are raising our financial guidance for 2004 and believe that we will be able to achieve 2004 net sales of approximately $600 million. Further, we reaffirm our previous guidance for Lidoderm® net sales, which we continue to expect 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 $1.06 per share. Of course, there can be no assurance of Endo achieving these results.

Gross Profit. Gross profit for the nine months ended September 30, 2004 decreased by 4% to $357.8 million from $372.8 million in the comparable 2003 period. Gross profit margins decreased to 78% from 82% due to the shift in revenues from higher-margin Percocet® to generic Endocet® combined with the impact of pricing pressures on our generic morphine sulfate product and our generic Endocet® and the introduction of child-resistant packaging for Lidoderm® during the second quarter of 2004.

Selling, General and Administrative Expenses. Selling, general and administrative expenses for the nine months ended September 30, 2004 increased by 10% to $125.3 million from $113.7 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 for our growing business including our products Lidoderm®, Frova® and DepoDur .

Research and Development Expenses. Research and development expenses for the nine months ended September 30, 2004 decreased by 9% to $38.5 million from $42.2 million in the comparable 2003 period. This decrease is primarily attributable to the overall stage of development of our development portfolio partially offset by $10 million in milestone payments in the first nine

Table of Contents

months of 2004 compared to $5 million in milestone payments in the comparable 2003 period. During 2003, our development efforts were focused on our since-discontinued oral mucositis product which was in Phase III clinical trials.

Depreciation and Amortization. Depreciation and amortization for the nine months ended September 30, 2004 increased to $7.1 million from $4.3 million in the comparable 2003 period primarily due to an increase in depreciation expense as a result of an increase in capital expenditures and an increase in amortization expense as a result of new license rights acquired during 2004. 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 nine months ended September 30, 2004 from $48.5 million during the nine months ended September 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 nine months ended September 30, 2004 was $796,000 in interest income compared to $165,000 in interest expense in the comparable 2003 period. This change is substantially due to the increased interest income earned as a result of higher average cash balances during the nine months of 2004 and interest income earned on our note receivable from Vernalis.

Income Tax. Income tax for the nine months ended September 30, 2004 increased to $69.9 million from $62.5 million in the comparable 2003 period. This increase is due to the increase in income before income tax for the nine months ended September 30, 2004.

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 $69.6 million for the nine months ended September 30, 2004 from $168.0 million for the nine months ended September 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 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® has not only been able to keep up with

demand, but we have been able to build 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 and into 2005 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 Used in Investing Activities. Net cash used in investing activities increased by $76.0 million to $105.2 million for the nine months ended September 30, 2004 from $29.2 million for the nine months ended September 30, 2003. During the nine months ended September 30, 2004, the Company loaned $50 million to a third party, paid $47.3 million in license fees, a termination penalty of $3.0 million to Lavipharm, invested $0.5 million in a limited partnership, and had capital expenditures of $4.7 million primarily

Table of Contents

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 $4.2 million in capital expenditures during the nine months ended September 30, 2003.

Net Cash Used in Financing Activities. Net cash used in financing activities increased to $9.0 million for the nine months ended September 30, 2004 from $0.3 million for the nine months ended September 30, 2003 primarily due to an $8.3 million payment to Endo Pharma LLC pursuant to the tax sharing agreement and an increase in capital lease obligations repayments made during the first nine months of 2004 compared to 2003 partially offset by an increase in the proceeds received from the exercise of stock options during the first nine months of 2004 compared to 2003. See Tax Sharing Agreement below.

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 September 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 are required to pay to Endo Pharma LLC upon the occurrence of a liquidity event, which occurred on August 9, 2004 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 September 30, 2004, approximately 7.6 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 September 30, 2004, approximately $96 million), which is estimated to result in a tax benefit amount of approximately $37 million. Under the tax sharing agreement, we are required to pay this $37 million to Endo Pharma LLC 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.

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 7.6 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

Table of Contents

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 had been made or accrued prior to August 9, 2004. 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 could, 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 closed on August 9, 2004. This offering, when combined with the 16.6 million shares sold in July 2003, constituted a liquidity event and thus triggered a payment obligation. 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 (which occurred on August 9, 2004), we are required 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 clarified 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 that closed on August 9, 2004 when added to the 16.6 million shares sold in July 2003 caused a liquidity event to occur, and we were obligated to pay to Endo Pharma LLC, within 30 business days, the tax benefit amounts attributable to 2001 and 2002 of approximately $2.0 million and $1.2 million, respectively. We were obligated to pay to Endo Pharma LLC, 50% of the estimated tax benefit amount of approximately $10.4 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 occurred in September 2004). Therefore, in September 2004, we paid $8.3 million to Endo Pharma LLC and, in October 2004, we paid $5.2 million to satisfy the tax sharing obligations attributable to 2001, 2002 and 2003. In addition, since 3.8 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised into common stock and sold in the offering 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 are obligated to pay Endo Pharma LLC a tax benefit of approximately $22 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 60-75 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). As of September 30, 2004, $5.2 million is included in accounts payable, $11.7 million is included in accrued expenses and $11.7 million is included in other liabilities related to tax sharing payments that we are obligated to pay which are attributable to 2003 and 2004. All payments made and accrued pursuant to the tax sharing agreement have been reflected as a reduction of stockholders equity in the accompanying financial statements. The 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 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 discussed above, up to 19 million shares remain eligible for sale 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.

Table of Contents

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 Laboratories, Inc.

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 nine months ended September 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.

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

Table of Contents

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. This amount was paid in October 2004. Both of these amounts, totaling $10 million, are included in research and development for the three months and nine months ended September 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 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. On September 20, 2004, we announced that the FDA has asked us to clarify some aspects of the analysis of the study outcome prior to granting final approval of this protocol. This additional request does not affect the already agreed-upon design of the oxymorphone ER clinical trial and we are in the process of complying with this request. 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 Development Limited

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 paid Vernalis an upfront fee of $30 million and we will make 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. Under the loan

Table of Contents

agreement, Endo provided Vernalis with a loan of $50 million at closing. The loan was primarily used to make a payment in full and final settlement of the amounts due to Elan Corporation from Vernalis in connection with Vernalis reacquisition of the North American rights to Frova®. The balance of the loan was available for general corporate purposes. The loan is 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.

Orexo AB

On August 18, 2004, we entered into an agreement granting us the exclusive rights to develop and market Orexo AB s (a privately held Swedish company) patented sublingual muco-adhesive fentanyl product (Rapinyl) in North America. Rapinyl is an oral, fast-dissolving tablet of fentanyl intended for the treatment of breakthrough cancer pain. Rapinyl is based on Orexo s unique patented technology for sublingual administration. The agreement provides for us to make an up-front license fee payment of $10 million, which we capitalized as an intangible asset representing the fair value of the exclusive right to market this product, in addition to other license fees and payments based on development and regulatory milestones, which may total up to $22.1 million through FDA approval of Rapinyl s New Drug Application. The agreement also provides for double-digit royalties upon commercial sales and may include sales milestones if defined sales thresholds are achieved. In addition, the license agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of the license agreement shall be until the later of (i) the expiration of the patents or (ii) the expiration of any market exclusivity right. We can terminate the license agreement under certain circumstances, including upon six months written notice and we may be required to pay a termination fee of up to $1.5 million.

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.

Expected Cash Requirements for Contractual Obligations. Our expected cash requirements for contractual obligations outstanding as of September 30, 2004 have increased, by $5.2 million for tax sharing payments due in 2004, $23.5 million for tax sharing payments due in 2005 and $30.0 million for two $15 million license payments due to Vernalis in both 2005 and 2006, when compared to the amounts contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2003.

Cash and Cash Equivalents. Our cash and cash equivalents totaled $185.0 million at September 30, 2004. We believe that our (a) cash and cash equivalents, (b) cash flow from operations and (c) our credit facility (which has an available unused line of credit of $75 million) will be sufficient to meet our normal operating, investing and financing

requirements in the foreseeable future, including the funding of our pipeline projects in the event that our collaboration partners are unable or unwilling to fund their portion of any particular project. We may use a portion of our cash and cash equivalents for possible acquisitions and licensing opportunities.

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

Table of Contents

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.

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

At September 30, 2004, we had publicly traded equity securities comprised of DURECT Corporation common stock at fair value totaling $2.1 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 September 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 $0.5 million, $0.9 million and $1.1 million, respectively. Our cost basis in this investment is $5.0 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 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.

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

Table of Contents

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. By an earlier order, the judge bifurcated the antitrust counterclaims for a separate and subsequent trial. On November 3, 2004, the oral arguments relating to the appeal of this case were heard by the U.S. Court of Appeals for the Federal Circuit in Washington, D.C., at which hearing both sides presented their arguments before a three-judge panel. We are awaiting the outcome of this appeal.

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.

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.

Litigation similar to that described above may also be brought by other plaintiffs in various jurisdictions. However, we cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against

us.

The City of New York v. Abbott Laboratories, Inc., et al., Index No. 04 CV 06054 (S.D.N.Y.)

On August 4, 2004, the City of New York filed a complaint in the United States District Court for the Southern District of New York against EPI and 43 other pharmaceutical companies. The complaint alleges that the defendants violated state and federal law by fraudulently overcharging the Medicaid program, and the plaintiff seeks monetary damages and other monetary relief, civil penalties, and injunctive relief. On October 11, 2004, the case was transferred to the United States District Court for the District of Massachusetts, by order of the United States Judicial Panel on Multidistrict Litigation. EPI intends to defend itself vigorously in this case.

Litigation similar to that described above may also be brought by other plaintiffs in various jurisdictions. However, we cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against us.

Table of Contents

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.

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

None.

Item 5. ***Other Information.***

None.

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

(a) *Exhibits*.

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

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

We filed the following Current Reports on Form 8-K during the quarter ended September 30, 2004:

Dates	Items
July 7, 2004	5 and 7
July 15, 2004	5, 7 and 12
July 16, 2004	5 and 7
July 19, 2004	5 and 7
August 9, 2004	5 and 7

No financial statements were filed in connection with any such Form 8-K.

33

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: November 5, 2004

Table of Contents

Exhibit Index

Exhibit No.	Title
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)
4.1.2	Amendment to Amended and Restated Executive Stockholders Agreement, dated as of June 28, 2004, by and among Endo, Endo LLC, KIA V, KEP V and the Management Stockholders (as defined therein)
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)
4.2.2	Amendment to Amended and Restated Employee Stockholders Agreement, dated as of June 28, 2004, by and among Endo, Endo LLC, KIA V, KEP V and the Management Stockholders (as defined therein)
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	[Intentionally Omitted.]
10.2	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)

10.3 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)

10.4 [Intentionally Omitted.]

10.5 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, 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)

Table of Contents

Exhibit No.	Title
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. (incorporated herein by reference to Exhibit 10.9 of the Form 10-Q for the Quarter ended June 30, 2004 filed with the Commission on August 9, 2004)
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	[Intentionally Omitted.]
10.12	[Intentionally Omitted.]
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)
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)

Table of Contents

Exhibit No.	Title
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)
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	[Intentionally Omitted.]
10.32	[Intentionally Omitted.]
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 (incorporated herein by reference to Exhibit 10.37 of the Form 10-Q for the Quarter ended June 30, 2004 filed with the Commission on August 9, 2004)

10.38 [Intentionally Omitted.]

Table of Contents

Exhibit No.	Title
10.39	Master Development and Toll Manufacturing Agreement, dated as of 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)

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