

ENDO PHARMACEUTICALS HOLDINGS INC  
Form 10-Q  
November 02, 2007  
Table of Contents

---

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

---

**FORM 10-Q**

---

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2007.

OR

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

Commission file number: 001-15989

---

**ENDO PHARMACEUTICALS HOLDINGS INC.**

(Exact Name of Registrant as Specified in Its Charter)

---

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

**100 Endo Boulevard**

**Chadds Ford, Pennsylvania 19317**

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

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

(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 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 period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). YES  NO

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

Common Stock: \$0.01 par value

Shares outstanding as of October 26, 2007: 134,112,148

---

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**INDEX**

	<b>Page</b>
<u>Forward-Looking Statements</u>	3
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
<u>Item 1. Financial Statements</u>	5
<u>Condensed Consolidated Balance Sheets (Unaudited) September 30, 2007 and December 31, 2006</u>	5
<u>Condensed Consolidated Statements of Operations (Unaudited) Three and Nine Months Ended September 30, 2007 and 2006</u>	6
<u>Condensed Consolidated Statements of Cash Flows (Unaudited) Nine Months Ended September 30, 2007 and 2006</u>	7
<u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>	8
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	25
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	46
<u>Item 4. Controls and Procedures</u>	46
<b><u>PART II. OTHER INFORMATION</u></b>	
<u>Item 1. Legal Proceedings</u>	47
<u>Item 1A. Risk Factors</u>	47
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	47
<u>Item 3. Defaults Upon Senior Securities</u>	47
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	47
<u>Item 5. Other Information</u>	47
<u>Item 6. Exhibits</u>	47
<b><u>SIGNATURES</u></b>	
	47

**Table of Contents**

**FORWARD LOOKING STATEMENTS**

This document contains information that includes or is based on forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements, including estimates of future net sales, future expenses, 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, plan, will, may or similar expressions are forward-looking statements. We make 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 or incorporated by reference in Item 1A Risk Factors in this document, supplement, and as otherwise enumerated herein, 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 document. Important factors that could cause our actual results to differ materially from the expectations reflected in the forward-looking statements in this document include those factors described in this document under Item 1A titled Risk Factors, including, among others:

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

timing and 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 our 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;

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

our ability to protect our proprietary technology;

the successful efforts of manufacturers of branded pharmaceuticals to use litigation and legislative and regulatory efforts to limit the use of generics and certain other products;

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

regulatory or other limits on 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 or future litigation or claims by the government;

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;

significant litigation expenses to defend or assert patent infringement claims;

any interruption or failure by our suppliers, distributors and collaboration partners to meet their obligations pursuant to various agreements with us;

a determination by a regulatory agency that we are engaging in inappropriate sales or marketing activities, including promoting the off-label use of our products;

**Table of Contents**

existing suppliers become unavailable or lose their regulatory status as an approved source, causing an inability to obtain required components, raw materials or products on a timely basis or at commercially reasonable prices; and

the loss of branded product exclusivity periods and related intellectual property.

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. You are advised, however, to consult any further disclosures we make on related subjects in our 10-Q, 10-K and 8-K reports to the Securities and Exchange Commission (or SEC). Also note that we provide the preceding cautionary discussion of risks, uncertainties and possibly inaccurate assumptions relevant to our business. These are factors that, individually or in the aggregate, we think could cause our actual results to differ materially from expected and historical results. We note these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider the preceding to be a complete discussion of all potential risks or uncertainties.

**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,	December 31,
	2007	2006
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 274,884	\$ 628,085
Marketable securities	608,000	
Accounts receivable, net	214,252	279,159
Inventories	74,509	62,129
Prepaid expenses and other current assets	13,680	11,663
Deferred income taxes	50,950	54,978
<b>Total current assets</b>	<b>1,236,275</b>	<b>1,036,014</b>
PROPERTY AND EQUIPMENT, Net	44,783	36,565
GOODWILL	181,079	181,079
OTHER INTANGIBLES, Net	73,390	78,046
NOTE RECEIVABLE	50,016	52,872
DEFERRED INCOME TAXES		1,745
OTHER ASSETS	18,429	10,368
<b>TOTAL ASSETS</b>	<b>\$ 1,603,972</b>	<b>\$ 1,396,689</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 149,451	\$ 122,647
Accrued expenses	158,483	164,528
Due to Endo Pharma LLC	19,323	38,693
Estimated amount due seller, current portion	15,000	
Income taxes payable	5,679	12,231
<b>Total current liabilities</b>	<b>347,936</b>	<b>338,099</b>
DEFERRED INCOME TAXES	6,581	
ESTIMATED AMOUNT DUE SELLER	530	15,530
OTHER LIABILITIES	11,775	2,072
<b>COMMITMENTS AND CONTINGENCIES (NOTE 11)</b>		
<b>STOCKHOLDERS EQUITY:</b>		
Preferred Stock, \$0.01 par value; 40,000,000 shares authorized; none issued		
Common Stock, \$0.01 par value; 175,000,000 shares authorized; 134,111,380 and 133,600,959 shares issued and outstanding at September 30, 2007 and December 31, 2006, respectively	1,341	1,336
Additional paid-in capital	700,685	679,704

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

Retained earnings	533,021	358,831
Accumulated other comprehensive income	2,103	1,117
Total stockholders' equity	1,237,150	1,040,988
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 1,603,972	\$ 1,396,689

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		Nine Months Ended	
	September 30, 2007	September 30, 2006	September 30, 2007	September 30, 2006
NET SALES	\$ 269,470	\$ 217,125	\$ 781,026	\$ 650,188
COST OF SALES (1)	49,779	44,406	151,634	143,551
GROSS PROFIT	219,691	172,719	629,392	506,637
COSTS AND EXPENSES:				
Selling, general and administrative	107,399	87,850	287,205	252,281
Research and development	26,886	14,456	79,571	59,382
Depreciation and amortization	5,068	4,636	12,996	12,944
OPERATING INCOME	80,338	65,777	249,620	182,030
INTEREST INCOME, Net	9,733	6,851	25,015	17,072
INCOME BEFORE INCOME TAX	90,071	72,628	274,635	199,102
INCOME TAX	30,924	27,737	97,793	76,037
NET INCOME	\$ 59,147	\$ 44,891	\$ 176,842	\$ 123,065
NET INCOME PER SHARE:				
Basic	\$ 0.44	\$ 0.34	\$ 1.32	\$ 0.92
Diluted	\$ 0.44	\$ 0.33	\$ 1.31	\$ 0.92
WEIGHTED AVERAGE SHARES:				
Basic	133,915	133,270	133,835	133,067
Diluted	134,611	134,147	134,491	133,961

(1) Excludes the following amounts of amortization expense related to commercial products:

\$ 1,230   \$ 1,972   \$ 3,690   \$ 5,495

See notes to Condensed Consolidated Financial Statements.

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

	<b>Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2007</b>	<b>2006</b>
<b>OPERATING ACTIVITIES:</b>		
Net income	\$ 176,842	\$ 123,065
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	12,996	12,944
Stock-based compensation	10,940	9,337
Interest earned on available-for-sale securities	(3,477)	
Accretion of interest on note receivable	(930)	(930)
Deferred income taxes	13,527	15,015
Amortization of deferred financing costs		287
(Gain) loss on disposal of property and equipment	(326)	975
Selling, general and administrative expenses to be funded by Endo Pharma LLC		41,330
Changes in assets and liabilities which provided (used) cash:		
Accounts receivable	64,907	30,902
Inventories	(12,380)	(17,371)
Note receivable	(254)	(2,019)
Prepaid and other assets	5,878	5,139
Accounts payable	24,508	21,712
Accrued expenses	(4,577)	(41,825)
Due to Endo Pharma LLC		(5,624)
Other liabilities	2,626	
Income taxes receivable/payable	(2,849)	82,606
 Net cash provided by operating activities	 287,431	 275,543
<b>INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	(15,905)	(8,882)
Proceeds from the sale of property and equipment	125	94
Purchases of available-for-sale securities	(676,091)	
Sales of available-for-sale securities	62,951	
Acquisitions of license rights		(32,900)
Distribution from equity method investee	1,096	
Other investments	(2,800)	
 Net cash used in investing activities	 (630,624)	 (41,688)
<b>FINANCING ACTIVITIES:</b>		
Capital lease obligations repayments	(766)	(1,856)
Tax sharing payments to Endo Pharma LLC	(20,000)	(96,715)
Tax benefits of stock options exercised	3,661	32,106
Exercise of Endo Pharmaceuticals Holdings Inc. Stock Options	7,097	6,304
 Net cash used in financing activities	 (10,008)	 (60,161)
 NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	 (353,201)	 173,694

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

CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	628,085	500,956
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 274,884	\$ 674,650
SUPPLEMENTAL INFORMATION:		
Interest paid	90	\$ 1,519
Income taxes paid	80,961	\$ 15,533
SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES		
Purchase of property and equipment financed by capital leases	73	\$ 218
Change in accrual for purchases of property and equipment	\$ (2,296)	\$ (3,124)
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, 2007**

**1. BASIS OF PRESENTATION**

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission for interim financial information. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, the accompanying condensed consolidated financial statements of Endo Pharmaceuticals Holdings Inc. (the Company or we or Endo ) and its subsidiaries, which are unaudited, include all normal and recurring adjustments considered necessary to present fairly the Company's financial position as of September 30, 2007 and the results of our operations and our cash flows for the periods presented. Operating results for the three-month and nine-month periods ended September 30, 2007 is not necessarily indicative of the results that may be expected for the year ended December 31, 2007.

The accompanying condensed consolidated balance sheet as of December 31, 2006 is derived from the Company's audited financial statements at that date but does not include all of the information and footnotes required by generally accepted accounting principles for complete 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, 2006 contained in the Company's Annual Report on Form 10-K.

**2. RECENT ACCOUNTING PRONOUNCEMENTS**

In July 2006, the Financial Accounting Standards Board ( FASB ) issued FASB Interpretation No. 48 ( FIN 48 ), *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109, Accounting for Income Taxes*. FIN 48 creates a single model to address uncertainty in tax positions. FIN 48 clarifies the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. In addition, FIN 48 clearly scopes out income taxes from Statement of Financial Accounting Standards ( SFAS ) No. 5, *Accounting for Contingencies*. FIN 48 is effective for fiscal years beginning after December 15, 2006. We have adopted FIN No. 48 as of January 1, 2007. The adoption resulted in a charge of \$2.7 million recorded directly to retained earnings as a cumulative effect of a change in accounting principle. See Note 13 for further discussion.

In September 2006, the FASB issued SFAS No.157 ( SFAS 157 ), *Fair Value Measurements*, which addresses how companies should measure fair value when they are required to use a fair value measure for recognition or disclosure purposes under accounting principles generally accepted in the United States. SFAS 157 is effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact of the adoption of this Statement on its financial statements.

In February 2007, the FASB issued SFAS No. 159 ( SFAS 159 ) *The Fair Value Option for Financial Assets and Financial Liabilities*, providing companies with an option to report selected financial assets and liabilities at fair value. This Standard's objective is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. Generally accepted accounting principles have required different measurement attributes for different assets and liabilities that can create artificial volatility in earnings. SFAS 159 helps to mitigate this type of accounting-induced volatility by enabling companies to report related assets and liabilities at fair value, which would likely reduce the need for companies to comply with detailed rules for hedge accounting. SFAS 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. This Standard requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of the Company's choice to use fair value on its earnings. It also requires entities to display the fair value of those assets and liabilities for which the Company has chosen to use fair value on the face of the balance sheet. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact of the adoption of this Statement on its financial statements.

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

In June 2007, the Emerging Issues Task Force (Task Force) of the FASB reached a consensus on Issue No. 07-3 ( EITF 07-3 ), *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*. Under

## **Table of Contents**

EITF 07-3, nonrefundable advance payments for goods or services that will be used or rendered for research and development activities should be deferred and capitalized. Such payments should be recognized as an expense as the goods are delivered or the related services are performed, not when the advance payment is made. If a company does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. EITF 07-3 is effective for financial statements issued for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. Earlier application is not permitted. Companies are required to report the effects of applying EITF 07-3 prospectively for new contracts entered into on or after the effective date. The Company is currently evaluating the impact of the adoption of EITF 07-3 on its consolidated financial statements.

In September 2007, the Emerging Issues Task Force (Task Force) of the FASB reached a consensus on Issue No. 07-1 ( EITF 07-1 ), *Accounting for Collaborative Arrangements*. The scope of EITF 07-1 is limited to collaborative arrangements where no separate legal entity exists and in which the parties are active participants and are exposed to significant risks and rewards that depend on the success of the activity. The Task Force concluded that revenue transactions with third parties and associated costs incurred should be reported in the appropriate line item in each company's financial statements pursuant to the guidance in EITF 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*. The Task Force also concluded that the equity method of accounting under Accounting Principles Board Opinion 18, *The Equity Method of Accounting for Investments in Common Stock*, should not be applied to arrangements that are not conducted through a separate legal entity. The Task Force also concluded that the income statement classification of payments made between the parties in an arrangement should be based on a consideration of the following factors: the nature and terms of the arrangement; the nature of the entities' operations; and whether the partners' payments are within the scope of existing GAAP. To the extent such costs are not within the scope of other authoritative accounting literature, the income statement characterization for the payments should be based on an analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. The provisions of EITF 07-1 are effective for fiscal years beginning on or after December 15, 2007, and companies will be required to apply the provisions through retrospective application. The Company is currently evaluating the impact of the adoption of EITF 07-1 on its consolidated financial statements.

### **3. MARKETABLE SECURITIES**

The Company accounts for investments in marketable securities in accordance with the provisions of SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. We classify our marketable securities as available-for-sale securities. Management determines the appropriate classification of marketable securities at the time of purchase and reevaluates such designation as of each balance sheet date. Available-for-sale securities are carried at fair market value. Unrealized gains and losses, net of tax, are included in accumulated other comprehensive income as a separate component of stockholders' equity. The Company recognizes an impairment charge when the declines in the fair values of its investments below the cost basis are judged to be other-than-temporary. The Company considers various factors in determining whether to recognize a decline in value, including the length of time and extent to which the fair value has been less than the Company's cost basis, the financial condition and near-term prospects of the issuer or investee, and the Company's intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value. The Company has not recorded any such impairment in any of the periods presented. The cost of securities sold is based on the specific identification method. The Company classifies investments in marketable securities as current when their remaining time to maturity is less than or equal to 12 months or, if time to maturity is greater than 12 months, when they represent investments of cash that are intended to be used in current operations.

The cost of the debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, when present. Such amortization and accretion, along with realized gains and losses, are included in interest income, net. Available-for-sale securities held by the Company as of September 30, 2007 and December 31, 2006 were as follows (in thousands):

**Table of Contents**

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized (Losses)	Fair Value
<b>September 30, 2007:</b>				
Money market funds	\$ 249,259	\$	\$	\$ 249,259
<i>Total included in Cash and cash equivalents</i>	249,259			249,259
Auction-rate securities	505,779			505,779
Variable-rate demand obligations	91,221			91,221
Equity securities	11,000			11,000
<i>Total included in Marketable securities</i>	608,000			608,000
Municipal bond	5,140			5,140
Equity securities	5,000	23,267	(19,862)	8,405
<i>Total included in Other Assets</i>	10,140	23,267	(19,862)	13,545
<i>Total available-for-sale securities</i>	\$ 867,399	\$ 23,267	\$ (19,862)	\$ 870,804
<b>December 31, 2006:</b>				
Money market funds	\$ 578,903	\$	\$	\$ 578,903
<i>Total included in Cash and cash equivalents</i>	578,903			578,903
Equity securities	5,000	20,092	(18,282)	6,810
<i>Total included in Other Assets</i>	5,000	20,092	(18,282)	6,810
<i>Total available-for-sale securities</i>	\$ 583,903	\$ 20,092	\$ (18,282)	\$ 585,713

Auction rate securities and variable rate demand obligations are long-term variable rate bonds tied to short-term interest rates. After the initial issuance of the securities, the interest rate on the securities is reset periodically, at intervals established at the time of issuance (e.g., every seven, twenty-eight, or thirty-five days; every six months; etc.), based on the market demand for a reset period. Auction rate securities are bought and sold in the marketplace through a competitive bidding process, often referred to as a "Dutch auction". Variable rate demand obligations are typically bought and sold through a remarketing process, whereby an investor tenders their bonds to a trustee for purchase at any auction or remarketing date. A remarketing agent resets the interest rate on variable rate demand obligations to a rate that will successfully allow remarketing of those bonds and remarkets the bonds to new investors. Equity securities included in Marketable Securities in the Condensed Consolidated Balance Sheets consist of investments in open-end mutual funds that invest in U.S. government securities. These investments are classified as equity investments since it is the shares of the fund, and not the ultimate debt securities, that are owned. Investments in open-end mutual funds represent the investment of cash available for current operations, and therefore are classified as current assets of the Company. Equity securities included in Other Assets in the Condensed Consolidated Balance Sheets consists of publicly traded equity securities which are not held to support current operations. Accordingly, they are classified as non-current assets. Money market funds represent a type of mutual fund required by law to invest in low-risk securities (for example, U.S. government bonds, U.S. Treasury Bills and commercial paper). Money market funds are structured to maintain the fund's net asset value at \$1 per unit, which assists in ensuring adequate liquidity upon demand by the holder. Money market funds pay dividends that generally reflect short-term interest rates. Thus, only the dividend yield fluctuates.

The amortized cost and estimated fair value of debt and equity securities by contractual maturities are shown below (in thousands). Actual maturities may differ from contractual maturities because borrowers may have the right to call or prepay obligations with or without call or prepayment penalties.

**Table of Contents**

	September 30, 2007		December 31, 2006	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Debt Securities:				
Due in less than 1 year	\$ 597,000	\$ 597,000	\$	\$
Due in 1 to 2 years	5,140	5,140		
Equity Securities	16,000	19,405	5,000	6,810
Money market funds	249,259	249,259	578,903	578,903
Total	\$ 867,399	\$ 870,804	\$ 583,903	\$ 585,713

While the underlying securities of auction rate securities and variable rate demand obligations generally have contractual maturities between 20 and 30 years, the interest rates on such securities typically reset at intervals between 7 to 35 days. Despite the underlying long-term maturity of these securities, from the investor's perspective, such securities are priced and subsequently trade as short-term investments because of the interest rate reset feature. As a result, the Company has the ability to quickly liquidate these securities. The Company has no cumulative gross unrealized holding gains (losses) or gross realized gains (losses) from these investments. All income generated from these short-term investments has been recorded as interest income.

Our investments in marketable securities are governed by our investment policy, which has been approved by our Board of Directors. Our investment policy seeks to preserve the value of capital, consistent with maximizing return on the Company's investment, while maintaining adequate liquidity.

**4. INVENTORIES, NET**

Inventories are comprised of the following at September 30, 2007 and December 31, 2006, respectively (in thousands):

	September 30,	December 31,
	2007	2006
Raw Materials	\$ 10,178	\$ 7,619
Work-in-Process	16,878	9,718
Finished Goods	47,453	44,792
Total	\$ 74,509	\$ 62,129

**5. LICENSE AND COLLABORATION AGREEMENTS***DURECT Corporation*

In April 2007, DURECT and Endo entered into Amendment No. 4 to the Development, Commercialization and Supply License Agreement dated November 8, 2002 (the "DURECT CHRONOGESIC<sup>TM</sup> License Agreement") relating to the development and commercialization of the CHRONOGESIC<sup>TM</sup> product candidate in the U.S. and Canada. Prior to the present amendment, in addition to other specified termination rights provided to both parties, the DURECT CHRONOGESIC<sup>TM</sup> License Agreement provided Endo with a right to terminate the DURECT CHRONOGESIC<sup>TM</sup> License Agreement starting March 31, 2007 in the event that DURECT had not commenced a specified clinical trial for the CHRONOGESIC<sup>TM</sup> product candidate on or before March 31, 2007, *provided that* Endo provided DURECT written notice of such termination prior to April 30, 2007. Under Amendment No. 4, the foregoing termination right was amended to provide Endo with the right to terminate the DURECT CHRONOGESIC<sup>TM</sup> License Agreement in the event that (i) DURECT had not delivered to Endo on or before March 31, 2008 a written notice that a human pharmacokinetic trial had been completed with the CHRONOGESIC<sup>TM</sup> product candidate, together with a full study report of the results of the trial or (ii) Endo, determines, in its sole discretion, to terminate the DURECT CHRONOGESIC<sup>TM</sup> License Agreement during the sixty-day period after DURECT's delivery of such notice, *provided that*, in each case Endo delivers to DURECT its written notice of termination prior to April 30, 2008. Under Amendment No. 4, Endo shall not be responsible for any development costs for the CHRONOGESIC<sup>TM</sup> product candidate prior to May 1, 2008. Commencing on May 1, 2008, unless the DURECT CHRONOGESIC<sup>TM</sup> License Agreement is earlier terminated by Endo, Endo will fund 50% of the ongoing development costs for the CHRONOGESIC<sup>TM</sup> product candidate in accordance with the terms of the DURECT CHRONOGESIC<sup>TM</sup> License Agreement. Endo will also reimburse DURECT for a portion of its prior development costs upon the achievement of certain milestones. Milestone payments made by Endo under the DURECT CHRONOGESIC



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

License Agreement could total up to \$52.0 million. Endo and DURECT will share profits equally, based on projected financial performance of CHRONOGESIC . In addition, the DURECT CHRONOGESIC License Agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. The DURECT CHRONOGESIC License Agreement generally lasts until the underlying patents on the product expire. With respect to termination rights, the DURECT CHRONOGESIC License Agreement permits Endo to terminate its continued participation under a number of circumstances, one of which could require Endo to pay DURECT up to \$10.0 million.

**Table of Contents***SkyePharma, Inc.*

In January 2007, following an assessment of the status of DepoDur<sup>®</sup>, we announced that we notified SkyePharma PLC of our intent to terminate our development and commercialization agreement for this product and, in February 2007, entered into a termination agreement with SkyePharma whereby the Development and Marketing Strategic Alliance Agreement terminated in its entirety on March 31, 2007. In order to provide for the continued commercial support of the DepoDur<sup>®</sup> product and the transition of such product to SkyePharma on March 31, 2007, Endo provided a number of services and undertook certain activities. Specifically, Endo employed commercially reasonable efforts to maintain and continue all U.S. commercial activities in support of DepoDur<sup>®</sup> through March 31, 2007, and supported and/or undertook the transition of certain Endo functions and activities (including third party activities) to SkyePharma that were useful and necessary for SkyePharma to assume commercial and related responsibilities for DepoDur<sup>®</sup> in the U.S. All such transition services and activities were completed by March 31, 2007.

*Orexo AB*

Our agreement with Orexo provides for us to make additional 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, \$17.7 million of which has been recorded through September 30, 2007 and included in research and development expense. Of this \$17.7 million expensed from the inception of the agreement through September 30, 2007, \$5.2 million has been recorded during each of the nine month periods ended September 30, 2007 and 2006. In November 2007, we announced that we have decided to conduct an interim statistical analysis of the Phase III placebo-controlled efficacy trial of this sublingual fentanyl tablet being studied for the treatment of breakthrough cancer pain.

*Vernalis Development Limited*

In July 2007, Vernalis and Endo entered into Amendment No. 3 (Amendment) to the License Agreement dated July 14, 2004. Under the Amendment, Vernalis granted to Endo, a sole and exclusive (even as against Vernalis) license to make, have made, use, commercialize and have commercialized the product Frova<sup>®</sup> (frovatriptan) in Canada, under the Canadian Trademark. In September 2007, the FDA issued to the Company and our development partner Vernalis, a not approvable letter pertaining to our supplemental New Drug Application (sNDA) for Frova<sup>®</sup> (frovatriptan succinate) 2.5 mg tablets for the additional indication of short-term prevention of menstrual migraine. See Note 7 for a discussion of the impact of this development on our note receivable with Vernalis.

*Novopharm Limited*

In July 2007, Novopharm Limited (Novopharm) and Endo entered into a License Agreement (the Novopharm Agreement) whereby Endo granted to Novopharm the exclusive right to use, import, sell, have sold, offer to sell, distribute, market, promote and otherwise exploit the product Frova<sup>®</sup> (frovatriptan) in Canada. Novopharm paid to the Company an upfront license fee of approximately \$0.2 million. Novopharm has also agreed to make additional milestone payments totaling \$0.7 million upon the occurrence of certain events or based on the passage of time. In addition to the milestone payments, Novopharm will pay to Endo royalties based on a certain percentage of net sales as defined in the Novopharm Agreement. The term of the Novopharm Agreement will continue until the later to occur of 10 years after its July 2007 effective date or the expiration of the last Frova<sup>®</sup> patent in Canada. We have the right after December 31, 2010 to terminate the Novopharm Agreement upon one hundred eighty (180) days, prior written notice to Novopharm, and may be required to make annual royalty payments to Novopharm for a period of up to three years after such termination on any sales in Canada made by Endo or any of its affiliates during that three-year period.

**6. GOODWILL AND OTHER INTANGIBLES**

Our goodwill and other intangible assets consist of the following at September 30, 2007 and December 31, 2006, respectively (in thousands):

	September 30,	December 31,
	2007	2006
Goodwill	\$ 181,079	\$ 181,079
Amortizable Intangibles:		
Licenses	\$ 94,621	\$ 94,621



**Table of Contents**

	September 30,	December 31,
	2007	2006
Patents	3,200	3,200
	97,821	97,821
Less accumulated amortization	(24,431)	(19,775)
Other intangibles, net	\$ 73,390	\$ 78,046

In November 2007, we announced that we have decided to conduct an interim statistical analysis of the Phase III placebo-controlled efficacy trial of Rapinyl, our sublingual fentanyl tablet being studied for the treatment of breakthrough cancer pain. As a result of this development, we reviewed our agreement with Orexo AB, pursuant to which we license Rapinyl. We have evaluated our Orexo intangible asset, which has a net book value of \$8.5 million at September 30, 2007, for impairment and determined that an impairment did not exist at such time. However, we will continue to monitor this asset, including determining if the results of the interim statistical analysis have any impact on the carrying value of the asset.

Estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2006 is as follows (in thousands):

2007	\$ 6,209
2008	6,209
2009	6,209
2010	6,209
2011	6,209

**7. NOTE RECEIVABLE**

In July 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 the rights to market Frova<sup>®</sup> (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<sup>®</sup>. The loan is secured against the revenues receivable by Vernalis under the license agreement. At our election, if and when we obtain FDA approval for the additional indication of Frova<sup>®</sup> for the short-term (six days per month) prevention of menstrual migraine, we will be able to offset \$20 million of the \$40 million menstrual migraine indication approval milestone by providing the requisite written notice of our intentions to Vernalis within five (5) business days of the payment due date. Also at our election, we are able to offset 50% of all royalties to be paid under the license agreement to Vernalis to repay the loan *provided that*, in each case Endo delivers to Vernalis written notice not less than five (5) business days prior to the due date of any payment. During the three and nine months ended September 30, 2007, we expensed royalties payable to Vernalis in the amount of approximately \$2.0 million and \$5.8 million, respectively. We have notified Vernalis that 50% of these royalties will not be paid to Vernalis, but will be used to offset a portion of the unpaid accrued interest on the note receivable. 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. Vernalis has elected to defer the payment of the first six semi-annual interest amounts otherwise due January 31 and July 31 totaling approximately \$7.8 million. We have and expect to continue to offset 50% of future royalty payment obligations to Vernalis against these interest payment deferrals, and consequently we have reclassified a portion of the accrued interest on the note receivable to other current assets.

At inception, we estimated that an approximate fair market rate of interest for this type of secured loan was 8% per annum and therefore recorded the note receivable at its present value at inception of \$43.8 million. The note receivable is being accreted up to its face amount 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, net.

In September 2007, the FDA issued to the Company and our development partner Vernalis, a not approvable letter pertaining to our sNDA for Frova<sup>®</sup> for the additional indication of short-term prevention of menstrual migraine. The companies are continuing to evaluate the points raised in the not approvable letter and are seeking a meeting with the FDA to review in detail the agency's concerns and determine what kind of information is needed before deciding on the appropriate course of action.

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

The Company continually evaluates the collectibility of our note receivable with Vernalis based on current information and events, including an assessment of Vernalis' ability to pay the amounts due on this loan at maturity. At September 30, 2007, we reviewed the collectibility of our note receivable with Vernalis in accordance with Statement of Financial Accounting Standards No. 114 ( SFAS 114 ), *Accounting by Creditors for Impairment of a Loan*. Under SFAS 114, loans are measured for potential impairment based on the present value of expected future cash flows, or the fair value of the collateral if the loan is collateral dependent. As such, we assessed the recoverability of the note receivable by comparing our book value to the fair value of the expected future cash flows from the underlying collateral. As of September 30, 2007, we concluded that the value of the loan was not impaired and therefore a valuation allowance was not required. We will continue to re-evaluate the fair value of the expected future cash flows and could be required to record a valuation allowance, and/or cease recognition of interest income in a future period.

**Table of Contents****8. COMPREHENSIVE INCOME**

Comprehensive income includes the following components for the three and nine months ended September 30, 2007 and 2006 (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2007	September 30, 2006	September 30, 2007	September 30, 2006
Net income	\$ 59,147	\$ 44,891	\$ 176,842	\$ 123,065
Other comprehensive income:				
Unrealized gains / (losses) on securities, net of tax	1,544	218	986	(918)
Total comprehensive income	\$ 60,691	\$ 45,109	\$ 177,828	\$ 122,147

**9. 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 reserved an aggregate of 25,615,339 shares of common stock of the Company held by Endo Pharma LLC for issuance. Stock options granted under the Endo Pharma LLC 1997 Stock Option Plans expired 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 were issued. Endo Pharma LLC is a limited liability company that is no longer affiliated with the Company and in which affiliates of Kelso & Company have a controlling interest. Exercise of these stock options did not result in the issuance of additional shares in the Company and did not dilute the ownership interests of our public stockholders.

Pursuant to the Company's merger with Algos Pharmaceutical Corporation (Algos) 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 reserved an aggregate of 10,672,314 shares of common stock of the Company held by Endo Pharma LLC for issuance. Stock options granted under the Endo Pharma LLC 2000 Supplemental Stock Option Plans expired 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. No additional shares of Company common stock were issued as a result of the exercise of these stock options, because these stock options were exercisable only into shares of Company common stock that were held by Endo Pharma LLC. Accordingly, exercise of these stock options did not result in the issuance of additional shares in the Company and did not dilute the ownership interests of our public stockholders.

**Endo Pharmaceuticals Holdings Inc. 2000, 2004 and 2007 Stock Incentive Plans**

On August 11, 2000, we established the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan. The 2000 Stock Incentive Plan reserves an aggregate of 4,000,000 shares of common stock of the Company for issuance to employees, officers, directors and consultants. The 2000 Stock Incentive Plan provides for the issuance of stock options, restricted stock, stock bonus awards, stock appreciation rights or performance awards. 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 Stock Incentive 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. In May 2007, our stockholders approved the Endo Pharmaceuticals Holdings Inc. 2007 Stock Incentive Plan. The maximum number of shares of Company stock reserved for issuance under the 2007 Stock Incentive Plan is seven million (7,000,000) shares (subject to adjustment for certain transactions), but in no event may the total number of shares of Company stock subject to awards awarded to any one participant during any tax year of the Company exceed seven hundred fifty thousand (750,000) shares (subject to adjustment for certain transactions). As of September 30, 2007, only stock options have been awarded under the 2000 Stock Incentive Plan, and both stock options and restricted stock have been awarded under the 2004 Stock Incentive Plan. Stock options granted under the 2000, 2004 and

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

2007 Stock Incentive Plans generally vest over four years and expire ten years from the date of grant. 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, 2004 and 2007 Stock Incentive Plans will dilute the ownership interests of our public stockholders.

**Table of Contents****Stock-Based Compensation**

The Company accounts for its stock-based compensation plans in accordance with SFAS No. 123(R), *Share-Based Payment* ( SFAS 123R ). Under SFAS 123R, all stock-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as an expense in the income statement over the requisite service period.

The Company recognized stock-based compensation expense of \$3.7 million and \$10.9 million during the three and nine months ended September 30, 2007 and \$3.8 million and \$9.3 million during the three and nine months ended September 30, 2006. Presented below is the allocation of stock-based compensation as recorded in our Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2007 and 2006 (in thousands).

	Three Months Ended		Nine Months Ended	
	September 30, 2007	September 30, 2006	September 30, 2007	September 30, 2006
Selling, general and administrative expenses	\$ 3,320	\$ 3,332	\$ 9,694	\$ 8,217
Research and development expenses	\$ 387	469	\$ 1,246	1,120
Total stock-based compensation expense	\$ 3,707	\$ 3,801	\$ 10,940	9,337

**Stock Options**

For all of the Company's stock-based compensation plans, the fair value of each option grant was estimated at the date of grant using the Black-Scholes option-pricing model. Black-Scholes utilizes assumptions related to volatility, the risk-free interest rate, the dividend yield (which is assumed to be zero, as the Company has not paid cash dividends to date and does not currently expect to pay cash dividends) and the expected term of the option. Expected volatilities utilized in the model are based mainly on the historical volatility of the Company's stock price over a period commensurate with the expected life of the share option as well as other factors. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. During 2006, in accordance with Staff Accounting Bulletin No. 107 ( SAB 107 ), *Share-Based Payment*, the Company calculated the expected term of options granted using the simplified method. The simplified method was intended to be a temporary estimation technique and was to be phased out as more detailed information about exercise behavior became readily available, but no later than December 31, 2007. Beginning in 2007, we estimate the expected term of options granted based on our historical experience with our employees' exercise of stock options and other factors.

A summary of the activity under 2000 and 2004 Stock Incentive Plans for the nine months ended September 30, 2007 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted	
			Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding, January 1, 2007	3,910,768	\$ 21.19		
Granted	1,167,350	30.66		
Exercised	(496,849)	14.28		
Forfeited	(200,962)	27.36		
Expired	(3,027)	20.89		
Outstanding, September 30, 2007	4,377,280	24.22	7.63	\$ 30,016,643
Vested and expected to vest, September 30, 2007	4,102,165	23.94	7.56	\$ 29,263,036



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

Exercisable, September 30, 2007	1,794,002	18.13	6.13	\$ 23,147,350
---------------------------------	-----------	-------	------	---------------

The total intrinsic value of options exercised during the nine months ended September 30, 2007 and 2006 was \$9.2 million and \$12.5 million, respectively. The weighted-average grant date fair value of the stock options granted in the nine months ended September 30, 2007 and 2006 was \$15.18 per option and \$15.69 per option, respectively, determined using the following weighted average assumptions:

	2007	2006
Average expected term (years)	5.50	6.25
Risk-free interest rate	4.63%	4.61%
Dividend yield	0.00	0.00
Expected volatility	48%	50%

**Table of Contents**

As of September 30, 2007, the total remaining unrecognized compensation cost related to non-vested stock options amounted to \$34.8 million. The weighted average remaining requisite service period of the non-vested stock options was 2.61 years. This expected cost does not include the impact of any future stock-based compensation awards.

A summary of the activity under the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans for the nine months ended September 30, 2007 is as follows:

	Number	Weighted	Weighted	Aggregate
	of	Average	Average	Intrinsic
	Shares	Exercise Price	Remaining	Value
			Contractual Term	
Outstanding, vested and exercisable, January 1, 2007	75,259	\$ 2.42		
Granted		\$		
Exercised	(75,259)	\$ 2.42		
Forfeited		\$		

**Outstanding, vested and exercisable, September 30, 2007**

The total intrinsic value of options exercised during the nine months ended September 30, 2007 and 2006 was \$2.3 million and \$72.3 million, respectively.

**Restricted Stock**

During the nine months ended September 30, 2007, the Company granted restricted stock awards to non-employee directors of the Company as part of their annual stock compensation award. This restricted stock will vest ratably over a two-year vesting period (50% on the first anniversary of the grant date and the remaining 50% on the second anniversary of the grant date). We recognize expense for our restricted stock using the straight-line method over the requisite service period. The total value of compensation expense for restricted stock is equal to the closing price of Endo shares on the date of grant.

A summary of our restricted stock as of September 30, 2007, is presented below:

	Number of	Weighted	Aggregate
	Shares	Average	Intrinsic
	Shares	Fair Value Per	Value
		Share	
Non-vested, January 1, 2007		\$	
Granted	13,572	\$ 29.84	
Forfeited		\$	
Vested		\$	\$
Non-vested, September 30, 2007	13,572	\$ 29.84	

As of September 30, 2007, the total remaining unrecognized compensation cost related to non-vested restricted stock awards amounted to \$0.3 million. The weighted average remaining requisite service period of the non-vested restricted stock was 1.45 years. This expected cost does not include the impact of any future stock-based compensation awards.

**10. RELATED PARTY TRANSACTIONS**

***Tax Sharing Agreement.*** On July 14, 2000, Endo Pharma LLC was formed in connection with our merger with Algos Pharmaceutical Corporation (Algos) 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. Endo Pharma LLC is a limited liability company that is no longer affiliated with the Company but had historically held significant portions of our common stock, in which affiliates of Kelso & Company and certain current and former members of management have an interest. Upon the exercise of these stock options, only currently outstanding shares of our common stock held by Endo Pharma LLC were delivered. Because Endo Pharma LLC, and not us, had provided the shares upon the exercise of these options, we entered into a tax sharing agreement (as amended) with Endo Pharma LLC under which we are required to pay to Endo Pharma LLC the amount of the tax benefits usable by us as a result of

---

**Table of Contents**

the exercise of these stock options into shares of our common stock held by Endo Pharma LLC. As of September 30, 2007, all 36 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 are generally 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, 2007, approximately \$775 million), which is estimated to result in a tax benefit amount of approximately \$299 million. Under the tax sharing agreement, we are required to pay this \$299 million, \$272 million of which has already been paid as of September 30, 2007, 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. Additionally, as part of the tax sharing agreement, Endo Pharma LLC will reimburse us for the after-tax employer payroll taxes paid by us as a result of the exercise of the 36 million options discussed above. We have paid approximately \$12 million in employer payroll taxes, of which Endo Pharma LLC will reimburse us for approximately \$8 million, which represents the after-tax employer payroll tax paid by us for the periods from 2001 through September 30, 2007. As of September 30, 2007, our net liability due to Endo Pharma LLC is approximately \$19 million. 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. In October 2007, we made a tax sharing payment to Endo Pharma LLC of approximately \$18.5 million. Our remaining liability subsequent to this payment is approximately \$0.8 million, which relates to Endo Pharma LLC options exercised during 2007.

During the nine months ended September 30, 2007, the final 75,259 shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised. Since we expect the attributable compensation charge deductions to be usable to reduce our taxes in 2007, we are obligated, under our amended tax sharing agreement, to pay to Endo Pharma LLC an additional tax benefit amount of approximately \$0.8 million, which is included in our net liability due to Endo Pharma LLC referred to above. Fifty percent of the estimated tax benefit amount attributable to these exercises and any additional tax benefits attributable to the exercise of stock options granted under the Endo Pharma LLC stock option plans in 2007 will be due within 15 business days of the date we receive a report on our final audited 2007 financial statements from our independent registered public accounting firm, and the remaining tax benefit amount attributable to 2007 is due within 30 business days of the date on which we file our 2007 tax return with the Internal Revenue Service. This would represent the final tax sharing payment due to Endo Pharma LLC.

As of September 30, 2007, there were no options remaining to be granted under the Endo Pharma LLC stock option plans.

In October 2007, our board of directors approved a plan to amend our tax sharing agreement with Endo Pharma LLC. This will enable us to pay the final additional tax benefit amount of approximately \$0.8 million to Endo Pharma LLC during the year-ended December 31, 2007. As described in more detail above, we are required to pay fifty percent of the estimated tax benefit subsequent to the receipt of final audited 2007 financial statement and the remaining fifty percent after the date our tax return was filed with the Internal Revenue Service.

**Executive Compensation.** In March 2006, Endo Pharma LLC advised our Board of Directors that it intended to pay a one-time cash bonus to each of Mr. Peter Lankau, our President and Chief Executive Officer, Ms. Caroline Manogue, our Executive Vice President, Chief Legal Officer and Secretary, and Mr. Jeffrey Black, our former Executive Vice President, Chief Financial Officer and Treasurer in the amount of \$3 million, \$6 million and \$10 million, respectively, in recognition of their significant contributions to our success. These bonus payments have been recorded in selling, general and administrative expenses during the year ended December 31, 2006. These payments were made by the Company in April 2006 and repaid to us by Endo Pharma LLC in the third quarter of 2006 with interest. In addition, only a portion of these bonus payments will be deductible for federal and state income tax purposes. We are not required to pay nor will we pay to Endo Pharma LLC the amount of any of the tax benefits related to these bonus payments pursuant to the tax sharing agreement between us and Endo Pharma LLC. These bonuses will be funded entirely by Endo Pharma LLC, with no contribution by us and they have been treated as a capital contribution by Endo Pharma LLC.

Endo Pharma LLC also informed us that, in connection with its eventual winding-up, it would make a special allocation to Ms. Carol Ammon, our Chairman of the Board and former Chief Executive Officer, of approximately \$22 million, with all or a portion of Ms. Ammon's payment being satisfied by granting to her the remaining unallocated Endo Pharma LLC stock options representing approximately 0.8 million shares under the Endo Pharma LLC stock option plans. This amount has been recorded in selling, general and administrative expenses during the year ended December 31, 2006 and as a capital contribution by Endo Pharma LLC. This grant of options to Ms. Ammon was made during the fourth quarter of 2006. The 0.8 million options were granted by Endo Pharma LLC to Ms. Ammon in the fourth quarter of 2006, as described above, at an exercise price of \$2.42 per share. Therefore, approximately \$20 million of the approximately \$22 million recorded in the first quarter of 2006 was reclassified as a stock compensation expense representing the fair value of the option on the date of grant. These options were immediately vested and exercised by Ms. Ammon and the resulting compensation charge deduction of approximately \$19 million and the resulting tax sharing obligation to Endo Pharma LLC is included in our tax sharing liability discussed above. Endo Pharma LLC funded the remaining \$2 million to Ms. Ammon in June 2007.



---

**Table of Contents**

**Related Party Matters.** Robert Ammon, the brother of our former Chairman and former Chief Executive Officer, is employed by the Company as a senior national account executive and has been since the company's founding as a private company in 1997. It is expected that his 2007 total compensation, including base salary, incentive compensation, long-term incentive compensation and all benefits (including health benefits), will not exceed \$255,000. Marisa O'Donnell, the daughter of our President and Chief Executive Officer, is employed by the Company as a sales representative and has been since 2006. It is expected that her 2007 total compensation, including base salary, incentive compensation, long-term incentive compensation and all benefits (including health benefits), will not exceed \$125,000.

**11. COMMITMENTS AND CONTINGENCIES**

**Manufacturing, Supply and Other Service Agreements** We contract with various third party manufacturers and suppliers to provide us with our raw materials used in our products and finished goods. Our most significant agreements are with Novartis Consumer Health, Inc., Teikoku Seiyaku Co., Ltd., and Mallinckrodt Inc. If for any reason we are unable to obtain sufficient quantities of any of the finished goods or raw materials or components required for our products, this may have a material adverse effect on our business, financial condition and results of operations.

*Novartis Consumer Health, Inc.*

On May 3, 2001, we entered into a long-term manufacturing and development agreement with Novartis Consumer Health, Inc. whereby Novartis has agreed to manufacture certain of our commercial products and products in development. We are required to purchase, on an annual basis, a minimum amount of product from Novartis. The purchase price per product is equal to a predetermined amount per unit, subject to periodic adjustments. This agreement had a five-year term, with automatic five-year renewals thereafter. In August 2005, we extended this agreement until 2011. We are required to purchase a minimum of approximately \$17 million per year through December 31, 2009. Either party may terminate this agreement on three-years' notice, effective at any time after December 31, 2006. Either party may also terminate this agreement on account of a material breach by the other.

*Teikoku Seiyaku Co., Ltd.*

Under the terms of this agreement, Teikoku, a Japanese manufacturer, manufactures Lidoderm® at its Japanese facility for commercial sale by us in the United States. We also have an option to extend the supply area to other territories. On April 24, 2007, we amended this agreement. The material components of the Amended Agreement are as follows:

We have agreed to purchase a certain number of patches per year for each year in the remaining term of the Amended Agreement.

Teikoku has agreed to fix the supply price of Lidoderm® for a period time after which the price will be adjusted at future dates certain based on a price index defined in the Amended Agreement.

Following cessation of our obligation to pay royalties to Hind Healthcare Inc. (Hind) under the Sole and Exclusive License Agreement dated as of November 23, 1998, as amended, between Hind and Endo, we will pay to Teikoku annual royalties based on our annual net sales of the Product.

The Amended Agreement will expire on December 31, 2021, unless terminated in accordance with its terms. After December 31, 2021, the Amended Agreement shall be automatically renewed on the first day of January each year unless (i) we and Teikoku agree to terminate the Amended Agreement upon mutual written agreement or (ii) either we or Teikoku terminates the Amended Agreement with 180-day written notice to the other party, which notice shall not in any event be effective prior to July 1, 2022.

*Mallinckrodt Inc.*

Under the terms of this agreement, Mallinckrodt manufactures and supplies to us narcotic active drug substances for inclusion in our controlled substance pharmaceutical products. We are required to purchase a fixed percentage of our annual requirements of each narcotic active drug substance from Mallinckrodt. The purchase price for these substances is equal to a fixed amount, adjusted on an annual basis. The initial term of this agreement is July 1, 1998 until June 30, 2013, with an automatic renewal provision for unlimited successive one-year periods. Either party

may terminate this agreement for a material breach.

## **Table of Contents**

### *Properties*

In June 2007, we agreed to provide approximately \$2.7 million in funding for certain tenant improvements to be made at a building currently under construction at the Company's corporate headquarters in Chadds Ford, Pennsylvania, which will be leased by the Company upon completion. The payments are to be made in two equal installments, the first of which was paid in July 2007 with the remainder to be paid upon completion of the building currently anticipated to be in the first half of 2008.

### *General*

In addition to the manufacturing and supply agreements described above, we have agreements with (1) UPS Supply Chain Solutions, Inc. (f/d/b/a Livingston Healthcare Services, Inc.) for customer service support, warehouse and distribution services and certain financial functions that expires in 2010, (2) Kunitz and Associates Inc. for assistance with adverse event reporting and (3) PPD Development, LP for clinical development services, business development support, medical information services and adverse event reporting. Although we have no reason to believe that these agreements will not be honored, failure by any of these third parties to honor their contractual obligations may have a materially adverse effect on our business, financial condition and results of operations.

## **License Agreements, Milestones and Royalties**

### *Hind Healthcare Inc.*

Under the terms of the Hind License Agreement, 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®. The royalty rate is 10% of net sales through the shorter of (1) the expiration of the last licensed patent or (2) November 20, 2011, including a minimum royalty of at least \$500,000 per year. During the three months ended September 30, 2007 and 2006, we recorded \$19.4 million and \$14.1 million, respectively, for these royalties payable to Hind. During the nine months ended September 30, 2007 and 2006, we recorded \$55.1 million and \$43.5 million, respectively, for these royalties payable to Hind.

### *Penwest Pharmaceuticals*

In January 2007, the Company and Penwest entered into an amendment (the 2007 Amendment) to the 2002 amended and restated strategic alliance agreement between the parties (the 2002 Agreement). Under the terms of the 2007 Amendment, Endo and Penwest agreed to restructure the 2002 Agreement to provide that royalties payable to Penwest for U.S. sales of Opana® ER will be calculated based on net sales of the product rather than on operating profit, and to change certain other provisions of the 2002 Agreement. The 2007 Amendment also resolved the parties' ongoing disagreement with regard to sharing of marketing expenses during the period prior to when Opana® ER reaches profitability. The key financial terms of the 2007 Amendment are summarized as follows:

With respect to U.S. sales of Opana® ER, Endo's royalty payments to Penwest will be calculated starting at 22% of annual net sales of the product, and, based on agreed-upon levels of annual net sales achieved, the royalty rate can increase to a maximum of 30%.

No royalty payments will be due to Penwest for the first \$41 million of royalties that would otherwise have been payable beginning from the time of the product launch in July 2006.

Penwest is entitled to receive milestone payments of up to \$90 million based upon the achievement of certain agreed-upon annual sales thresholds.

In 2003, Penwest opted out of funding development costs for Opana® ER. Under the 2007 Amendment, the parties have agreed that Penwest's share of these unfunded development costs will be fixed at \$28 million and will be recouped by Endo through a temporary 50% reduction in royalties payable to Penwest. This temporary reduction in royalties will not apply until the \$41 million royalty threshold referred to above has been met.

As a result of the terms described above, the Company anticipates that no royalties are or will be due on the first \$186.3 million of net sales of Opana® ER as we recoup our previously recognized launch expenses. After this initial \$186.3 million of net sales, royalties will be reduced by



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

fifty percent (50%) until we recoup our previously recognized certification period expenses, after which time royalties will be payable on annual net sales based on the royalty rates described above.

### *DURECT Corporation*

In April 2007, DURECT and Endo entered into Amendment No. 4 to the Development, Commercialization and Supply License Agreement dated November 8, 2002 (the "DURECT CHRONOGESIC™ License Agreement"). Under Amendment No. 4, Endo shall not be responsible for any development costs for the CHRONOGESIC™ product candidate prior to May 1, 2008. Commencing on May 1, 2008, unless the DURECT CHRONOGESIC™ License Agreement is earlier terminated by Endo, Endo will fund 50% of the ongoing development costs for the CHRONOGESIC™ product candidate in accordance with the terms of the DURECT CHRONOGESIC™ License Agreement. Endo will also reimburse DURECT for a portion of its prior development costs upon the achievement of certain milestones. Milestone payments made by Endo under the DURECT CHRONOGESIC™ License

**Table of Contents**

Agreement could total up to \$52.0 million. Endo and DURECT will share profits equally, based on projected financial performance of CHRONOGESIC. With respect to termination rights, the DURECT CHRONOGESIC License Agreement permits Endo to terminate its continued participation under a number of circumstances, one of which could require Endo to pay DURECT up to \$10.0 million.

In addition, in March 2005, we signed an agreement that gives us the exclusive license to develop and commercialize DURECT's sufentanil-containing transdermal patch in the U.S. and Canada (the DURECT Sufentanil Agreement). Under the terms of the DURECT Sufentanil Agreement, in April 2005, we paid DURECT a \$10 million upfront fee, which was expensed as research and development, and are subject to potential additional payment requirements of up to approximately \$35 million upon achievement of predetermined regulatory and commercial milestones. We will also pay royalties to DURECT on net sales of the sufentanil transdermal patch. The DURECT Sufentanil Agreement provides each party with specified termination rights, including the right of each party to terminate the DURECT Sufentanil Agreement upon material breach of the DURECT Sufentanil Agreement by the other party and the right of Endo to terminate the DURECT Sufentanil Agreement at any time without cause subject to a specified notice period.

*EpiCept Corp.*

Our license agreement with EpiCept provides for Endo to pay EpiCept milestones as well as royalties on the net sales of EpiCept's LidoPAIN<sup>®</sup> BP product. EpiCept has also retained an option to co-promote the LidoPAIN<sup>®</sup> BP product. Under this agreement, Endo also received an exclusive, worldwide license to certain patents of EpiCept Corp. Milestone payments made by Endo under this agreement, including regulatory milestones and sales thresholds, could total up to \$82.5 million.

*Vernalis Development Limited*

Under the terms of the license agreement with Vernalis, we could be required to make a \$40 million milestone payment upon FDA approval for the menstrual migraine indication (MM). In September 2007, the FDA issued to the Company and our development partner Vernalis, a not approvable letter pertaining to our sNDA for Frova<sup>®</sup> for the additional indication of short-term prevention of menstrual migraine. See Note 7 for a discussion of the impact of this development on our note receivable with Vernalis. In addition, Vernalis could 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<sup>®</sup> beginning on January 1, 2007. We can terminate the license agreement under certain circumstances, including upon one year's written notice. During the three and nine months ended September 30, 2007, we expensed royalties payable to Vernalis in the amount of approximately \$2.0 million and \$5.8 million, respectively. We have notified Vernalis that 50% of those royalties will not be paid to Vernalis, but will be used to offset a portion of the unpaid accrued interest on the note receivable (See Note 7). In July 2007, Vernalis and Endo entered into Amendment No. 3 (Amendment) to the License Agreement dated July 14, 2004. Under the Amendment, Vernalis granted to Endo, a sole and exclusive (even as against Vernalis) license to make, have made, use, commercialize and have commercialized the product Frova<sup>®</sup> (frovatriptan) in Canada, under the Canadian Trademark.

*Novopharm Limited*

In July 2007, Novopharm Limited (Novopharm) and Endo entered into a License Agreement (the Novopharm Agreement) whereby Endo granted to Novopharm the exclusive right to use, import, sell, have sold, offer to sell, distribute, market, promote and otherwise exploit the product Frova<sup>®</sup> (frovatriptan) in Canada. Novopharm will pay to the Company an upfront license fee of approximately \$0.2 million and has agreed to make additional milestone payments totaling \$0.7 million upon the occurrence of certain events or based on the passage of time. In addition to the milestone payments, Novopharm will pay to Endo royalties based on a certain percentage of net sales as defined in the Novopharm Agreement. The term of the Novopharm Agreement will continue until the later to occur of 10 years after its July 2007 effective date or the expiration of the last Frova<sup>®</sup> patent in Canada. We have the right after December 31, 2010 to terminate the Novopharm Agreement upon one hundred eighty (180) days, prior written notice to Novopharm, and may be required to make annual royalty payments to Novopharm for a period of up to three years after such termination on any sales in Canada made by Endo or any of its affiliates during that three-year period.

*Orexo AB*

Our agreement with Orexo provides for us to make additional 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, \$17.7 million of which has been recorded through September 30, 2007 and included in research and development expense. Of this \$17.7 million expensed from the inception of the agreement through September 30, 2007, \$5.2 million has been recorded during each of the nine months ended September 30, 2007 and 2006. The agreement also provides for royalties upon commercial sales and may include sales milestones, up to \$39.2 million, if defined sales thresholds

are achieved. 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 \$750,000. In

## **Table of Contents**

November 2007, we announced that we have decided to conduct an interim statistical analysis of the Phase III placebo-controlled efficacy trial of this sublingual fentanyl tablet being studied for the treatment of breakthrough cancer pain.

### *ZARS Pharma*

Under the terms of our agreement with ZARS Pharma, we may be required to make additional payments of up to approximately \$19 million upon achievement of certain commercial milestones. We will also pay ZARS royalties on net sales of Synera™.

### *ProEthic Pharmaceuticals, Inc.*

Under the terms of our agreement with ProEthic, in March 2005, we paid a \$10 million upfront fee that was expensed as research and development during the year ended December 31, 2005 for the ketoprofen patch, our development product being studied for the treatment of soft-tissue injuries. During 2006, we made an additional \$5 million milestone payment that has been expensed as research and development. We could be required to make additional payments of approximately \$8 million upon the achievement of certain regulatory and other milestones. We will also pay royalties on net sales of the ketoprofen patch. We can terminate the agreement at any time upon no more than ninety days written notice. In July 2007, the Company announced that it has withdrawn its guidance pertaining to the anticipated first-half 2008 filing date of its New Drug Application (NDA) for the topical ketoprofen patch. Our decision regarding the ketoprofen patch is based on the outcome of two Phase III double-blind, placebo-controlled clinical trials. In November 2007, we announced that we had achieved positive results for a four-week, double-blind, placebo-controlled efficacy trial in patients with osteoarthritis flare of the knee. This trial represented the first part of a three-month safety study of the ketoprofen patch. A third Phase III study, evaluating the ketoprofen patch in the treatment of pain associated with tendonitis or bursitis of the shoulder, elbow or knee, is ongoing.

### *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. During the nine months ended September 30, 2007, we invested an additional \$2.8 million in this partnership, bringing our cumulative cash investment to \$5.5 million as of September 30, 2007. We are accounting for this investment utilizing the equity method.

## **Employment Agreements**

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

## **Research Contracts**

In addition to our agreement with PPD Development, LP, 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.

## **Other Collaboration Agreements**

We have also entered into certain collaboration agreements with third parties for the development of pain management and other products. Potential milestone payments pursuant to these contracts could total up to approximately \$5.2 million. 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.

## **Legal Proceedings**

While we cannot predict the outcome of the following legal proceedings, we believe that the claims against us are without merit, and we intend to vigorously defend our position. An adverse outcome in any of these proceedings could have a material adverse effect on our current and future financial position and results of operations. No amounts have been accrued with respect to any of these unsettled legal proceedings at September 30, 2007.



**Table of Contents***Department of Health and Human Services Subpoena.*

In January 2007, the Company received a subpoena issued by the United States Department of Health and Human Services, Office of Inspector General (OIG). The subpoena requests documents relating to Lidoderm® (lidocaine patch 5%), focused primarily on the sale, marketing and promotion of Lidoderm®. The Company is cooperating with the government to provide the requested documents. At this time, the Company cannot predict or determine the outcome of the above matter or reasonably estimate the amount or range of amounts of fines or penalties, if any, that might result from an adverse outcome.

*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) 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'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's OxyContin®, 40mg strength, challenged the listed patents for OxyContin® 40mg tablets. On March 13, 2001 and August 30, 2001, Purdue filed two more suits for infringement of the same patents against us and EPI in the Southern District of New York, in response to EPI's ANDA amendments adding bioequivalent versions of the 10, 20 and 80 mg strengths of OxyContin®. In each of the three cases, EPI pleaded counterclaims that the patents asserted by Purdue are invalid, unenforceable and/or not infringed by EPI's formulation of oxycodone hydrochloride extended-release tablets, and that Purdue violated antitrust laws by enforcing fraudulently procured patents.

On August 28, 2006, we executed a settlement agreement with Purdue pursuant to which we agreed to cease selling our oxycodone extended-release products on December 31, 2006. We and EPI, as well as our manufacturers, distributors, purchasers, and patients, are released from all liability for infringement of Purdue's patents in connection with EPI's prior and future sales of these products. Though the settlement agreement has been submitted to the U.S. Federal Trade Commission and the Antitrust Division of the Department of Justice as required by statute, the release will survive unless overturned by a court order. On October 6, 2006, the district court entered a Consent Judgment, the effect of which is to conclude the litigation in accordance with the terms of the settlement agreement.

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.

*Pricing Litigation*

A number of cases brought by local and state government entities are pending that allege generally that EPI and numerous other pharmaceutical companies reported false pricing information in connection with certain drugs that are reimbursable under Medicaid. These cases generally seek damages, treble damages, disgorgement of profits, restitution and attorneys' fees.

The federal court cases have been or are in the process of being consolidated in the United States District Court for the District of Massachusetts under the Multidistrict Litigation Rules as *In re: Pharmaceutical Industry Average Wholesale Price Litigation, MDL 1456*. The following previously reported cases are pending in MDL 1456 and have been consolidated into one consolidated complaint: *City of New York v. Abbott Laboratories, Inc., et al.*; *County of Albany v. Abbott Laboratories, Inc., et al.*; *County of Allegany v. Abbott Laboratories, Inc., et al.*; *County of Broome v. Abbott Laboratories, Inc., et al.*; *County of Cattaraugus v. Abbott Laboratories, Inc., et al.*; *County of Cayuga v. Abbott Laboratories, Inc., et al.*; *County of Chautauqua v. Abbott Laboratories, Inc., et al.*; *County of Chemung v. Abbott Laboratories, Inc., et al.*; *County of Chenango v. Abbott Laboratories, Inc., et al.*; *County of Columbia v. Abbott Laboratories, Inc., et al.*; *County of Cortland v. Abbott Laboratories, Inc., et al.*; *County of Dutchess v. Abbott Laboratories, Inc., et al.*; *County of Essex v. Abbott Laboratories, Inc., et al.*; *County of Fulton v. Abbott Laboratories, Inc., et al.*; *County of Genesee v. Abbott Laboratories, Inc., et al.*; *County of Greene v. Abbott Laboratories, Inc., et al.*; *County of Herkimer v. Abbott Laboratories, Inc., et al.*; *County of Jefferson v. Abbott Laboratories, Inc., et al.*; *County of Lewis v. Abbott Laboratories, Inc., et al.*; *County of Madison v. Abbott Laboratories, Inc., et al.*; *County of Monroe v. Abbott Laboratories, Inc., et al.*; *County of Niagara v. Abbott Laboratories, Inc., et al.*; *County of Oneida v. Abbott Laboratories, Inc., et al.*; *County of Onondaga v. Abbott Laboratories, Inc., et al.*; *County of Ontario v. Abbott Laboratories, Inc., et al.*; *County of Orleans v. Abbott Laboratories, Inc., et al.*; *County of Putnam v. Abbott Laboratories, Inc., et al.*; *County of Rensselaer v. Abbott Laboratories, Inc., et al.*; *County of Rockland v. Abbott Laboratories, Inc., et al.*; *County of St. Lawrence v. Abbott Laboratories, Inc., et al.*; *County of Saratoga v. Abbott Laboratories, Inc., et al.*; *County of Schuyler v. Abbott Laboratories, Inc., et al.*; *County of Seneca v. Abbott Laboratories, Inc., et al.*; *County of Steuben v. Abbott Laboratories, Inc., et al.*; *County of Suffolk v. Abbott Laboratories, Inc., et al.*; *County of Tompkins v.*



**Table of Contents**

*Abbott Laboratories, Inc., et al.*; *County of Ulster v. Abbott Laboratories, Inc., et al.*; *County of Warren v. Abbott Laboratories, Inc., et al.*; *County of Washington v. Abbott Laboratories, Inc., et al.*; *County of Wayne v. Abbott Laboratories, Inc., et al.*; *County of Westchester v. Abbott Laboratories, Inc., et al.*; *County of Wyoming v. Abbott Laboratories, Inc., et al.*; and *County of Yates v. Abbott Laboratories, Inc., et al.*

In addition, a previously reported case originally filed in the Southern District of New York, *County of Orange v. Abbott Laboratories, Inc., et al.*, has been transferred to the MDL and consolidated with the cases listed above

Three previously reported cases, *County of Erie v. Abbott Laboratories, Inc., et al.*, originally filed in the Supreme Court of the State of New York, Erie County, *County of Oswego v. Abbott Laboratories, Inc., et al.*, originally filed in the Supreme Court of the State of New York, Oswego County, and *County of Schenectady v. Abbott Laboratories, Inc., et al.*, originally filed in the Supreme Court of the State of New York, Schenectady County, were remanded from the MDL to the state courts in which they were originally filed.

There is a previously reported case pending in the Circuit Court of Montgomery County, Alabama against EPI and numerous other pharmaceutical companies: *State of Alabama v. Abbott Laboratories, Inc., et al.*

A case has been filed in the Third Judicial District Court of Salt Lake County Utah by the State of Utah against EPI and nine other pharmaceutical companies, containing allegations similar to the allegations contained in the case filed by the State of Alabama: *State of Utah v. Actavis US, Inc., et al.*, Civ. Action No. 070913719.

A case has been filed in the United States District Court for the Southern District of Iowa by the State of Iowa against EPI and 77 other pharmaceutical companies, containing allegations similar to the allegations contained in the cases filed by New York City and the New York Counties that make up the consolidated complaint described above: *State of Iowa v. Abbott Laboratories, Inc., et al.*, Civ. Action No. 4:07-cv-00461.

There is a previously reported case against EPI and numerous other pharmaceutical companies, *State of Mississippi v. Abbott Laboratories, Inc., et al.*, originally filed in the Chancery Court of Hinds County, Mississippi. The State of Mississippi offered to enter an agreed order of dismissal with respect to Endo, and Endo filed a notice of acceptance of that offer in Hinds County Chancery Court.

The Company intends to contest all of these cases vigorously. 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 the Company.

*Other Legal Proceedings*

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

**12. 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		Nine Months Ended	
	September 30, 2007	September 30, 2006	September 30, 2007	September 30, 2006
<b>Numerator:</b>				
Net income available to common stockholders	\$ 59,147	\$ 44,891	\$ 176,842	\$ 123,065
<b>Denominator:</b>				
For basic per share data weighted average shares	133,915	133,270	133,835	133,067
Effect of dilutive stock options	696	877	656	894



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

For diluted per share data	weighted average shares	134,611	134,147	134,491	133,961
Basic earnings per share		\$ 0.44	\$ 0.34	\$ 1.32	\$ 0.92
Diluted earnings per share		\$ 0.44	\$ 0.33	\$ 1.31	\$ 0.92

**Table of Contents****13. INCOME TAXES**

On January 1, 2007, the Company adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48), which became effective for fiscal years beginning after December 15, 2006. FIN 48 creates a single model to address uncertainty in tax positions and clarifies the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. The provisions of FIN 48 apply to all material tax positions in all taxing jurisdictions for all open tax years. FIN 48 establishes a two-step process for evaluating tax positions. Step 1 – Recognition, requires the Company to determine whether a tax position, based solely on its technical merits, has a likelihood of more than 50 percent ( more-likely-than-not ) that the tax position taken will be sustained upon examination. Step 2 – Measurement, which is only addressed if Step 1 has been satisfied, requires the Company to measure the tax benefit as the largest amount of benefit, determined on a cumulative probability basis that is more-likely-than-not to be realized upon ultimate settlement.

The Company files income tax returns in the U.S. federal jurisdiction, Puerto Rico, Canada and in various state and local jurisdictions. In general, the Company is no longer subject to U.S. federal, state and local income tax examinations by tax authorities for years before 2002.

Under FIN 48 we determined that certain income tax positions did not meet the more-likely-than-not recognition threshold and, therefore, required a 100% reserve. Accordingly, as of January 1, 2007, the Company recorded a non-cash cumulative transition charge of approximately \$2.7 million, recorded as a reduction to beginning retained earnings and we have not restated any prior period amounts. The Company records accrued interest and penalties related to unrecognized tax benefits in income tax expense. As of January 1, 2007, the Company has accrued \$2.2 million in interest and penalties. The total amount of unrecognized tax benefits as of January 1, 2007 was \$6.4 million. The total amount of unrecognized tax benefits as of September 30, 2007 is \$10.8 million, with the increase primarily due to additional unrecognized tax benefits incurred during the nine months ended September 30, 2007 and additional interest and penalties. The additional unrecognized tax benefits incurred during 2007 relate to the uncertain income tax positions previously identified at January 1, 2007. The increase in the total amount of unrecognized tax benefits did not have a material impact on the Company's results of operations for the three and nine months ended September 30, 2007 or our financial position as of September 30, 2007. Any future adjustments to our uncertain tax position liability will result in an impact to our income tax provision and effective tax rate.

It is expected that the amount of unrecognized tax benefits will change during the next twelve months; however, the Company does not anticipate any adjustments that would lead to a material impact on our results of operations or our financial position.

**14. ACQUISITIONS***RxKinetix, Inc.*

On October 12, 2006, the Company acquired all of the outstanding common stock of privately held RxKinetix, Inc. RxKinetix specializes in developing new therapeutics focused on improving the quality of life for patients being treated for cancer. RxKinetix's most advanced product, now named EN 3285, is currently in clinical Phase II for the prevention of oral mucositis, a painful, debilitating and often dose-limiting side effect that afflicts many patients being treated for cancer with radiation and/or chemotherapy. RxKinetix is a development stage company and therefore was accounted for as an asset acquisition. The results of operations for RxKinetix have been included in our consolidated financial statements beginning on the acquisition date.

The purchase price of RxKinetix, as of the acquisition date, was \$20.5 million which was funded from our existing cash on hand. Additional contingent cash purchase consideration of up to \$95 million may become due upon the achievement of certain clinical and regulatory milestones. The Company has allocated the purchase price to the RxKinetix assets acquired and liabilities assumed at their estimated fair values, based on a number of factors, including the use of an independent appraisal. Estimated fair values were determined through the use of a discounted cash flow analysis using market participant assumptions. Of the purchase price, approximately \$26.0 million has been allocated to tangible and intangible assets to be used in research and development activities and those assets have been written-off to purchased in-process research and development, as of the acquisition date. The excess of fair value of the net assets acquired compared to the amount paid as of the acquisition date has been reflected as estimated amount due seller in accordance with SFAS No. 141, *Business Combinations*. Any contingent consideration paid in the future will be first applied to reduce the amount recorded as estimated amount due seller, and thereafter to the net assets acquired based on their relative fair values. Our purchase allocation is substantially complete, and any subsequent revisions are not expected to be material. At September 30, 2007, the Company has recorded, as a current liability, \$15 million of the estimated amount due seller which at December 31, 2006 was classified, in its entirety, as a non-current liability. The current portion of the estimated amount due seller is payable upon the commencement of Phase III clinical trials of EN 3285. There has not been any material change in the estimated fair values assigned to the assets acquired and liabilities assumed since the date of acquisition.



**Table of Contents**

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed as of the date of acquisition (in thousands):

Cash consideration	\$ 20,000
Direct acquisition costs	482
<b>Total purchase price</b>	<b>\$ 20,482</b>
Allocation of purchase price:	
Cash	\$ 9
Property and equipment	127
Purchased in-process research and development	26,046
Other assets	461
Deferred tax assets	10,699
Other liabilities	(1,330)
Estimated amounts due seller	(15,530)
<b>Total purchase price</b>	<b>\$ 20,482</b>

As a result of our acquisition of RxKinetix, Inc., we acquired one significant in-process research and development project, now known as EN 3285, a topical oral rinse with the active ingredient formulated in its proprietary ProGelz<sup>®</sup> drug delivery platform. All of the purchased in-process research and development value from this transaction was assigned to EN 3285 since the other products, as of the acquisition date, were very early stage and did not meet the criteria to be recognized as assets. As of the acquisition date, EN 3285 was in clinical Phase II for the prevention of oral mucositis, painful mouth sores that often occur in cancer patients undergoing radiation and chemotherapeutic treatment. During the course of high-dose cancer therapy and bone marrow transplantation, patients often develop painful and debilitating oral inflammation, or mucositis, in the mouth. The resulting weight loss, dehydration and, in some cases, infection often lead to dose-limitation of chemotherapy and radiation therapy, and contribute considerably to cancer and transplant-related morbidity and mortality. Further, these side effects add to related medical costs by prolonging hospital stays, increasing antibiotic, fluid, and analgesic use, and requiring patients to receive parenteral nutritional support. Of the estimated 800,000 patients treated for cancer in the United States, as many as 400,000 may develop the debilitating complications of oral mucositis as a result of their treatment. RxKinetix also had other products in early-stage development based on the ProGelz<sup>®</sup> technology. We expect to initiate the first of two Phase III clinical studies of EN 3285 in the fourth quarter of 2007, at which time the \$15 million milestone payment discussed above will become due.

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations describes the principal factors affecting the results of operations, liquidity and capital resources, and critical accounting policies and estimates of Endo. This discussion should be read in conjunction with the accompanying quarterly unaudited condensed consolidated financial statements and our Annual Report on Form 10-K, for the year ended December 31, 2006 (Annual Report). Our Annual Report includes additional information about our significant accounting policies, practices and the transactions that underlie our financial results, as well as a detailed discussion of the most significant risks and uncertainties associated with our financial and operating results. 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 beginning on page 3 of this Report.

**Overview**

We are a specialty pharmaceutical company with market leadership in pain management. We are engaged in the research, development, sale and marketing of branded and generic prescription pharmaceuticals used primarily to treat and manage pain. According to Wolters Kluwer Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled \$19.7 billion in 2006. This represents an approximately 8% compounded annual growth rate since 2002. Our primary area of focus within this market is analgesics and, specifically, opioid analgesics. In 2006, analgesics were the fourth most prescribed medication in the United States with over 260 million prescriptions written for this classification. Opioid analgesics is a segment that comprised approximately 80% of the analgesics prescriptions for 2006. Total U.S. sales for the opioid analgesic segment were \$7.3 billion in 2006, representing a compounded annual growth rate of 8% since

2002.

## **Table of Contents**

We have a portfolio of branded products that includes established brand names such as Lidoderm<sup>®</sup>, Percocet<sup>®</sup>, Frova<sup>®</sup> and Percodan<sup>®</sup>, as well as two newly launched products in 2006 – Opana<sup>®</sup> ER and Opana<sup>®</sup>. Branded products comprised approximately 80% of our net sales in 2006, with 62% of our net sales coming from Lidoderm<sup>®</sup>. Our non-branded generic portfolio, which accounted for 20% of net sales in 2006, currently consists of products primarily focused in pain management, with our generic oxycodone extended-release tablets having accounted for 6% of our net sales in 2006. We focus on selective generics that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing.

We have established research and development expertise in analgesics and devote significant resources to this effort so that we can maintain and develop our product pipeline. Our late-stage branded product pipeline includes the filed supplemental New Drug Application (sNDA) for Frova<sup>®</sup> for the additional indication of short-term prevention of menstrual migraine, two products in Phase III clinical trials and four products in Phase II clinical trials.

We enhance our financial flexibility by outsourcing certain of our functions, including manufacturing and distribution. Currently, our primary suppliers of contract manufacturing services are Novartis Consumer Health, Inc. and Teikoku Seiyaku Co., Ltd.

Through a dedicated sales force of approximately 690 sales representatives in the United States, we market our branded pharmaceutical products to high-prescribing physicians in pain management, neurology, surgery, anesthesiology, oncology and primary care. Our sales force also targets retail pharmacies and other healthcare professionals throughout the United States.

On a continuous basis, we evaluate and, where appropriate, pursue acquisition opportunities on terms we consider favorable. In particular, we look to continue to enhance our product line by acquiring or licensing rights to additional products and compounds and therefore regularly evaluate selective acquisition and license opportunities. Such acquisitions or licenses may be carried out through the purchase of assets, joint ventures and licenses or by acquiring other companies. Currently, however, we have no binding commitment related to any acquisitions.

Our wholly-owned subsidiary, Endo Pharmaceuticals Inc. (EPI), commenced operations in 1997 by acquiring certain pharmaceutical products, related rights and assets of The DuPont Merck Pharmaceutical Company, which subsequently became DuPont Pharmaceuticals Company and was thereafter purchased by the Bristol-Myers Squibb Pharma Company in 2001. Endo Pharmaceuticals Inc. was formed by some members of the then-existing management of DuPont Merck and an affiliate of Kelso & Company who were also parties to the purchase agreement, under which we acquired these initial assets.

### *Recent Developments*

In November 2007, we announced that we will initiate the first of two Phase III clinical studies in the fourth quarter of 2007 for EN 3285, a topical oral-rinse in development for the prevention or delay of severe oral mucositis (OM), painful mouth sores that often occur in cancer patients undergoing radiation and chemotherapeutic treatment. Endo has agreed to the trial design with the FDA under the Special Protocol Assessment (SPA) process. Under the terms of the SPA, Endo will initiate a multicenter, double-blind, placebo-controlled trial in approximately 240 OM patients undergoing chemoradiation therapy for head and neck cancer. A second Phase III study is expected to begin during the first half of 2008. The FDA will require two Phase III, double-blind, placebo-controlled trials as the basis for an NDA for this indication. As such, the Company is currently projecting a 2010 NDA filing date for this product but may provide future updates depending upon the pace of patient enrollment in the clinical trials.

In November 2007, we announced that we have decided to conduct an interim statistical analysis of the Phase III placebo-controlled efficacy trial of Rapinyl<sup>™</sup>, the sublingual fentanyl tablet being studied for the treatment of breakthrough cancer pain.

In November 2007, we announced that our topical ketoprofen patch achieved positive results for a four-week, double-blind, placebo-controlled efficacy trial evaluating this once-daily analgesic patch in 309 patients with osteoarthritis flare of the knee. This trial represented the first part of a three-month safety study of the product (the final two months of the study were an open-label extension). The double-blind, placebo-controlled portion of the study met its predetermined primary objective: statistically significant difference from placebo at day 14 in the WOMAC pain sub-scale ( $p=0.014$ ). Significant treatment differences were observed at all measurement points in this parameter during the double-blind phase. Secondary outcomes, including physician global assessment of study medication and KOOS sub-scales (pain, symptoms and function), also demonstrated statistically significant differences from placebo. Pain relief was sustained throughout the open-label phase. As Endo previously disclosed, two earlier Phase III double-blind, placebo-controlled clinical trials in patients with ankle sprains and strains and in patients with tendonitis or bursitis of the shoulder, elbow or knee did not meet their primary endpoints. As a result, in July 2007, the Company announced that it has withdrawn its guidance pertaining to the anticipated first-half 2008 filing date of its New Drug Application (NDA) for the topical ketoprofen patch. The Company continues to evaluate and analyze these results, which may have been due to such factors as insufficient severity of pain on entry into the studies and the use of ibuprofen as rescue medication. A third Phase III study, evaluating the ketoprofen patch in the

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

treatment of pain associated with tendonitis or bursitis of the shoulder, elbow or knee, has been amended based on the above findings and is ongoing. The positive outcome observed in the efficacy portion of the osteoarthritis long-term safety study of the ketoprofen patch provides further information that could contribute to the design of additional clinical trials, and the Company intends to request a meeting with the FDA to discuss its clinical development plans for this product.

**Table of Contents**

In October 2007, we announced that we have received a notice from IMPAX Laboratories, Inc. advising of the filing by IMPAX of an Abbreviated New Drug Application (ANDA) containing a Paragraph IV certification under 21 U.S.C § 355 (j) for oxymorphone hydrochloride extended-release tablets CII. This Paragraph IV certification notice refers to Penwest's U.S. Patent No. 7,276,250, which covers the formulation of Opana® ER. On November 1, 2007, we received a patent certification notice from IMPAX relating to Penwest's U.S. Patent Nos. 5,662,933 and 5,958,456, which cover the formulation of Opana® ER and were recently listed in the Orange Book. In addition to all of these patents, Opana® ER has a new dosage form (NDA) exclusivity that prevents final approval of any ANDA by the FDA until the exclusivity expires on June 22, 2009. Endo is currently reviewing the details of these notices from IMPAX. Endo intends to pursue all available legal and regulatory avenues in defense of Opana® ER, including enforcement of our intellectual property rights and approved labeling. Impax has disclosed that, following the acceptance of its ANDA for filing by the FDA, the agency informed Impax that the FDA has rescinded its initial acceptance.

In September 2007, we announced that the FDA identified deficiencies and asked for additional information pertaining to our supplemental New Drug Application (sNDA) for Frova® (frovatriptan succinate) 2.5 mg tablets in a not approvable letter. The sNDA is for the additional indication of Frova® for the short-term (six days per month) prevention of menstrual migraine. Frova® is already approved and marketed for the acute treatment of migraine with or without aura in adults where a clear diagnosis of migraine has been established. While the FDA acknowledged that both pivotal efficacy trials that had been submitted as part of this sNDA met their primary endpoints in significantly improving the number of headache-free perimenstrual periods (PMPs), it questioned whether the benefit demonstrated was clinically meaningful. The FDA also expressed concern about the potential for increased risk of serious vascular adverse events, though none were observed in the clinical development program. The Company, along with our development partner Vernalis Plc, is continuing to evaluate the points raised in the not approvable letter and are seeking a meeting with the FDA to review in detail the agency's concerns and determine what kind of information is needed before deciding on the appropriate course of action.



**Table of Contents**

In September 2007, we announced the appointment of Nancy J. Wysenski as Chief Operating Officer. Ms. Wysenski has 30 years of health care industry experience, most recently as President of EMD Pharmaceuticals, Inc., the U.S. subsidiary of Merck KGaA. In her position, Ms. Wysenski will have direct responsibility for business development, strategic alliances, sales and marketing, technical operations and supply chain, and corporate services, including human resources and information management.

In July 2007, Vernalis Development Limited ( Vernalis ) and Endo entered into Amendment No. 3 (Amendment) to the License Agreement dated July 14, 2004. Under the Amendment, Vernalis granted to Endo, a sole and exclusive (even as against Vernalis) license to make, have made, use, commercialize and have commercialized the product Frova® (frovatriptan) in Canada, under the Canadian Trademark.

In July 2007, Novopharm Limited ( Novopharm ) and Endo entered into a License Agreement (the Novopharm Agreement ) whereby Endo granted to Novopharm the exclusive right to use, import, sell, have sold, offer to sell, distribute, market, promote and otherwise exploit the product Frova® (frovatriptan) in Canada. Novopharm paid to the Company an upfront license fee of approximately \$0.2 million and has agreed to make additional milestone payments totaling \$0.7 million upon the occurrence of certain events or based on the passage of time. In addition to the milestone payments, Novopharm will pay to Endo royalties based on a certain percentage of net sales as defined in the Novopharm Agreement. The term of the Novopharm Agreement will continue until the later to occur of 10 years after its July 2007 effective date or the expiration of the last Frova® patent in Canada. We have the right after December 31, 2010 to terminate the Novopharm Agreement upon one hundred eighty (180) days, prior written notice to Novopharm, and may be required to make annual royalty payments to Novopharm for a period of up to three years after such termination on any sales in Canada made by Endo or any of its affiliates during that three-year period.

In April 2007, the Company and Teikoku Seiyaku Co., Ltd. / Teikoku Pharma USA, Inc. (collectively, Teikoku ) amended their Supply and Manufacturing Agreement dated as of November 23, 1998 by and between Endo and Teikoku, pursuant to which Teikoku manufactures and supplies Lidoderm® (lidocaine patch 5%) (the Product ) to Endo. This amendment is referred to as the Amended Agreement. The material components of the Amended Agreement are as follows:

We have agreed to purchase a certain number of patches per year for each year in the remaining term of the Amended Agreement.

Teikoku has agreed to fix the supply price of Lidoderm® for a period time after which the price will be adjusted at future dates certain based on a price index defined in the Amended Agreement.

Following cessation of our obligation to pay royalties to Hind Healthcare Inc. ( Hind ) under the Sole and Exclusive License Agreement dated as of November 23, 1998, as amended, between Hind and Endo, we will pay to Teikoku annual royalties based on our annual net sales of the Product.

---

## Table of Contents

The Amended Agreement will expire on December 31, 2021, unless terminated in accordance with its terms. After December 31, 2021, the Amended Agreement shall be automatically renewed on the first day of January each year unless (i) we and Teikoku agree to terminate the Amended Agreement upon mutual written agreement or (ii) either we or Teikoku terminates the Amended Agreement with 180-day written notice to the other party, which notice shall not in any event be effective prior to July 1, 2022.

In April 2007, we announced that Carol A. Ammon, Founder and Chairman of the Board, had informed the company that she had decided to retire, effective May 30, 2007, from her position as Endo's Chairman to devote more time to her philanthropic activities, and accordingly, did not run for re-election to the Company's board of directors. The Company also announced that Roger H. Kimmel, an independent director of Endo since 2000, had been appointed by the Board to serve as Chairman, effective May 30, 2007.

In April 2007, the Company announced that it received notice from Anesiva, Inc., advising of the filing of a New Drug Application (NDA) under 21 U.S.C. § 355(b)(2)(A)(iv) (also referred to as Section 505(b)(2)(A)(iv) of the Federal Food, Drug and Cosmetic Act) for its Zingo™ Dermal Powder/Ject Lidocaine HCl topical powder and referring to the patents that cover the method of use and formulation of Endo's lidocaine-containing topical patch products, Lidoderm® and Synera™. Section 505(b)(2) does not allow for automatic generic substitution of these prescription products for any other products. If approved, Endo believes that Zingo™ will not be a generic to, nor will it compete with, Lidoderm® because of Zingo™'s indication and formulation. Anesiva's notice stated that Zingo™'s proposed indication is for preventing or reducing pain associated with blood draws and intravenous placements. Unlike Lidoderm®, Zingo™ is not a topical patch. However, Endo believes that, although Zingo™ would not be a substitutable generic to Synera™ and uses a different delivery mechanism, Zingo™ may compete with Synera™ because their indications may be similar. According to Anesiva's notice letter, Zingo's injection device drives lidocaine powder into the skin surface using accelerated inert gas particles. An NDA for Zingo™ was filed in late 2006 and accepted for filing in January 2007.

In January 2007, the Company and Penwest entered into an amendment (the 2007 Amendment) to the 2002 amended and restated strategic alliance agreement between the parties (the 2002 Agreement). Under the terms of the 2007 Amendment, Endo and Penwest agreed to restructure the 2002 Agreement to provide that royalties payable to Penwest for U.S. sales of Opana® ER will be calculated based on net sales of the product rather than on operating profit, and to change certain other provisions of the 2002 Agreement. The 2007 Amendment also resolved the parties' ongoing disagreement with regard to sharing of marketing expenses during the period prior to when Opana® ER reaches profitability. The key financial terms of the 2007 Amendment are summarized as follows:

With respect to U.S. sales of Opana® ER, Endo's royalty payments to Penwest will be calculated starting at 22% of annual net sales of the product, and, based on agreed-upon levels of annual net sales achieved, the royalty rate can increase to a maximum of 30%.

No royalty payments will be due to Penwest for the first \$41 million of royalties that would otherwise have been payable beginning from the time of the product launch in July 2006.

Penwest is entitled to receive milestone payments of up to \$90 million based upon the achievement of certain agreed-upon annual sales thresholds.

In 2003, Penwest opted out of funding development costs for Opana® ER. Under the 2007 Amendment, the parties have agreed that Penwest's share of these unfunded development costs will be fixed at \$28 million and will be recouped by Endo through a temporary 50% reduction in royalties payable to Penwest. This temporary reduction in royalties will not apply until the \$41 million royalty threshold referred to above has been met.

As a result of the terms described above, the Company anticipates that no royalties are or will be due on the first \$186.3 million of net sales of Opana® ER as we recoup our previously recognized launch expenses. After this initial \$186.3 million of net sales, royalties will be reduced by fifty percent (50%) until we recoup our previously recognized certification period expenses, after which time royalties will be payable on annual net sales based on the royalty rates described above.

In January 2007, following an assessment of the status of DepoDur®, we announced that we notified SkyePharma PLC of our intent to terminate our development and commercialization agreement for this product and, in February 2007, entered into a termination agreement with SkyePharma whereby the Development and Marketing Strategic Alliance Agreement was terminated in its entirety on March 31, 2007. In order to provide for the continued commercial support of the DepoDur® product and the transition of such product to SkyePharma on March 31, 2007, Endo provided a number of services and undertook certain activities. Specifically, Endo employed commercially reasonable efforts to maintain

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

and continue all U.S. commercial activities in support of DepoDur<sup>®</sup> through March 31, 2007 and supported and/or undertook the transition of certain Endo functions and activities (including third party activities) to SkyePharma that were useful and necessary for SkyePharma to assume commercial and related responsibilities for DepoDur<sup>®</sup> in the U.S. All such transition services and activities were completed by March 31, 2007.

In January 2007, the Company received a subpoena issued by the United States Department of Health and Human Services, Office of Inspector General (OIG). The subpoena requests documents relating to Lidoderm<sup>®</sup> (lidocaine patch 5%), focused primarily on the sale, marketing and promotion of Lidoderm<sup>®</sup>. The Company is cooperating with the government to provide the requested documents. At this time, the Company cannot predict or determine the outcome of the above matter or responsibly estimate the amount or range of amounts of fines or penalties, if any, that might result from an adverse outcome.

## **Table of Contents**

### **Critical Accounting Policies and Estimates**

To understand our financial statements, it is important to understand our critical accounting policies and estimates. The preparation of our financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions are required in the determination of revenue recognition and sales deductions for estimated chargebacks, rebates, sales incentives and allowances, certain royalties, distribution service fees, returns and losses. Significant estimates and assumptions are also required in the appropriateness of capitalization and amortization periods for identifiable intangible assets, inventories and related inventory reserves, the potential impairment of goodwill and other intangible assets, income taxes, contingencies and stock-based compensation. 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. Although we believe that our estimates and assumptions are reasonable, they are based upon information available at the time the estimates and assumptions were made. Actual results may differ significantly from our estimates. Our most critical accounting policies and estimates are described below:

#### ***Revenue Recognition***

Our net sales consist of revenues from sales of our pharmaceutical products, less estimates for chargebacks, rebates, sales incentives and allowances, certain royalties, distribution service fees, returns and losses. We recognize revenue for product sales when title and risk of loss has passed to the customer, which is typically upon delivery to the customer, when estimated provisions for chargebacks, rebates, sales incentives and allowances, certain royalties, distribution service fees, returns and losses are reasonably determinable, and when collectibility is reasonably assured. Revenue from the launch of a new or significantly unique product, for which we are unable to develop the requisite historical data on which to base estimates of returns, due to the uniqueness of the therapeutic area or delivery technology as compared to other products in our portfolio and in the industry, may be deferred until such time that an estimate can be determined and all of the conditions above are met and when the product has achieved market acceptance, which is typically based on dispensed prescription data and other information obtained during the period following launch.

Decisions made by wholesaler customers and large retail chain customers regarding the levels of inventory they hold (and thus the amount of product they purchase from us) can materially affect the level of our sales in any particular period and thus may not correlate to the number of prescriptions written for our products based on external third-party data. We believe that speculative buying of product, particularly in anticipation of possible price increases, has been the historic practice of many pharmaceutical wholesalers. Over the past two years, our wholesaler customers, as well as others in the industry, began modifying their business models from arrangements where they derive profits from the management of various discounts and rebates, to arrangements where they charge a fee for their services. In connection with this new wholesaler business model we have entered into distribution service agreements (or DSAs) with four of our wholesaler customers. These agreements, which pertain to branded products only, obligate the wholesalers to provide us with specific services, including the provision of periodic retail demand information and current inventory levels for our branded products held at their warehouse locations; additionally, under these DSAs, the wholesalers have agreed to manage the variability of their purchases and inventory levels within specified limits based on product demand.

As of September 30, 2007, we received information from four of our large U.S. wholesaler customers about the levels of inventory they held for our branded products. Based on this information, which we have not independently verified, we believe that total branded inventory held at these wholesalers is within normal levels. In addition, we also evaluate market conditions for products primarily through the analysis of wholesaler and other third party sell-through and market research data, as well as internally-generated information. We believe sales recorded for the three and nine months ended September 30, 2007 were generally representative of underlying demand for the products.

#### ***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, certain royalties, DSA fees, returns and losses. These provisions, as described in greater detail below, 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 materially impacted. During the nine months ended September 30, 2007, adjustments for prior periods sales deduction accruals amounted to approximately \$0.7 million related to a shortage in 2006 accruals.



## **Table of Contents**

### *Returns*

Our provision for returns consists of our estimates of future product returns, pricing adjustments and delivery errors. Consistent with industry practice, we maintain a return policy that allows our customers to return product within a specified period of time both prior and subsequent to the product's expiration date. Our return policy allows customers to receive credit for expired products within six months prior to expiration and within one year after expiration. The primary factors we consider in estimating our potential product returns include:

the shelf life or expiration date of each product;

historical levels of expired product returns;

external data with respect to inventory levels in the wholesale distribution channel;

external data with respect to prescription demand for our products; and

estimated returns liability to be processed by year of sale based on analysis of lot information related to actual historical returns.

In determining our estimates for returns, we are required to make certain assumptions regarding the timing of the introduction of new products and the potential of these products to capture market share. In addition, we make certain assumptions with respect to the extent and pattern of decline associated with generic competition. To make these assessments we utilize market data for similar products as analogs for our estimations. We use our best judgment to formulate these assumptions based on past experience and information available to us at the time. We continually reassess and make the appropriate changes to our estimates and assumptions as new information becomes available to us.

Our estimate for returns may be impacted by a number of factors, but the principal factor relates to the level of inventory in the distribution channel. When we are aware of an increase in the level of inventory of our products in the distribution channel, we consider the reasons for the increase to determine if the increase may be temporary or other-than-temporary. Increases in inventory levels assessed as temporary will not result in an adjustment to our provision for returns. Other-than-temporary increases in inventory levels, however, may be indication that future product returns could be higher than originally anticipated and, accordingly, we may need to adjust our estimate for returns. Some of the factors that may be an indication that an increase in inventory levels will be temporary include:

recently implemented or announced price increases for our products; and

new product launches or expanded indications for our existing products.

Conversely, factors that may be an indication that an increase in inventory levels will be other-than-temporary include:

declining sales trends based on prescription demand;

recent regulatory approvals to extend the shelf life of our products, which could result in a period of higher returns related to older product with the shorter shelf life;

introduction of new product or generic competition;

increasing price competition from generic competitors; and

recent changes to the National Drug Codes ( NDCs ) of our products, which could result in a period of higher returns related to product with the old NDC, as our customers generally permit only one NDC per product for identification and tracking within their inventory systems.

*Rebates*

We establish contracts with wholesalers, chain stores and indirect customers that provide for rebates, sales incentives, DSA fees, 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. Our rebate programs can generally be categorized into the following four types:

direct rebates;

indirect rebates;

managed care rebates; and

Medicaid and Medicare Part D rebates.

---

## **Table of Contents**

Direct rebates are generally rebates paid to direct purchasing customers based on a percentage applied to a direct customer's purchases from us, including DSA fees paid to wholesalers under our DSA agreements, as described above. Indirect rebates are rebates paid to indirect customers which have purchased our products from a wholesaler under a contract with us.

We are subject to rebates on sales made under governmental and managed-care pricing programs. In estimating our provisions for these types of rebates, we consider relevant statutes with respect to governmental pricing programs and contractual sales terms with managed-care providers and group purchasing organizations. We estimate an accrual for managed-care, Medicaid and Medicare Part D rebates as a reduction of revenue at the time product sales are recorded. These rebate reserves are estimated based upon the historical utilization levels, historical payment experience, historical relationship to revenues and estimated future trends. Changes in the level of utilization of our products through private or public benefit plans and group purchasing organizations will affect the amount of rebates that we owe.

We participate in state government-managed Medicaid programs, as well as certain other qualifying federal and state government programs whereby discounts and rebates are provided to participating government entities. Medicaid rebates are amounts owed based upon contractual agreements or legal requirements with public sector (Medicaid) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. Medicaid reserves are based on expected payments, which are driven by patient usage, contract performance, as well as field inventory that will be subject to a Medicaid rebate. Medicaid rebates are typically billed up to 180 days after the product is shipped, but can be as much as 270 days after the quarter in which the product is dispensed to the Medicaid participant. As a result, our Medicaid rebate provision includes an estimate of outstanding claims for end-customer sales that occurred but for which the related claim has not been billed, and an estimate for future claims that will be made when inventory in the distribution channel is sold through to plan participants. Our calculation also requires other estimates, such as estimates of sales mix, to determine which sales are subject to rebates and the amount of such rebates. Periodically, we adjust the Medicaid rebate provision based on actual claims paid. Due to the delay in billing, adjustments to actual may incorporate revisions of this provision for several periods. Medicaid pricing programs involve particularly difficult interpretations of statutes and regulatory guidance, which are complex and thus our estimates could differ from actual experience.

We continually update these factors based on new contractual or statutory requirements, and significant changes in sales trends that may impact the percentage of our products subject to rebates.

### *Chargebacks*

The provision for chargebacks is one of the most significant and the most complex estimate used in the recognition of our revenue. We market and sell products directly to wholesalers, distributors, warehousing pharmacy chains, and other direct purchasing groups. We also market products indirectly to independent pharmacies, non-warehousing chains, managed care organizations, and group purchasing organizations, collectively referred to as indirect customers. We enter into agreements with some indirect customers to establish contract pricing for certain products. These indirect customers then independently select a wholesaler from which to purchase the products at these contracted prices. Alternatively, we may pre-authorize wholesalers to offer specified contract pricing to other indirect customers. Under either arrangement, we provide credit to the wholesaler for any difference between the contracted price with the indirect customer and the wholesaler's invoice price. Such credit is called a chargeback. The primary factors we consider in developing and evaluating our provision for chargebacks include:

the average historical chargeback credits;

estimated future sales trends; and

an estimate of the inventory held by our wholesalers, based on internal analysis of a wholesaler's historical purchases and contract sales.

### *Other sales deductions*

We offer our customers 2% prompt pay cash discounts. Provisions for prompt pay discounts are estimated and recorded at the time of sale. We estimate provisions for cash discounts based on contractual sales terms with customers, an analysis of unpaid invoices and historical payment experience. Estimated cash discounts have historically been predictable and less subjective, due to the limited number of assumptions involved, the consistency of historical experience and the fact that we generally settle these amounts within thirty to sixty days.



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

Shelf-stock adjustments are credits issued to our customers to reflect decreases in the selling prices of our products. These credits are customary in the industry and are intended to reduce a customer's inventory cost to better reflect current market prices.

---

## **Table of Contents**

The determination to grant a shelf-stock credit to a customer following a price decrease is at our discretion rather than contractually required. The primary factors we consider when deciding whether to record a reserve for a shelf-stock adjustment include:

the estimated number of competing products being launched as well as the expected launch date, which we determine based on market intelligence;

the estimated decline in the market price of our product, which we determine based on historical experience and input from customers; and,

the estimated levels of inventory held by our customers at the time of the anticipated decrease in market price, which we determine based upon historical experience and customer input.

### *Royalties*

Royalties represent amounts accrued pursuant to the license agreement with Hind Healthcare Inc. (Hind). Royalties, payable to Hind, 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®.

### *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.

### *Goodwill and Other Intangibles*

Goodwill and other intangibles represent a significant portion of our assets and stockholders' equity. As of September 30, 2007, goodwill and other intangibles comprised approximately 16% of our total assets and 21% of our stockholders' equity. SFAS No. 142, *Goodwill and Other Intangible Assets*, 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. 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. On January 1, 2007 and 2006, our goodwill was evaluated for impairment and, based on the fair value of our reporting unit, no impairment was identified.

The cost of licenses are either expensed immediately or, if capitalized, are stated at cost, less accumulated amortization and are amortized using the straight-line method over their estimated useful lives ranging from ten to twenty years, with a weighted average useful life of approximately 16 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. The value of these licenses is subject to continuing scientific, medical and marketplace uncertainty. Patents acquired in the Algos merger are stated at cost, less accumulated amortization, and are amortized using the

straight-line method over their estimated useful lives of seventeen years.

Licenses and patents are assessed 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), whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. 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

**Table of Contents**

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, generally calculated using a discounted future cash flow method. An impairment loss would be recognized in net income in the period that the impairment occurs. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. As a result of the significance of our amortizable intangibles, any recognized impairment loss could have a material adverse impact on our financial position and/or results of operations.

Our goodwill and other intangible assets consist of the following at September 30, 2007 and December 31, 2006, respectively (in thousands):

	September 30,	December 31,
	2007	2006
Goodwill	\$ 181,079	\$ 181,079
Amortizable Intangibles:		
Licenses	\$ 94,621	\$ 94,621
Patents	3,200	3,200
	97,821	97,821
Less accumulated amortization	(24,431)	(19,775)
Other Intangibles, net	\$ 73,390	\$ 78,046

In November 2007, we announced that we have decided to conduct an interim statistical analysis of the Phase III placebo-controlled efficacy trial of Rapinyl<sup>®</sup>, our sublingual fentanyl tablet being studied for the treatment of breakthrough cancer pain. As a result of this development, we reviewed our agreement with Orexo AB, pursuant to which we license Rapinyl<sup>™</sup>. We have evaluated our Orexo intangible asset, which has a net book value of \$8.5 million at September 30, 2007, for impairment and determined that an impairment did not exist at such time. However, we will continue to monitor this asset, including determining if the results of the interim statistical analysis have any impact on the carrying value of the asset.

Estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2006 is as follows (in thousands):

2007	\$ 6,209
2008	6,209
2009	6,209
2010	6,209
2011	6,209

**Income Taxes**

Provisions for income taxes are calculated on reported pre-tax income based on current tax laws, statutory tax rates and available tax incentives and planning opportunities in various jurisdictions in which we operate. Such provisions differ from the amounts currently receivable or payable because certain items of income and expense are recognized in different time periods for financial reporting purposes than for income tax purposes. Significant judgment is required in determining income tax provisions and evaluating tax positions. On January 1, 2007, the Company adopted the provisions of FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes, an Interpretation of FASB Statement No. 109 (FIN 48). FIN 48 creates a single model to address uncertainty in tax positions and clarifies the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. The provisions of FIN 48 apply to all material tax positions in all taxing jurisdictions for all open tax years. FIN 48 establishes a two-step process for evaluating tax positions. Step 1 Recognition, requires the Company to determine whether a tax position, based solely on its technical merits, has a likelihood of more than 50 percent (more-likely-than-not) that the tax position taken will be sustained upon examination. Step 2 Measurement, which is only addressed if Step 1 has been satisfied, requires the Company to measure the tax benefit as the largest amount of benefit, determined on a cumulative probability basis that is more-likely-than-not to be realized upon ultimate settlement. Whether the more-likely-than-not recognition threshold is met for a tax position, is a matter of judgment based on the individual facts and circumstances of that position evaluated in light of all available evidence.



## **Table of Contents**

### ***Contingencies***

The Company is subject to various patent, product liability, government investigations and other legal proceedings in the ordinary course of business. Legal fees and other expenses related to litigation are expensed as incurred and included in selling, general and administrative expenses. Contingent accruals are recorded when the Company determines that a loss related to a litigation matter is both probable and reasonably estimable. Due to the fact that legal proceedings and other contingencies are inherently unpredictable, our assessments involve significant judgments regarding future events.

### ***Stock-Based Compensation***

Prior to January 1, 2006, the Company accounted for its stock-based compensation plans under the recognition and measurement provisions of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations ( APB 25 ), as permitted by FASB Statement No. 123, *Accounting for Stock-Based Compensation*. No stock-based employee compensation cost was recognized in the Statement of Operations for the years ended December 31, 2005 and 2004. Effective January 1, 2006, the Company adopted the fair value recognition provisions of FASB Statement No. 123(R), *Share-Based Payment*, using the modified-prospective-transition method. Under that transition method, compensation cost recognized during the three and nine months ended September 30, 2007 includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of Statement No. 123, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of Statement No. 123(R). Results for prior periods have not been restated.

For all of the Company's stock-based compensation plans, the fair value of each option grant was estimated at the date of grant using the Black-Scholes option-pricing model. Black-Scholes utilizes assumptions related to volatility, the risk-free interest rate, the dividend yield (which is assumed to be zero, as the Company has not paid cash dividends to date and does not currently expect to pay cash dividends) and the expected term of the option. Expected volatilities utilized in the model are based mainly on the historical volatility of the Company's stock price and other factors. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. During 2006, in accordance with Staff Accounting Bulletin No. 107 ( SAB 107 ), *Share-Based Payment*, the Company calculated the expected term of options granted using the simplified method. The simplified method was intended to be a temporary estimation technique and was to be phased out as more detailed information about exercise behavior became readily available, but no later than December 31, 2007. Beginning in 2007, we estimate the expected term of options granted based on our historical experience with our employees' exercise of stock options and other factors. Changes in the inputs and assumptions can materially affect the measure of the estimated fair value of our employee stock options. Also, the accounting estimate of stock-based compensation expense is reasonably likely to change from period to period as further stock options are granted and adjustments are made for stock option forfeitures and cancellations. Option-pricing models were developed for use in estimating the value of traded options that have no vesting or hedging restrictions and are fully transferable. Because the Company's employee stock options have certain characteristics that are significantly different from traded options, and because changes in the subjective assumptions can materially affect the estimated value, in management's opinion, the existing valuation models may not provide an accurate measure of the fair value of the Company's employee stock options. Although the fair value of employee stock options has been determined in accordance with SFAS 123(R), using an option-pricing model, that value may not be indicative of the fair value observed in a willing buyer/willing seller market transaction. The total value of compensation expense for restricted stock is equal to the closing price of Endo shares on the date of grant.

As of September 30, 2007, the total remaining unrecognized compensation cost related to non-vested stock options and restricted stock amounted to \$35.1 million. The weighted average remaining requisite service period of the non-vested stock options and restricted stock was 2.61 years and 1.45 years, respectively. This unrecognized compensation cost does not include the impact of any future stock-based compensation awards.

### **Results of Operations for the Three and Nine Months Ended September 30, 2007 Compared to the Three and Nine Months Ended September 30, 2006**

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 compensation paid by Endo Pharma LLC, impairment of intangible assets, purchased in-process research and development charges and certain upfront, milestone and certain other payments made or accrued pursuant to acquisition or licensing agreements.

**Net Sales.** Net sales for the three and nine months ended September 30, 2007 increased by \$52.3 million or 24%, and \$130.8 million or 20%, respectively, compared to the same periods of 2006. This increase in net sales is primarily driven by increased sales of Lidoderm® as well as sales of Opana® and Opana® ER, which were launched in the second half of 2006. These increases are



**Table of Contents**

partially offset by the reduction in sales of our generic oxycodone extended-release tablets, resulting from the Company's settlement with Purdue (as described in more detail below). For the three months ended September 30, 2007, increased sales volume contributed 19% of the total sales growth of 24%, while selling price increases contributed the remaining 5% of the total sales growth. For the nine months ended September 30, 2007, increased sales volume contributed 14% of the total sales growth of 20%, while selling price increases contributed the remaining 6% of the total sales growth. The volume growth for the three and nine months ended September 30, 2007 includes the unfavorable impact of reduced inventories at our major wholesaler customers. We believe this decline in inventory levels at these wholesalers is due to improved distribution efficiencies, resulting in their ability to maintain lower levels of inventory on-hand.

The following table displays our net sales by product category and as a percentage of total net sales for the three and nine months ended September 30, 2007 and 2006 (dollars in thousands):

	Three Months Ended				Nine Months Ended			
	September 30,		September 30,		September 30,		September 30,	
	2007	2006	2007	2006	2007	2006	2007	2006
	\$	%	\$	%	\$	%	\$	%
Lidoderm®	\$ 174,326	64	\$ 127,390	59	\$ 496,926	63	\$ 393,284	60
Percocet®	31,644	12	25,264	12	91,183	12	74,901	12
Frova®	13,465	5	9,090	4	38,365	5	29,108	4
Opana® ER and Opana®	23,998	9			78,274	10		
Other brands	2,707	1	2,742	1	7,837	1	10,838	2
Total brands	246,140	91	164,486	76	712,585	91	508,131	78
Generic oxycodone extended-release tablets			18,971	9			43,263	7
Other generics	23,330	9	33,668	15	68,441	9	98,794	15
Total generics	23,330	9	52,639	24	68,441	9	142,057	22
Total net sales	\$ 269,470	100	\$ 217,125	100	\$ 781,026	100	\$ 650,188	100

*Lidoderm®*. Net sales of Lidoderm® for the three and nine months ended September 30, 2007 increased by \$46.9 million or 37%, and \$103.6 million or 26%, respectively, over the comparable periods of 2006. The increase is primarily attributable to continued prescription growth of the product during both the third quarter and nine months ended September 30, 2007. We believe the continued growth of Lidoderm® is driven by the product's proven clinical effectiveness combined with the expansion of our sales force in 2006.

*Percocet®*. Net sales of Percocet® for the three and nine months ended September 30, 2007 increased by \$6.4 million or 25%, and \$16.3 million or 22%, respectively, over the comparable periods of 2006. The increase is primarily attributable to improved pricing during both the third quarter and nine months ended September 30, 2007.

*Frova®*. Net sales of Frova® for the three and nine months ended September 30, 2007 increased by \$4.4 million or 48%, and \$9.3 million or 32%, respectively, over the comparable periods of 2006. The growth in net sales is primarily attributable to continued prescription growth of the product, as we continue to drive our promotional efforts through our expanded sales force.

*Opana® ER and Opana®*. Net Sales of Opana® ER and Opana® for the three and nine months ended September 30, 2007 were completely incremental over the comparable 2006 period as these products were not launched until the second half of 2006. Net sales of Opana® and Opana® ER for the nine months ended September 30, 2007 includes \$13.8 million of deferred revenue recognized during the first quarter of 2007 for commercial shipments made to customers during 2006.

*Generics*. Net sales of our generic products for the three and nine months ended September 30, 2007 decreased by \$29.3 million or 56%, and \$73.6 million or 52%, respectively, over the comparable periods of 2006. The decrease is primarily attributable to the fact that sales of our generic oxycodone extended-release tablets ceased on December 31, 2006. In addition, continued generic competition for these generic products also contributed to the decrease in sales over the comparable periods of 2006. Generic competition with our products may have a material impact on our results of operations and cash flows in the future.





**Table of Contents**

**2007 Outlook.** Due primarily to our strong year-to-date results and the expected increases in the net sales of Lidoderm® and Opana® ER and Opana®, we expect net sales in 2007 to be approximately \$1.050 billion and \$1.075 billion. There can be no assurance of Endo achieving these results.

**Gross Profit.** Gross profit for the three and nine months ended September 30, 2007 increased by \$47.0 million, or 27%, and \$122.8, or 24%, respectively, over the comparable 2006 period. The Company's gross profit does not include amortization expense of intangible assets related to commercial products. Amortization expense related to these intangible assets for the three months ended September 30, 2007 and 2006 is approximately \$1.2 million and \$2.0 million, respectively. For the nine months ended September 30, 2007 and 2006, amortization expense related to these intangible assets is approximately \$3.7 and \$5.5, respectively. Diversity in practice exists with respect to the inclusion of amortization expense of intangible assets in cost of sales and therefore such a lack of consistency should be considered when comparing cost of sales and gross profit amounts to other companies. Gross profit margins, excluding amortization expense of intangible assets related to commercial products, increased to 82% and 81% from 80% and 78% in the comparable 2006 three and nine month periods. This increase is primarily attributable to a favorable mix of product revenues, as we derived a higher proportion of total revenue from higher margin branded products compared to revenues in the comparable 2006 periods. Partially offsetting this favorability was the impact of royalties payable to Vernalis for sales of Frova®, which are included in cost of sales. The requirement to pay royalties to Vernalis began in 2007. We expect to continue to benefit from this favorable product mix for the remainder of 2007, as higher-margin branded products will continue to represent a higher proportion of total revenue when compared to 2006. However, this favorability is expected to be partially offset by a decrease in our average selling price as we pursue contracting activities, particularly with managed care organizations, throughout the remainder of 2007.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses for the three and nine months ended September 30, 2007 increased by 22% to \$107.4 million, and 14% to \$287.2 million, respectively, from the comparable 2006 periods. This increase is primarily due to an increase in sales and promotional efforts in 2007 over the comparable 2006 period due to our continued investment in our commercial business and our infrastructure to support our products and pipeline, including the addition of approximately 220 sales representatives, occurring in the second half of 2006, the pre-launch expenses for Frova® (MM) and the continued launch expenses of Opana® ER and Opana®. During 2007, selling, general and administrative expenses are expected to rise due to increased promotional support behind Endo's key on-market products, including the full-year impact of the expansion of the sales force that occurred in the second half of 2006, combined with continuing investments in infrastructure to support Endo's long-term growth including the addition of approximately 100 sales representatives during the second half of 2007. Selling, general and administrative expenses for the nine months ended September 30, 2006 includes compensation expense and the related employer payroll taxes of approximately \$41.3 million related to the one-time bonuses Endo Pharma LLC, a limited liability company that is no longer affiliated with the Company, but had historically held significant portions of our common stock, in which affiliates of Kelso & Company and certain current and former members of management have an interest, paid to certain of our executives.

**Research and Development Expenses.** Research and development expenses increased to \$26.9 million from \$14.5 million, and to \$79.6 million from \$59.4 million, for the three and nine months ended September 30, 2007, respectively, over the comparable 2006 periods. This increase is primarily attributable to the ongoing clinical development of Rapinyl™, our topical ketoprofen patch, our transdermal sufentanil patch and EN 3285, our oral rinse for the treatment of oral mucositis obtained through our acquisition of RxKinetix in October 2006.

In 2007, we expect to direct the majority of our incremental research and development spending on the ongoing clinical trials for Rapinyl™, the topical ketoprofen patch, the transdermal sufentanil patch and EN 3285. Additionally, we expect to increase our investment in post-marketing clinical studies in support of our on-market products.

**Depreciation and Amortization.** Depreciation and amortization for the three and months ended September 30, 2007 increased to \$5.1 million from \$4.6 million and to \$13.0 from \$12.9 million, for the three and nine months ended September 30, 2007, respectively, over the comparable 2006 periods primarily due to an increase in depreciation expense as a result of an increase in capital expenditures. This increase was partially offset by a decrease in amortization expense primarily due to reduced intangible asset balances as a result of the impairment charges recorded in the fourth quarter of 2006 related to the SkyePharma and ZARS intangible assets (DepoDur® and Synera, respectively). We expect depreciation and amortization will increase from current levels as we increase our capital expenditures and as we continue to license in products and technologies.

**Interest Income, Net.** Interest income, net for the three months ended September 30, 2007 increased to \$9.7 million from \$6.9 million in the comparable 2006 period. For the nine months ended September 30, 2007, interest income increased to \$25.0 million from \$17.1 million in the comparable 2006 period. This change is due to the increased interest income earned as a result of higher cash and marketable securities balances and higher returns earned during the third quarter and nine months ended September 30, 2007 compared to the same

**Table of Contents**

periods of the prior year. During the second quarter of 2007, the Company began investing in marketable securities. Our investments in marketable securities are governed by our investment policy, which has been approved by our Board of Directors. Our investment policy seeks to preserve the value of capital, consistent with maximizing return on the Company's investment, while maintaining adequate liquidity.

**Income Tax.** Income tax for the three months ended September 30, 2007 increased to \$30.9 million from \$27.7 million in the comparable 2006 period. Income tax expense for the nine months ended September 30, 2007 increased to \$97.8 million from \$76.0 million in the comparable 2006 period. The increase in income tax expense for the three and nine months ended September 30, 2007 is primarily a result of the increase in income before income tax for the three and nine months ended September 30, 2007 compared to the comparable periods in 2006. The impact of the increase in income before income tax is partially offset by a reduction in our effective tax rate. Our effective tax rate for the three months ended September 30, 2007 decreased to 34.3% from 38.2% in the comparable period of 2006, while our effective rate for the nine months ended September 30, 2007 decreased to 35.6% from 38.2% in the comparable period of 2006. The decrease in the effective income tax rate is primarily related to certain compensation charges recorded in 2006 that were not deductible for income tax purposes and tax-free interest income earned in 2007.

**Liquidity and Capital Resources**

Our principal source of liquidity is cash generated from operations. Our principal liquidity requirements are for working capital for operations, acquisitions, licenses, milestone payments and capital expenditures.

During the second quarter of 2007, the Company began investing in marketable securities. Our investments in marketable securities are governed by our investment policy, which has been approved by our Board of Directors. Our investment policy seeks to preserve the value of capital, consistent with maximizing return on the Company's investment, while maintaining adequate liquidity. During the nine months ended September 30, 2007 cash and cash equivalents decreased by \$353.2 million, primarily as a result of our investment in marketable securities offset by the cash generated by our operating activities. As of September 30, 2007, our combined cash and cash equivalents and current marketable securities balance has reached a total of \$882.9 million. These funds, in addition to our cash generated from future operations are expected to be sufficient to meet our normal operating, investing and financing requirements in the foreseeable future, including the funding of our pipeline research and development 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.

**Net Cash Provided by Operating Activities.** Net cash provided by operating activities were \$287.4 million for the nine months ended September 30, 2007, a 4.3% increase from the comparable 2006 period. Significant components of our operating cash flows for the nine months ended September 30, 2007 and 2006 are as follows (dollars in thousands):

	<b>Nine Months Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>
<b>Cash Flow Data-Operating Activities:</b>		
Net income	176,842	123,065
Depreciation and amortization	12,996	12,944
Stock-based compensation	10,940	9,337
Selling, general and administrative expenses to be funded by Endo Pharma LLC		41,330
Deferred income taxes	13,527	15,015
Changes in assets and liabilities which provided cash:	77,859	73,520
Other, net	(4,733)	332
<b>Net cash provided by operating activities</b>	<b>287,431</b>	<b>275,543</b>

Significant changes in operating cash flow line items include a \$53.8 million increase in net income and a \$4.3 million increase in the operating cash flow impact of the changes in operating assets and liabilities, offset by changes in other items reconciling net income to cash provided by operating activities, the largest of which is a \$41.3 million decrease in the operating cash flow impact related to selling, general and administrative expenses to be funded by Endo Pharma LLC. During the nine months ended September 30, 2006, due to Endo Pharma LLC's payment of one-time bonuses, the Company recorded in selling, general and administrative expense, executive compensation of \$41.3 million for one-time cash bonuses paid to each of Ms. Carol Ammon, our former Chairman of the Board and former Chief Executive Officer, Mr. Peter Lankau, our President and Chief Executive Officer, Ms. Caroline Manogue, our Executive Vice President, Chief Legal Officer and Secretary, and Mr. Jeffrey Black, our former Executive Vice President, Chief Financial Officer and Treasurer. These bonus payments were made by the

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

Company in April 2006 and repaid to us by Endo Pharma LLC in the third quarter of 2006 with interest. The cash flow impact of the changes in operating

**Table of Contents**

assets and liabilities is primarily attributable to the following items: (1) a \$34.0 million increase in the cash flow impact of accounts receivable as a result of the timing and volume of our sales during the nine months ended September 30, 2007 when compared to the nine months ended 2006 and due to the overall reduction in days sales outstanding, discussed in more detail under the *Working Capital* section below; (2) a \$37.2 million increase in the cash flow impact of accrued expenses primarily due to the decrease in revenue reserves from December 31, 2005 to September 30, 2006 related to our generic oxycodone extended-release tablets. Our generic oxycodone extended-release tablets were launched in June 2005 with a 180-day market exclusivity period. Immediately following the expiration of our market exclusivity period, other generic competitors entered the marketplace causing a sharp decline in sales of our generic oxycodone extended-release tablets which resulted in a corresponding decline in the level of required revenue reserves; (3) a \$5.6 million increase in the cash flow impact of amounts due to Endo Pharma LLC due to the timing of reimbursements from Endo Pharma LLC with respect to the executive compensation discussed above; (4) a \$85.5 million decrease in the cash flow impact related to income taxes, due to the receipt of an income tax refund in 2006 as a result of the significant tax deductions generated in 2005 from the exercises of 22.2 million Endo Pharma LLC stock options; and (5) a \$5.0 million increase in the cash flow impact of inventories primarily due to the fact that sales of our generic oxycodone extended-release tablets ceased on December 31, 2006.

**Net Cash Used in Investing Activities.** Net cash used in investing activities increased to \$630.6 million for the nine months ended September 30, 2007 from \$41.7 million for the nine months ended September 30, 2006. Beginning in June 2007, the Company initiated an investment strategy with the intent to maximize investment returns while preserving capital and maintaining adequate liquidity. During the nine months ended September 30, 2007, purchases of marketable securities classified as available-for-sale, totaled \$676.1 million, and sales of marketable securities classified as available-for-sale totaled \$63.0 million. Also, during the nine months ended September 30, 2007, the Company paid \$15.9 million for capital expenditures and invested an additional \$2.8 million in Life Sciences Opportunities Fund (Institutional) II, L.P. (the Fund), bringing our total cash investment to \$5.5 million as of September 30, 2007. In addition, during the second quarter of 2007, we received \$1.1 million from the Fund accounted for as a return of capital. During the nine months ended September 30, 2006, the Company paid \$8.9 million for capital expenditures and \$32.9 million for the purchase of a license right.

**Net Cash Used in Financing Activities.** Net cash used in financing activities decreased to \$10.0 million for the nine months ended September 30, 2007 from \$60.2 million for the nine months ended September 30, 2006. The decrease is primarily due to a \$20.0 million payment to Endo Pharma LLC pursuant to the tax sharing agreement compared to a \$96.7 million payment in 2006 partially offset by a \$28.4 million decrease in the cash flow impact related to the tax benefits of stock options exercised.

**Working Capital.** Working capital increased to \$888.3 million as of September 30, 2007 from \$697.9 million as of December 31, 2006. The components of our working capital as of September 30, 2007 and December 31, 2006 are below (dollars in thousands):

	September 30,	
	2007	December 31, 2006
Total current assets	\$ 1,236,275	\$ 1,036,014
Less: Total current liabilities	347,936	338,099
<b>Working capital</b>	<b>\$ 888,339</b>	<b>\$ 697,915</b>

The primary drivers for the increase in working capital were the increase in the combination of cash and cash equivalents and current marketable securities of \$254.8 million as well as a reduction in the amounts due to Endo Pharma LLC as a result of payments to Endo Pharma LLC during the first nine months of 2007, which reduced the balance due to Endo Pharma LLC to \$19.3 million at September 30, 2007 from \$38.7 million at December 31, 2006. In addition, inventory increased \$12.4 million due primarily to the normal fluctuations in the timing of inventory receipts and customer orders. Further, during the first quarter of 2007, we reduced our accrued liabilities by recognizing \$13.8 million of Opana® and Opana® ER deferred revenue from 2006. This reduction was offset by a modest increase in certain accrued liabilities mainly driven by an increase in headcount during the period.

The working capital increases above were partially offset by several items, the most significant being a decrease in accounts receivable of \$64.9 million from December 31, 2006 to September 30, 2007. Day sales in accounts receivable decreased to 46 days as of September 30, 2007 from 55 days as of December 31, 2006. The decrease in day sales outstanding is primarily attributable to a higher proportion of sales from branded products than generic products during the nine months ended September 30, 2007, which resulted in a faster collection rate as payment on branded products generally, is received more quickly than from generic products. At September 30, 2007, we reclassified to a current liability, \$15.0 million of the estimated amount due seller which at December 31, 2006 was classified, in its entirety, as a non-current liability. The

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

current portion of the estimated amount due seller is payable upon the achievement of certain clinical and regulatory milestones under the terms of the RxKinetix acquisition. In addition, accounts payable increased by \$26.8 million due to the timing of payments related to our on-going research and development activity; marketing promotions; and IT infrastructure enhancements.

**Table of Contents**

**Acquisition.** On October 12, 2006, the Company acquired all of the outstanding common stock of privately held RxKinetix, Inc. RxKinetix specializes in developing new therapeutics focused on improving the quality of life for patients being treated for cancer. RxKinetix's most advanced product, now named EN 3285, is currently in clinical Phase II for the prevention of oral mucositis, a painful, debilitating and often dose-limiting side effect that afflicts many patients being treated for cancer with radiation and/or chemotherapy. RxKinetix is a development stage company and therefore was accounted for as an asset acquisition. The results of operations for RxKinetix have been included in our consolidated financial statements beginning on the acquisition date.

The purchase price of RxKinetix, as of the acquisition date, was \$20.5 million which was funded from our existing cash on hand. Additional contingent cash purchase consideration of up to \$95 million may become due upon the achievement of certain clinical and regulatory milestones. The Company has allocated the purchase price to the RxKinetix assets acquired and liabilities assumed at their estimated fair values, based on a number of factors, including the use of an independent appraisal. Estimated fair values were determined through the use of a discounted cash flow analysis using market participant assumptions. Of the purchase price, approximately \$26.0 million has been allocated to tangible and intangible assets to be used in research and development activities and those assets have been written-off to purchased in-process research and development, as of the acquisition date. The excess of fair value of the net assets acquired compared to the amount paid as of the acquisition date has been reflected as estimated amount due seller in accordance with SFAS No. 141, *Business Combinations*. Any contingent consideration paid in the future will be first applied to reduce the amount recorded as estimated amount due seller, and thereafter to the net assets acquired based on their relative fair values. Our purchase allocation is substantially complete, and any subsequent revisions are not expected to be material. At September 30, 2007, the Company has recorded, as a current liability, \$15 million of the estimated amount due seller which at December 31, 2006 was classified, in its entirety, as a non-current liability. The current portion of the estimated amount due seller is payable upon the commencement of Phase III clinical trials of EN 3285. There has not been any material change in the estimated fair values assigned to the assets acquired and liabilities assumed since the date of acquisition.

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed as of the date of acquisition (in thousands):

Cash consideration	\$ 20,000
Direct acquisition costs	482
<b>Total purchase price</b>	<b>\$ 20,482</b>
Allocation of purchase price:	
Cash	\$ 9
Property and equipment	127
Purchased in-process research and development	26,046
Other assets	461
Deferred tax assets	10,699
Other liabilities	(1,330)
Estimated amounts due seller	(15,530)
<b>Total purchase price</b>	<b>\$ 20,482</b>

As a result of our acquisition of RxKinetix, Inc., we acquired one significant in-process research and development project, now known as EN 3285, a topical oral rinse with the active ingredient formulated in its proprietary ProGelz® drug delivery platform. All of the purchased in-process research and development value from this transaction was assigned to EN 3285 since the other products, as of the acquisition date, were very early stage and did not meet the criteria to be recognized as assets. As of the acquisition date, EN 3285 was in clinical Phase II for the prevention of oral mucositis, painful mouth sores that often occur in cancer patients undergoing radiation and chemotherapeutic treatment. During the course of high-dose cancer therapy and bone marrow transplantation, patients often develop painful and debilitating oral inflammation, or mucositis, in the mouth. The resulting weight loss, dehydration and, in some cases, infection often lead to dose-limitation of chemotherapy and radiation therapy, and contribute considerably to cancer and transplant-related morbidity and mortality. Further, these side effects add to related medical costs by prolonging hospital stays, increasing antibiotic, fluid, and analgesic use, and requiring patients to receive parenteral nutritional support. Of the estimated 800,000 patients treated for cancer in the United States, as many as 400,000 may develop the debilitating complications of oral mucositis as a result of their treatment. RxKinetix also had other products in early-stage development based on the ProGelz® technology. We expect to initiate the first of two Phase III clinical studies of EN 3285 in the fourth quarter of 2007, at which time the \$15 million milestone payment discussed above will become due.





**Table of Contents**

**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 provided us with a line of credit of \$75.0 million. We did not borrow any amounts under the facility during 2006, and the line of credit expired on December 21, 2006. The Company has not renegotiated a credit facility at this time.

**Tax Sharing Agreement.** On July 14, 2000, Endo Pharma LLC was formed in connection with our merger with Algos Pharmaceutical Corporation (Algos) 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. Endo Pharma LLC is a limited liability company that is no longer affiliated with the Company but had historically held significant portions of our common stock, in which affiliates of Kelso & Company and certain current and former members of management have an interest. Upon the exercise of these stock options, only currently outstanding shares of our common stock held by Endo Pharma LLC were delivered. Because Endo Pharma LLC, and not us, had provided the shares upon the exercise of these options, we entered into a tax sharing agreement (as amended) with Endo Pharma LLC under which we are required to pay to Endo Pharma LLC 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, 2007, all 36 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 are generally 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, 2007, approximately \$775 million), which is estimated to result in a tax benefit amount of approximately \$299 million. Under the tax sharing agreement, we are required to pay this \$299 million, \$272 million of which has already been paid as of September 30, 2007, 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. Additionally, as part of the tax sharing agreement, Endo Pharma LLC will reimburse us for the after-tax employer payroll taxes paid by us as a result of the exercise of the 36 million options discussed above. We have paid approximately \$12 million in employer payroll taxes, of which Endo Pharma LLC will reimburse us for approximately \$8 million, which represents the after-tax employer payroll tax paid by us for the periods from 2001 through September 30, 2007. As of September 30, 2007, our net liability due to Endo Pharma LLC is approximately \$19 million. 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. In October 2007, we made a tax sharing payment to Endo Pharma LLC of approximately \$18.5 million. Our remaining liability subsequent to this payment is approximately \$0.8 million, which relates to Endo Pharma LLC options exercised during 2007.

During the nine months ended September 30, 2007, the final 75,259 shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised. Since we expect the attributable compensation charge deductions to be usable to reduce our taxes in 2007, we are obligated, under our amended tax sharing agreement, to pay to Endo Pharma LLC an additional tax benefit amount of approximately \$0.8 million, which is included in our net liability due to Endo Pharma LLC referred to above. Fifty percent of the estimated tax benefit amount attributable to these exercises and any additional tax benefits attributable to the exercise of stock options granted under the Endo Pharma LLC stock option plans in 2007 will be due within 15 business days of the date we receive a report on our final audited 2007 financial statements from our independent registered public accounting firm, and the remaining tax benefit amount attributable to 2007 is due within 30 business days of the date on which we file our 2007 tax return with the Internal Revenue Service. This would represent the final tax sharing payment due to Endo Pharma LLC.

As of September 30, 2007, there were no options remaining to be granted under the Endo Pharma LLC stock option plans.

In October 2007, our board of directors approved a plan to amend our tax sharing agreement with Endo Pharma LLC. This will enable us to pay the final additional tax benefit amount of approximately \$0.8 million to Endo Pharma LLC during the year-ended December 31, 2007. As described in more detail above, we are required to pay fifty percent of the estimated tax benefit subsequent to the receipt of final audited 2007 financial statement and the remaining fifty percent after the date our tax return was filed with the Internal Revenue Service.

**Executive Compensation.** In March 2006, Endo Pharma LLC advised our Board of Directors that it intended to pay a one-time cash bonus to each of Mr. Peter Lankau, our President and Chief Executive Officer, Ms. Caroline Manogue, our Executive Vice President, Chief Legal Officer and Secretary, and Mr. Jeffrey Black, our former Executive Vice President, Chief Financial Officer and Treasurer in the amount of \$3 million, \$6 million and \$10 million, respectively, in recognition of their significant contributions to our success. These bonus payments have been recorded in selling, general and administrative expenses during the year ended December 31, 2006. These payments were made by the Company in April 2006 and repaid to us by Endo Pharma LLC in the third quarter of 2006 with interest. In addition, only a portion of these bonus payments will be deductible for federal and state income tax.

**Table of Contents**

purposes. We are not required to pay nor will we pay to Endo Pharma LLC the amount of any of the tax benefits related to these bonus payments pursuant to the tax sharing agreement between us and Endo Pharma LLC. These bonuses will be funded entirely by Endo Pharma LLC, with no contribution by us and they have been treated as a capital contribution by Endo Pharma LLC.

Endo Pharma LLC also informed us that, in connection with its eventual winding-up, it would make a special allocation to Ms. Carol Ammon, our Chairman of the Board and former Chief Executive Officer, of approximately \$22 million, with all or a portion of Ms. Ammon's payment being satisfied by granting to her the remaining unallocated Endo Pharma LLC stock options representing approximately 0.8 million shares under the Endo Pharma LLC stock option plans. This amount has been recorded in selling, general and administrative expenses during the year ended December 31, 2006 and as a capital contribution by Endo Pharma LLC. This grant of options to Ms. Ammon was made during the fourth quarter of 2006. The 0.8 million options were granted by Endo Pharma LLC to Ms. Ammon in the fourth quarter of 2006, as described above, at an exercise price of \$2.42 per share. Therefore, approximately \$20 million of the approximately \$22 million recorded in the first quarter of 2006 was reclassified as a stock compensation expense representing the fair value of the option on the date of grant. These options were immediately vested and exercised by Ms. Ammon and the resulting compensation charge deduction of approximately \$19 million and the resulting tax sharing obligation to Endo Pharma LLC is included in our tax sharing liability discussed above. Endo Pharma LLC funded the remaining \$2 million to Ms. Ammon in June 2007.

**Related Party Matters.** Robert Ammon, the brother of our former Chairman and former Chief Executive Officer, is employed by the Company as a senior national account executive and has been since the company's founding as a private company in 1997. It is expected that his 2007 total compensation, including base salary, incentive compensation, long-term incentive compensation and all benefits (including health benefits), will not exceed \$255,000. Marisa O'Donnell, the daughter of our President and Chief Executive Officer, is employed by the Company as a sales representative and has been since 2006. It is expected that her 2007 total compensation, including base salary, incentive compensation, long-term incentive compensation and all benefits (including health benefits), will not exceed \$125,000.

**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 took place during the nine months ended September 30, 2007 follows:

*Novopharm Limited*

In July 2007, Novopharm Limited (Novopharm) and Endo entered into a License Agreement (the Novopharm Agreement) whereby Endo granted to Novopharm the exclusive right to use, import, sell, have sold, offer to sell, distribute, market, promote and otherwise exploit the product Frova® (frovatriptan) in Canada. Novopharm paid to the Company an upfront license fee of approximately \$0.2 million. Novopharm has also agreed to make additional milestone payments totaling \$0.7 million upon the occurrence of certain events or based on the passage of time. In addition to the milestone payments, Novopharm will pay to Endo royalties based on a certain percentage of net sales as defined in the Novopharm Agreement. The term of the Novopharm Agreement will continue until the later to occur of 10 years after its July 2007 effective date or the expiration of the last Frova® patent in Canada. We have the right after December 31, 2010 to terminate the Novopharm Agreement upon one hundred eighty (180), days prior written notice to Novopharm, and may be required to make annual royalty payments to Novopharm for a period of up to three years after such termination on any sales in Canada made by Endo or any of its affiliates during that three-year period.

*DURECT Corporation*

In April 2007, DURECT and Endo entered into Amendment No. 4 to the Development, Commercialization and Supply License Agreement dated November 8, 2002 (the DURECT CHRONOGESIC™ License Agreement) relating to the development and commercialization of the CHRONOGESIC™ product candidate in the U.S. and Canada. Prior to the present amendment, in addition to other specified termination rights provided to both parties, the DURECT CHRONOGESIC™ License Agreement provided Endo with a right to terminate the DURECT CHRONOGESIC™ License Agreement starting March 31, 2007 in the event that DURECT had not commenced a specified clinical trial for the CHRONOGESIC™ product candidate on or before March 31, 2007, provided that Endo provided DURECT written notice of such termination prior to April 30, 2007. Under Amendment No. 4, the foregoing termination right was amended to provide Endo with the right to terminate the DURECT CHRONOGESIC™ License Agreement in the event that (i) DURECT had not delivered to Endo on or before March 31, 2008 a written notice that a human pharmacokinetic trial had been completed with the CHRONOGESIC™ product candidate, together with a full study report of the results of the trial or (ii) Endo, determines, in its sole discretion, to terminate the DURECT CHRONOGESIC™ License Agreement during the sixty-day period after DURECT's delivery of such notice, provided that, in each case Endo delivers to DURECT its written notice of termination prior to April 30, 2008. Under Amendment No. 4, Endo shall not be responsible for any development costs for the CHRONOGESIC™ product candidate prior to May 1, 2008. Commencing on May 1, 2008, unless the DURECT CHRONOGESIC™



**Table of Contents**

License Agreement is earlier terminated by Endo, Endo will fund 50% of the ongoing development costs for the CHRONOGESIC™ product candidate in accordance with the terms of the DURECT CHRONOGESIC™ License Agreement. A copy of Amendment No. 4 to the Development, Commercialization and Supply License Agreement between DURECT Corporation and Endo is filed hereto as Exhibit 10.42.5 in Part II, Item 6 of this Report. Endo will also reimburse DURECT for a portion of its prior development costs upon the achievement of certain milestones. Milestone payments made by Endo under the DURECT CHRONOGESIC License Agreement could total up to \$52.0 million. Endo and DURECT will share profits equally, based on projected financial performance of CHRONOGESIC. In addition, the DURECT CHRONOGESIC License Agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. The DURECT CHRONOGESIC License Agreement generally lasts until the underlying patents on the product expire. With respect to termination rights, the DURECT CHRONOGESIC License Agreement permits Endo to terminate its continued participation under a number of circumstances, one of which could require Endo to pay DURECT up to \$10.0 million.

*SkyePharma, Inc.*

In January 2007, following an assessment of the status of DepoDur®, we announced that we notified SkyePharma PLC of our intent to terminate our development and commercialization agreement for this product and, in February 2007, entered into a termination agreement with SkyePharma whereby the Development and Marketing Strategic Alliance Agreement terminated in its entirety on March 31, 2007. In order to provide for the continued commercial support of the DepoDur® product and the transition of such product to SkyePharma on March 31, 2007, Endo provided a number of services and undertook certain activities. Specifically, Endo employed commercially reasonable efforts to maintain and continue all U.S. commercial activities in support of DepoDur® through March 31, 2007, and supported and/or undertook the transition of certain Endo functions and activities (including third party activities) to SkyePharma that were useful and necessary for SkyePharma to assume commercial and related responsibilities for DepoDur® in the U.S. All such transition services and activities were completed by March 31, 2007.

*Orexo AB*

Our agreement with Orexo provides for us to make additional 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, \$17.7 million of which has been recorded through September 30, 2007 and included in research and development expense. Of this \$17.7 million expensed from the inception of the agreement through September 30, 2007, \$5.2 million has been recorded during each of the nine month periods ended September 30, 2007 and 2006. In November 2007, we announced that we have decided to conduct an interim statistical analysis of the Phase III placebo-controlled efficacy trial of this sublingual fentanyl tablet being studied for the treatment of breakthrough cancer pain.

*Vernalis Development Limited*

In July 2007, Vernalis and Endo entered into Amendment No. 3 (Amendment) to the License Agreement dated July 14, 2004. Under the Amendment, Vernalis granted to Endo, a sole and exclusive (even as against Vernalis) license to make, have made, use, commercialize and have commercialized the product Frova® (frovatriptan) in Canada, under the Canadian Trademark. In September 2007, the FDA issued to the Company and our development partner Vernalis, a not approvable letter pertaining to our supplemental New Drug Application (sNDA) for Frova® for the additional indication of short-term prevention of menstrual migraine.

**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, the impact of competitive products and pricing as well as charges incurred for compensation related to stock options and compensation paid by Endo Pharma LLC, impairment of intangible assets, and upfront, milestone and certain other payments made or accrued pursuant to licensing agreements. Further, a substantial portion of our net sales are through three 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.

**Table of Contents**

**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. Management and the Endo Board of Directors have recently completed a review of our strategic plan in concert with outside advisors. Based on this review and current market conditions in the pharmaceutical industry, we intend to continue to focus our business development activities on further diversifying our revenue base through product licensing and company acquisitions, as well as other opportunities to enhance shareholder value. Consistent with our goal of becoming the leading pain company, we are evaluating and pursuing opportunities to deepen and broaden our penetration of the pain market, as well as in other specialty-focused therapeutic categories that have the potential to provide diversification and growth. Toward this end, we are targeting products that are clinically innovative and differentiated, including earlier stage opportunities, while continuing to advance our current development pipeline. Endo's management team and our Board of Directors continue to examine the best use of the Company's strong balance sheet and cash position, including consideration of opportunities in the evolving pharmaceutical market place that strengthen the Company and enhance shareholder value. We will continue to drive our top line growth by maximizing the growth of Lidoderm® for post-herpetic neuralgia and continuing to accelerate both the Opana® franchise and Frova® for the acute treatment of migraine headaches in adults. We will also selectively pursue high barrier to entry opportunities to invest in our generic business.

**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.** The following table presents our expected cash requirements for contractual obligations for each of the following years subsequent to December 31, 2006 (in thousands):

Contractual Obligations	Total	Payment Due by Period					
		2007	2008	2009	2010	2011	Thereafter
Operating Lease Obligations	\$ 17,090	\$ 2,875	\$ 2,901	\$ 2,603	\$ 2,392	\$ 1,969	\$ 4,350
Capital Lease Obligations	1,991	1,479	489	23			
Minimum Purchase Commitments to Novartis	51,000	17,000	17,000	17,000			
Estimated Tax Sharing Payments Due to Endo Pharma LLC	38,693	38,693					
Minimum Royalty Obligation Due to Hind	2,500	500	500	500	500	500	
Minimum Purchase Commitments to Teikoku(1)	480,000	32,000	32,000	32,000	32,000	32,000	320,000
Limited Partnership Commitment(2)	7,300	7,300					
Milestone Payment(3)	15,000	15,000					
Other Commitments(4)	2,665	1,333	1,332				
<b>Total</b>	<b>\$ 616,239</b>	<b>\$ 116,180</b>	<b>\$ 54,222</b>	<b>\$ 52,126</b>	<b>\$ 34,892</b>	<b>\$ 34,469</b>	<b>\$ 324,350</b>

- (1) On April 24, 2007, our wholly owned subsidiary Endo Pharmaceuticals Inc. ( Endo ) and Teikoku Seiyaku Co., Ltd. / Teikoku Pharma USA, Inc. (collectively, Teikoku ) amended their Supply and Manufacturing Agreement dated as of November 23, 1998 by and between Endo and Teikoku, pursuant to which Teikoku manufactures and supplies Lidoderm® (lidocaine patch 5%) (the Product ) to Endo. This amendment is referred to as the Amended Agreement. Under the terms of the Amended Agreement, Endo has agreed to purchase a certain number of patches per year for each year in the remaining term of the Amended Agreement. Teikoku has agreed to fix the supply price of Lidoderm® for a specified period of time after which the price will be adjusted at future dates certain based on a price index defined in the Amended Agreement. Since future price changes are unknown, for purposes of this contractual obligations table, all amounts scheduled above represent the minimum patch quantities at the price currently existing under the Amended Agreement. We will update the Teikoku purchase commitments upon future price changes made in accordance with the Amended Agreement.
- (2) 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 of December 31, 2006, we have invested \$2.7 million in this partnership. During the nine months ended September 30, 2007, we invested an additional \$2.8 million in this partnership, bringing our cumulative cash investment to \$5.5 million as of September 30, 2007 leaving a commitment balance of \$4.5 million. We are accounting for this investment utilizing the equity method.
- (3) This amount represents the contingent milestone payment due to the former owners of RxKinetix upon commencement of Phase III clinical trials of EN 3285, a topical oral-rinse in development for the prevention or delay of severe oral mucositis (OM), painful mouth sores that often occur in cancer patients undergoing radiation and chemotherapeutic treatment. We expect to initiate the first of the Phase III clinical studies of EN 3285 in the fourth quarter of 2007.



**Table of Contents**

- (4) In June 2007, we agreed to provide approximately \$2.7 million in funding for certain tenant improvements to be made at a building currently under construction at the Company's corporate headquarters in Chadds Ford, Pennsylvania, which will be leased by the Company upon completion. The payments are to be made in two equal installments, the first of which was paid in July 2007 with the remainder to be paid upon completion of the building currently anticipated to be in the second half of 2008.

In addition, we have agreed to certain contingent payments in certain of our acquisition, license, collaboration and other agreements. Payments under these agreements generally become due and payable only upon the achievement of certain developmental, regulatory, commercial and/or other milestones. Due to the fact that it is uncertain if and when these milestones will be achieved, such contingencies have not been recorded in our consolidated balance sheet, except for the \$15.5 million estimated amount due seller related to our acquisition of RxKinetix, and, with the exception of the \$15 million milestone payment discussed above, are not reflected in the table above. In addition, under certain arrangements, we may have to make royalty payments based on a percentage of future sales of the products in the event regulatory approval for marketing is obtained. From a business perspective, we view these payments favorably as they signify that the products are moving successfully through the development phase toward commercialization.

As more fully described in Note 13 to the Condensed Consolidated Financial Statements, on January 1, 2007, we adopted FIN 48 and recorded a \$6.4 million non-current liability representing the Company's unrecognized tax benefits with respect to our uncertain tax positions. As of September 30, 2007, our non-current liability for unrecognized tax benefits amounted to \$10.8 million. Due to the nature and timing of the ultimate outcome of these uncertain tax positions, we can not make a reasonably reliable estimate of the amount and period of related future payments. Therefore, our FIN 48 liability has been excluded from the above contractual obligations table.

**Recent Accounting Pronouncements**

In July 2006, the Financial Accounting Standards Board ( FASB ) issued FASB Interpretation No. 48 ( FIN 48 ), *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109, Accounting for Income Taxes*. FIN 48 creates a single model to address uncertainty in tax positions. FIN 48 clarifies the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. In addition, FIN 48 clearly scopes out income taxes from SFAS No. 5, *Accounting for Contingencies*. FIN 48 is effective for fiscal years beginning after December 15, 2006. We have adopted FIN No. 48 as of January 1, 2007. The adoption resulted in a charge of \$2.7 million recorded directly to retained earnings as a cumulative effect of a change in accounting principle. See 13 for further discussion.

In September 2006, the FASB issued SFAS No.157, *Fair Value Measurements*, which addresses how companies should measure fair value when they are required to use a fair value measure for recognition or disclosure purposes under accounting principles generally accepted in the United States. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact of the adoption of this Statement on its financial statements.

In February 2007, the FASB issued SFAS No. 159 ( SFAS 159 ) *The Fair Value Option for Financial Assets and Financial Liabilities*, providing companies with an option to report selected financial assets and liabilities at fair value. This Standard's objective is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. Generally accepted accounting principles have required different measurement attributes for different assets and liabilities that can create artificial volatility in earnings. SFAS 159 helps to mitigate this type of accounting-induced volatility by enabling companies to report related assets and liabilities at fair value, which would likely reduce the need for companies to comply with detailed rules for hedge accounting. SFAS 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. This Standard requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of the Company's choice to use fair value on its earnings. It also requires entities to display the fair value of those assets and liabilities for which the Company has chosen to use fair value on the face of the balance sheet. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact of the adoption of this Statement on its financial statements.

In June 2007, the Emerging Issues Task Force (Task Force) of the FASB reached a consensus on Issue No. 07-3 ( EITF 07-3 ), *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*. Under EITF 07-3, nonrefundable advance payments for goods or services that will be used or rendered for research and development activities should be deferred and capitalized. Such payments should be recognized as an expense as the goods are delivered or the related services are performed, not when the advance payment is made. If a company does not expect the goods to be delivered or services

**Table of Contents**

to be rendered, the capitalized advance payment should be charged to expense. EITF 07-3 is effective for financial statements issued for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. Earlier application is not permitted. Companies are required to report the effects of applying EITF 07-3 prospectively for new contracts entered into on or after the effective date. The Company is currently evaluating the impact of the adoption of EITF 07-3 on its consolidated financial statements.

In September 2007, the Emerging Issues Task Force (Task Force) of the FASB reached a consensus on Issue No. 07-1 ( EITF 07-1 ), *Accounting for Collaborative Arrangements*. The scope of EITF 07-1 is limited to collaborative arrangements where no separate legal entity exists and in which the parties are active participants and are exposed to significant risks and rewards that depend on the success of the activity. The Task Force concluded that revenue transactions with third parties and associated costs incurred should be reported in the appropriate line item in each company's financial statements pursuant to the guidance in EITF 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*. The Task Force also concluded that the equity method of accounting under Accounting Principles Board Opinion 18, *The Equity Method of Accounting for Investments in Common Stock*, should not be applied to arrangements that are not conducted through a separate legal entity. The Task Force also concluded that the income statement classification of payments made between the parties in an arrangement should be based on a consideration of the following factors: the nature and terms of the arrangement; the nature of the entities' operations; and whether the partners' payments are within the scope of existing GAAP. To the extent such costs are not within the scope of other authoritative accounting literature, the income statement characterization for the payments should be based on an analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. The provisions of EITF 07-1 are effective for fiscal years beginning on or after December 15, 2007, and companies will be required to apply the provisions through retrospective application. The Company is currently evaluating the impact of the adoption of EITF 07-1 on its consolidated financial statements.

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

For quantitative and qualitative disclosures about market risk, see Item 7A, *Quantitative and Qualitative Disclosures about Market Risk*, of our annual report on Form 10-K for the year ended December 31, 2006. Other than as disclosed below, our exposures to market risk have not changed materially since December 31, 2006.

*Interest Rate Risk*

Our exposure to interest rate risk relates primarily to our money market funds and current marketable securities portfolio. Our current marketable securities classified as *available for sale* consist principally of auction rate securities, variable rate demand obligations and open-end mutual funds that invest in U.S. government securities. Our non-current marketable securities subject to interest rate risk consist of a municipal bond holding. Our investments in marketable securities are governed by our investment policy, which has been approved by our Board of Directors. Our investment policy seeks to preserve the value of capital, consistent with maximizing return on the Company's investment, while maintaining adequate liquidity. To achieve this objective, we maintain our portfolio in a variety of high credit quality debt securities. With the exception of our municipal bond holding, all debt securities in our portfolio mature in less than three months, or are subject to an interest-rate reset date that occurs within that time period. The carrying value of these debt securities approximates their market value at September 30, 2007 and their value at maturity. Our interest rate risk with respect to these investments is limited due to the short-term duration of these arrangements and the yields earned, which approximate current interest rates.

**Item 4. Controls and Procedures.***Disclosure 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 were effective for timely gathering, analyzing and disclosing the information we are required to disclose in our reports filed with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended.

*Internal Control Over Financial Reporting*

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 third quarter of 2007 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.





**Table of Contents**

**PART II**

**OTHER INFORMATION**

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

The disclosures under Note 11. Commitments and Contingencies-Legal Proceedings included in Part 1 of this report is incorporated in this Part II, Item 1 by reference.

**Item 1A. *Risk Factors***

There has been no material change in our risk factors as previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2006 in response to Item 1A. to Part 1 of such Form 10-K.

**Item 2. *Unregistered Sale of Equity 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.***

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

**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/ PETER A. LANKAU

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

Name: Peter A. Lankau  
Title: *President and Chief Executive Officer*

/s/ CHARLES A. ROWLAND, JR.  
Name: Charles A. Rowland, Jr.  
Title: *Executive Vice President, Chief Financial Officer  
and Treasurer*

Date: November 1, 2007

**Table of Contents**

**Exhibit Index**

<b>Exhibit No.</b>	<b>Title</b>
3.1	Amended and Restated Certificate of Incorporation of Endo Pharmaceuticals Holdings Inc. ( Endo ) (incorporated herein by reference to Exhibit 3.1 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
3.2	Amended and Restated By-laws of Endo (incorporated herein by reference to Exhibit 3.2 of the Form 10-Q for the Quarter ended March 31, 2003 filed with the Commission on May 14, 2003)
4.1	Amended and Restated Executive Stockholders Agreement, dated as of July 7, 2003, by and among Endo, Endo Pharma LLC ( Endo LLC ), Kelso Investment Associates V, L.P. ( KIA V ), Kelso Equity Partners V, L.P. ( KEP V ) and the Management Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.1 of the Form 10-Q for the Quarter ended June 30, 2003 filed with the Commission on August 14, 2003)
4.1.2	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) (incorporated herein by reference to Exhibit 4.1 of the Form 10-Q for the Quarter ended September 30, 2004 filed with the Commission on November 5, 2004) the Commission on July 1, 2003)
4.1.3	Amendment 2 to the Amended and Restated Stockholders Agreement, dated September 20, 2005, by and among the Company, Endo LLC, Kelso and certain Amending Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.1.3 of the Current Report on Form 8-K filed with the Commission on September 22, 2005)
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, KEPV and the Management Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.1 of the Form 10-Q for the Quarter ended September 30, 2004 filed with the Commission on November 5, 2004)
4.2.3	Amendment 2 to the Amended and Restated Employee Stockholders Agreement, dated September 20, 2005, by and among the Company, Endo LLC, Kelso and certain Amending Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.2.3 of the Current Report on Form 8-K filed with the Commission on September 22, 2005)
4.3	Employee Stockholders Consent and Release, effective September 20, 2005, by and among the Company, Endo LLC, Kelso and certain Employee Stockholders (as defined therein) signatory thereto (incorporated herein by reference to Exhibit 4.3 of the Current Report on Form 8-K filed with the Commission on September 22, 2005)
4.4	Registration Rights Agreement, dated as of July 17, 2000, by and between Endo and Endo LLC (incorporated herein by reference to Exhibit 4.4 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
4.5	Amendment to Registration Rights Agreement, dated as of June 30, 2003, by and between Endo and Endo LLC (incorporated herein by reference to Exhibit 10.1 of Amendment No. 2 to the Form S-3 Registration Statement (Registration No. 333-105338) filed with the Commission on July 1, 2003)
10.1	Shelf Registration Agreement, dated September 21, 2005, by and between Endo, Endo LLC and certain Management Stockholders (as defined therein) (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the Commission on September 22, 2005)
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)

**Table of Contents**

<b>Exhibit No.</b>	<b>Title</b>
10.4	[Intentionally Omitted.]
10.5	[Intentionally Omitted.]
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	[Intentionally Omitted]
10.8	[Intentionally Omitted]
10.9	[Intentionally Omitted]
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)
10.14.1	First Amendment, dated April 24, 2007, to the Supply and Manufacturing Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals Inc. and Teikoku Seiyaku Co., Ltd. / Teikoku Pharma USA, Inc. (incorporated herein by reference to Exhibit 10.14.1 of the Current Report on Form 8-K dated April 30, 2007)
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)
10.16.1	First Amendment, effective July 1, 2000, to the 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 10.16.1 of the Current Report on Form 8-K dated April 14, 2006)
10.16.2	Second Amendment, dated April 10, 2006, to the 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 10.16.2 of the Current Report on Form 8-K dated April 14, 2006)
10.17	[Intentionally Omitted.]
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)
10.18.1	Amendment, dated January 7, 2007, to the Amended and Restated Strategic Alliance Agreement, dated as of April 2, 2002, by and between Endo Pharmaceuticals Inc. and Penwest Pharmaceuticals Company (incorporated herein by reference to Exhibit 10.18.1 of the Current report on Form 8-K dated January 11, 2007)
10.19	Agreement, dated as of February 1, 2000, by and between Endo Pharmaceuticals and UPS Supply Chain Solutions, 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)



**Table of Contents**

10.21	Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.21 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.22	Endo LLC Amended and Restated 1997 Employee Stock Option Plan (incorporated herein by reference to Exhibit 10.22 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.23	Endo LLC Amended and Restated 1997 Executive Stock Option Plan (incorporated herein by reference to Exhibit 10.23 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.24	Endo LLC 2000 Amended and Restated Supplemental Employee Stock Option Plan (incorporated herein by reference to Exhibit 10.24 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.25	Endo LLC 2000 Amended and Restated Supplemental Executive Stock Option Plan (incorporated herein by reference to Exhibit 10.25 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.26	Amended and Restated Employment Agreement, dated as of December 31, 2006, by and between the Company and Charles A. Rowland, Jr. (incorporated herein by reference to Exhibit 10.26 of the Current Report on Form 8-K dated January 5, 2007)
10.27	Amended and Restated Employment Agreement, dated as of December 31, 2006, by and between the Company and Joyce N. LaViscount (incorporated herein by reference to Exhibit 10.27 of the Current Report on Form 8-K dated January 5, 2007)
10.28	Employment Agreement, dated as of September 6, 2007, by and between the Company and Nancy J. Wysenski (incorporated herein by reference to Exhibit 10.28 of the Current Report on Form 8-K dated September 11, 2007)
10.29	Amended and Restated Employment Agreement, dated as of December 31, 2006, by and between the Company and David A. H. Lee (incorporated herein by reference to Exhibit 10.29 of the Current Report on Form 8-K dated January 5, 2007)
10.30	[Intentionally Omitted.]
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)
10.34.1	Amendment to Lease Agreement, dated as of November 6, 2006, by and between Endo Pharmaceuticals and Painters Crossing One Associates, L.P. (incorporated herein by reference to Exhibit 10.34.1 of the Form 10-Q for the quarter ended September 30, 2006 filed with the Commission on November 9, 2006)
10.35	Amended and Restated Employment Agreement, dated as of December 31, 2006, by and between the Company and Caroline B. Manogue (incorporated herein by reference to Exhibit 10.35 of the Current Report on Form 8-K dated January 5, 2007)
10.36	Amended and Restated Employment Agreement, dated as of December 31, 2006, by and between the Company and Peter A. Lankau (incorporated herein by reference to Exhibit 10.36 of the Current Report on Form 8-K dated January 5, 2007)
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.]
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)

**Table of Contents**

- 10.39.1 First Amendment, effective February 1, 2003, to the Master Development and Toll Manufacturing Agreement between Endo Pharmaceuticals and Novartis Consumer Health, Inc. (incorporated herein by reference to Exhibit 10.39.1 of the Form 10-Q for the Quarter Ended June 30, 2005 filed with the Commission on August 8, 2005)
- 10.39.2 Second Amendment, effective as of December 1, 2004, to the Master Development and Toll Manufacturing Agreement between Endo Pharmaceuticals and Novartis Consumer Health, Inc. (incorporated herein by reference to Exhibit 10.39.2 of the Form 10-Q for the Quarter Ended June 30, 2005 filed with the Commission on August 8, 2005)
- 10.40 Lease Agreement between Painters Crossing Three Associates, L.P. and Endo Pharmaceuticals Inc. dated January 19, 2007 (incorporated herein by reference to Exhibit 10.40 of the Annual Report on Form 10-K for the Year Ended December 31, 2006 filed with the Commission on March 1, 2007)
- 10.41 Policy of Endo Pharmaceuticals Holdings Inc. Relating to Insider Trading in Company Securities and Confidentiality of Information (incorporated herein by reference to Exhibit 10.41 of the Form 10-Q for the Quarter ended March 31, 2005 filed with the Commission on May 10, 2005)
- 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)
- 10.42.3 Amendment No. 2 to the Development, Commercialization and Supply License Agreement, dated November 22, 2004, between DURECT Corporation and Endo Pharmaceuticals Inc. (incorporated herein by reference to Exhibit 10.42.3 of the Current Report on Form 8-K dated November 29, 2004)
- 10.42.4 Amendment No. 3 to the Development, Commercialization and Supply License Agreement, dated January 20, 2006, between DURECT Corporation and Endo Pharmaceuticals Inc. (incorporated herein by reference to Exhibit 10.42.4 of the Current Report on Form 8-K dated January 25, 2006)
- 10.42.5 Amendment No. 4 to the Development, Commercialization and Supply License Agreement, dated April 30, 2007, between DURECT Corporation and Endo Pharmaceuticals Inc. (incorporated herein by reference to Exhibit 10.42.5 of the Form 10-Q for the Quarter Ended March 31, 2007 filed with the Commission on May 10, 2007)
- 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)
- 10.43.1 Agreement to Terminate the Development and Marketing Strategic Alliance Agreement between Endo Pharmaceuticals Inc., SkyePharma, Inc., and Jagotec AG, assignee of SkyePharma Canada, Inc., effective February 12, 2007 (incorporated herein by reference to Exhibit 10.43.1 of the Current Report on Form 8-K dated January 16, 2007)
- 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)
- 10.45.1 Amendment to Lease Agreement, dated as of February 16, 2005, by and between Endo Pharmaceuticals and Painters Crossing Two Associates, L.P. (incorporated herein by reference to Exhibit 10.45.1 of the Current Report on Form 8-K dated February 18, 2005)



**Table of Contents**

10.45.2	Amendment to Lease Agreement, dated as of November 6, 2006, by and between Endo Pharmaceuticals and Painters Crossing Two Associates, L.P. (incorporated herein by reference to Exhibit 10.34.1 of the Form 10-Q for the quarter ended September 30, 2006 filed with the Commission on November 9, 2006)
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)
10.46.1	Termination Agreement, dated as of February 24, 2006, by and between Noven Pharmaceuticals, Inc. and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.46.1 of the Annual Report on Form 10-K for the Year Ended December 31, 2005 filed with the Commission on March 8, 2006)
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)
10.48.1	Co-Promotion Agreement, dated as of July 1, 2005, by and between Endo Pharmaceuticals Inc. and Vernalis Development Limited (incorporated by reference to Exhibit 10.48.1 of the Current Report on Form 8-K dated July 8, 2005)
10.48.2	Second Amendment, dated as of December 12, 2005, to the License Agreement by and between Endo Pharmaceuticals Inc. and Vernalis Development Limited (incorporated by reference to Exhibit 10.48.2 of the Current Report on Form 8-K dated December 29, 2005)
10.48.3	First Amendment, dated as of December 12, 2005, to the Co-Promotion Agreement by and between Endo Pharmaceuticals Inc. and Vernalis Development Limited (incorporated by reference to Exhibit 10.48.3 of the Current Report on Form 8-K dated December 29, 2005)
10.48.4	Third Amendment, dated as of July 23, 2007, to the License Agreement by and between Endo Pharmaceuticals Inc. and Vernalis Development Limited (incorporated by reference to Exhibit 10.48.4 of the Current Report on Form 8-K dated July 27, 2007)
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 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	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002