

ENDO PHARMACEUTICALS HOLDINGS INC

Form 10-Q

October 30, 2008

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, 2008.

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)

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

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

**13-4022871**  
(I.R.S. Employer

Identification Number)

**100 Endo Boulevard**

**Chadds Ford, Pennsylvania 19317**

(Address of Principal Executive Offices)

**(610) 558-9800**

(Registrant's Telephone Number, Including Area Code)

**Not applicable**

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check 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 27, 2008: 134,240,337

**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>	
Item 1.	<u>Financial Statements</u>	5
	<u>Condensed Consolidated Balance Sheets (Unaudited) September 30, 2008 and December 31, 2007</u>	5
	<u>Condensed Consolidated Statements of Operations (Unaudited) Three and Nine Months Ended September 30, 2008 and 2007</u>	6
	<u>Condensed Consolidated Statements of Cash Flows (Unaudited) Nine Months Ended September 30, 2008 and 2007</u>	7
	<u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>	8
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	33
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	64
Item 4.	<u>Controls and Procedures</u>	64
	<b><u>PART II. OTHER INFORMATION</u></b>	
Item 1.	<u>Legal Proceedings</u>	65
Item 1A.	<u>Risk Factors</u>	65
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	65
Item 3.	<u>Defaults Upon Senior Securities</u>	65
Item 4.	<u>Submission of Matters to a Vote of Security Holders</u>	66
Item 5.	<u>Other Information</u>	66
Item 6.	<u>Exhibits</u>	66
	<b><u>SIGNATURES</u></b>	67

**Table of Contents**

**FORWARD LOOKING STATEMENTS**

Statements contained or incorporated by reference in this Quarterly Report on Form 10-Q contain information that includes or is based on forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of 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, in our Annual Report on Form 10-K for the year ended December 31, 2007, filed with the Securities and Exchange Commission on February 26, 2008, 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 believe that 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 under the caption Risk Factors in Item 1A of Amendment No. 1 on Form 10-K/A for the year ended December 31, 2007, filed with the Securities and Exchange Commission on April 29, 2008, and as otherwise enumerated herein or therein, could affect our future financial results and could cause our actual results to differ materially from those expressed in forward-looking statements contained in Amendment No. 1 on Form 10-K/A. Important factors that could cause our actual results to differ materially from the expectations reflected in the forward-looking statements in Amendment No. 1 on Form 10-K/A include those factors described herein under the caption Risk Factors and in documents incorporated herein by reference, 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;

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

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

our ability to protect our proprietary technology;

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 third parties or 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;

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;

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

**Table of Contents**

our exposure to securities that are subject to market risk including auction-rate securities that are currently illiquid due to an inactive auction-rate market; and

the holders of our 1.75% Convertible Senior Subordinated Notes due April 15, 2015 (the *Convertible Notes* ) could require us to repurchase the principal amount of the notes for cash before maturity of the notes upon the occurrence of a *Fundamental Change*, as defined in the indenture relating to the *Convertible Notes*. Such a repurchase could require significant amounts of cash and could adversely affect our financial condition.

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, 10-K/A 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 and per share data)

	September 30, 2008	December 31, 2007
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 632,959	\$ 350,325
Marketable securities	26,511	313,386
Accounts receivable, net	253,087	249,784
Inventories	91,628	69,228
Prepaid expenses and other current assets	16,502	26,539
Deferred income taxes	69,634	56,185
<b>Total current assets</b>	<b>1,090,321</b>	<b>1,065,447</b>
MARKETABLE SECURITIES	254,757	283,339
PROPERTY AND EQUIPMENT, Net	43,169	44,920
GOODWILL	181,079	181,079
OTHER INTANGIBLES, Net	215,738	70,949
NOTE RECEIVABLE		45,971
DEFERRED INCOME TAXES	41,235	4,211
OTHER ASSETS	27,672	6,722
<b>TOTAL ASSETS</b>	<b>\$ 1,853,971</b>	<b>\$ 1,702,638</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 135,470	\$ 178,869
Accrued expenses	226,056	185,264
Due to Endo Pharma LLC	329	685
Estimated amount due seller, current portion		15,000
Income taxes payable	29,318	17,140
<b>Total current liabilities</b>	<b>391,173</b>	<b>396,958</b>
CONVERTIBLE SENIOR SUBORDINATED NOTES DUE 2015	371,358	
OTHER LIABILITIES	55,571	13,390
COMMITMENTS AND CONTINGENCIES (NOTE 12)		
<b>STOCKHOLDERS' EQUITY:</b>		
Preferred stock, \$0.01 par value; 40,000,000 shares authorized; none issued		
Common stock, \$0.01 par value; 350,000,000 shares authorized; 134,244,634 and 134,144,993 shares issued; 117,076,831 and 134,144,993 outstanding at September 30, 2008 and December 31, 2007, respectively	1,342	1,341
Additional paid-in capital	703,097	704,305

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

Retained earnings	770,418	583,619
Accumulated other comprehensive (loss) income	(25,278)	3,025
Treasury stock, 17,167,803 and 0 shares at September 30, 2008 and December 31, 2007, respectively	(413,710)	
Total stockholders' equity	1,035,869	1,292,290
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 1,853,971</b>	<b>\$ 1,702,638</b>

See Notes to Condensed Consolidated Financial Statements.



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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
NET SALES	\$ 316,768	\$ 269,470	\$ 913,200	\$ 781,026
COSTS AND EXPENSES:				
Costs of sales	71,027	51,009	190,554	155,324
Selling, general and administrative	116,249	109,833	357,775	292,419
Research and development	22,165	28,290	82,244	83,663
Impairment of other intangible assets			8,083	
<b>OPERATING INCOME</b>	<b>107,327</b>	<b>80,338</b>	<b>274,544</b>	<b>249,620</b>
INTEREST EXPENSE	2,830	43	5,549	90
INTEREST AND OTHER INCOME	(5,017)	(9,776)	(21,295)	(25,105)
INCOME BEFORE INCOME TAX	109,514	90,071	290,290	274,635
INCOME TAX	41,268	30,924	103,491	97,793
NET INCOME	\$ 68,246	\$ 59,147	\$ 186,799	\$ 176,842
NET INCOME PER SHARE:				
Basic	\$ 0.57	\$ 0.44	\$ 1.49	\$ 1.32
Diluted	\$ 0.57	\$ 0.44	\$ 1.48	\$ 1.31
WEIGHTED AVERAGE SHARES:				
Basic	119,439	133,915	125,498	133,835
Diluted	119,954	134,611	126,012	134,491

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 September 30,</b>	
	<b>2008</b>	<b>2007</b>
<b>OPERATING ACTIVITIES:</b>		
Net income	\$ 186,799	\$ 176,842
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	32,367	12,996
Stock-based compensation	13,713	10,940
Interest earned on available-for-sale securities	(3,069)	(3,477)
Amortization of debt issuance costs and premium/discount	1,545	(930)
Deferred income taxes	(9,020)	13,527
Impairment of long-lived assets	12,680	
Loss (gain) on disposal of property and equipment	73	(326)
Changes in assets and liabilities which provided (used) cash:		
Accounts receivable	(3,303)	64,907
Inventories	(22,400)	(12,380)
Note receivable	(489)	(254)
Prepaid and other assets	6,990	5,878
Accounts payable	(39,283)	24,508
Accrued expenses	43,210	(4,577)
Other liabilities	(3,882)	2,626
Income taxes payable	12,178	(2,849)
Net cash provided by operating activities	228,109	287,431
<b>INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	(16,474)	(15,905)
Purchase of available-for-sale securities	(134,211)	(676,091)
Sales of available-for-sale securities	420,811	62,951
Proceeds from the sale of property and equipment	27	125
Principal payments on note receivable	3,333	
Acquisition of license rights	(85,000)	
Acquisition, net of cash acquired	(15,000)	
Distribution from equity method investee		1,096
Other investments	(20,000)	(2,800)
Net cash provided by (used in) investing activities	153,486	(630,624)
<b>FINANCING ACTIVITIES:</b>		
Capital lease obligations repayments	(565)	(766)
Tax sharing payments to Endo Pharma LLC	(343)	(20,000)
Tax benefits of stock options exercised	156	3,661
Exercise of Endo Pharmaceuticals Holdings Inc. Stock Options	1,225	7,097
Net proceeds from issuance of convertible senior subordinated notes due 2015	371,512	
Purchase of hedge on convertible senior subordinated notes due 2015	(107,607)	
Sale of common stock warrants	50,371	
Purchase of common stock	(413,710)	

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

Net cash used in financing activities	(98,961)	(10,008)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	282,634	(353,201)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	350,325	628,085
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 632,959	\$ 274,884
SUPPLEMENTAL INFORMATION:		
Interest paid	\$ 44	\$ 90
Income taxes paid	\$ 104,044	\$ 80,961
SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES		
Purchase of property and equipment financed by capital leases	\$ 425	\$ 73
Accrual for purchases of property and equipment	\$ 527	\$ 4,643
Settlement of note receivable	\$ (46,667)	\$
Acquisition of license rights	\$ 90,657	\$

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, 2008**

**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 financial 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, our, us 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, 2008 and the results of our operations and our cash flows for the periods presented. Operating results for the three months and nine months ended September 30, 2008 are not necessarily indicative of the results that may be expected for the year ending December 31, 2008.

The accompanying condensed consolidated balance sheet as of December 31, 2007 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 (GAAP) 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, 2007 contained in the Company's Annual Report on Form 10-K. Certain prior period amounts have been reclassified to conform to the current period presentation. For the three and nine months ended September 30, 2007, our costs of sales did not include amortization expense of intangible assets related to commercial products. However, we have reclassified the amortization expense of these intangible assets to costs of sales in our Consolidated Statement of Operations for the three and nine months ended September 30, 2007. Amortization expense for intangible assets related to products under development has been reclassified to research and development expense for the three and nine months ended September 30, 2007. As a result of the removal of a separate line item for depreciation and amortization, depreciation expense for the three and nine months ended September 30, 2007 has been reclassified to research and development expense or selling, general and administrative expense in our Consolidated Statement of Operations based upon usage of the underlying assets.

**2. RECENT ACCOUNTING PRONOUNCEMENTS**

In September 2006, the Financial Accounting Standards Board (FASB) issued SFAS No. 157, *Fair Value Measurements* (SFAS 157), 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. In February 2008, the FASB issued FASB Staff Position No. 157-2, *Effective Date of FASB Statement No. 157* (FSP 157-2). FSP 157-2 delays the effective date of SFAS 157 for certain non-financial assets and non-financial liabilities to fiscal years beginning after November 15, 2008. SFAS 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined under SFAS 157 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value under SFAS 157 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company has adopted SFAS 157 for financial assets and liabilities. The initial adoption of SFAS 157 did not have a material impact on the Company's consolidated results of operations and financial condition.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* ( SFAS 159 ), 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

**Table of Contents**

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. Upon adoption, we chose not to elect the fair value option for our then existing financial assets and liabilities. Therefore, adoption of SFAS 159 did not have any impact on our consolidated financial statements. We have not elected the fair value option for any financial asset or liability acquired or incurred subsequent to the adoption date.

In June 2007, the Emerging Issues Task Force ( EITF or Task Force ) of the FASB reached a consensus on Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ( EITF 07-3 ). 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 to be rendered, the capitalized advance payment should be charged to expense. EITF 07-3 is effective for new contracts entered into in fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. Earlier application is not permitted. We have adopted EITF 07-3 as of January 1, 2008. The adoption of EITF 07-3 did not have a material effect on the Company's consolidated results of operations or financial condition.

In November 2007, the EITF of the FASB issued a consensus on Issue No. 07-1, *Accounting for Collaborative Arrangements* ( EITF 07-1 ). 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, 2008, and companies will be required to apply the provisions through retrospective application to all collaborative arrangements existing at adoption as a change in accounting principle. If it is impracticable to apply the consensus to a specific arrangement, disclosure is required regarding the reason why retrospective application is not practicable and the effect of reclassification on the current period. The Company is currently evaluating the impact of the adoption of EITF 07-1 on its consolidated financial statements.

In December 2007, the FASB issued SFAS 141(R), *Business Combinations* ( SFAS 141(R) ) and SFAS 160, *Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51* ( SFAS 160 ). SFAS 141(R) will change how business acquisitions are accounted for and will impact financial statements both on the acquisition date and in subsequent periods. SFAS 160 will change the accounting and reporting for minority interests, which will be recharacterized as noncontrolling interests and classified as a component of equity. SFAS 141(R) and SFAS 160 are required to be adopted concurrently and are effective for fiscal years, beginning on or after December 15, 2008. Earlier adoption is prohibited.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, ( SFAS 162 ). SFAS 162 sets forth the sources of accounting principles and the framework, or hierarchy, for selecting principles to be used in financial statement preparation. Prior to the issuance of SFAS 162, the GAAP hierarchy was defined in the American Institute of Certified Public Accountants Statement on Auditing Standards No. 69, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. SFAS 162 will be effective following SEC approval. The FASB does not expect the issuance of SFAS 162 to result in a change in current practice.

In May 2008, the FASB issued FASB Staff Position APB 14-1, *Accounting for Convertible Debt Instruments That May be Settled in Cash upon Conversion (Including Partial Cash Settlement)* ( FSP APB 14-1 ). FSP APB 14-1 requires that issuers of convertible debt instruments that may be settled in cash or other assets on conversion to separately account for the liability and equity components of the instrument in a manner that will reflect the entity's nonconvertible debt borrowing rate on the instrument's issuance date when interest cost is recognized in subsequent periods. Our Convertible Notes are within the scope of FSP APB 14-1. Therefore, we will be required to separate the debt portion of our Convertible Notes from the equity portion at their fair value retrospective to the date of issuance and amortize the resulting discount into interest expense over the life of the debt. However, there will be no effect on our cash interest payments. FSP APB 14-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and will be applied retrospectively to all periods presented. The Company is currently evaluating the impact of adopting this pronouncement, however we expect there to be a dilutive effect on our earnings per share.



---

**Table of Contents**

In October 2008, the FASB issued FASB Staff Position SFAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active* ( FSP SFAS 157-3 ). FSP SFAS 157-3 clarifies the application of SFAS 157 when determining the fair value of a financial asset when the market for that asset is not currently active. FSP SFAS 157-3 emphasizes that approaches other than the market approach to determining fair value may be appropriate when it is determined that, as a result of market inactivity, other valuation approaches are more representative of fair value. Other valuation approaches can involve significant assumptions regarding future cash flows. FSP SFAS 157-3 clarifies that these assumptions must incorporate adjustments for nonperformance and liquidity risks that market participants would consider in valuing the asset in an inactive market. FSP SFAS 157-3 emphasizes the existing disclosure requirements under SFAS 157 regarding significant unobservable inputs (Level 3 inputs). FSP SFAS 157-3 became effective on October 10, 2008, including with respect to prior periods for which financial statements have not been issued. The Company has adopted FSP SFAS 157-3 for the quarterly period ended September 30, 2008. See Note 3 for a further discussion of fair value.

**NOTE 3. FAIR VALUE**

We have adopted the provisions of SFAS 157 as of January 1, 2008, for financial assets and liabilities. Although the adoption of SFAS 157 did not materially impact our financial condition, results of operations, or cash flows, we are now required to provide additional disclosures as part of our financial statements.

SFAS 157 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

As of September 30, 2008, the Company holds certain assets that are required to be measured at fair value on a recurring basis, including money market funds and available-for-sale securities. The Company's available-for-sale securities include auction-rate securities which consist of municipal bonds with an auction reset feature, the underlying assets of which are student loans that are backed substantially by the federal government and have underlying credit ratings of AA or better. Further, the issuers have been making interest payments promptly. We do not own any collateralized debt obligations or other types of mortgage-backed securities that have recently traded at significant discounts to their par amount.

Auction-rate securities 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.). In an active market, auction-rate securities are bought and sold at each reset date through a competitive bidding process, often referred to as a "Dutch auction". Auctions are successful when the supply and demand of securities are in balance. Financial institutions brokering the auctions would also participate in the auctions to balance the supply and demand. Beginning in the second half of 2007, auctions began to fail for specific securities and in mid-February 2008 auction failures became common, prompting market participants, including financial institutions, to cease or limit their exposure to the auction-rate market. Given the current negative liquidity conditions in the global credit markets, the auction-rate securities market has become inactive. Consequently, our auction-rate securities are currently illiquid through the normal auction process. As a result of the inactivity in the market, quoted market prices and other observable data are not available or their utility is limited. Prior to February 2008, the Company was able to determine the fair value of the auction-rate securities using a market approach valuation technique based on successful auctions of our securities or based on quoted prices in active markets for identical auction-rate securities without any adjustment (Level 1 of the fair value hierarchy).

Since mid-February 2008, the market for auction-rate securities has seen a dramatic decrease in the volume of trades relative to historical levels. At September 30, 2008, (the measurement date), the Company determined that the market for its auction-rate securities was inactive. That determination was made considering that there are very few observable transactions for the auction-rate securities or similar securities, the prices for transactions that have occurred are not current, and the observable prices for those transactions to the extent they exist vary substantially either over time or among market makers, thus reducing the potential usefulness of those observations. In addition, the current lack of liquidity prevents the Company from comparing our securities directly to securities with quoted market prices. Consequently, while we have appropriately considered those observable inputs, ultimately, our auction-rate securities will be classified within Level 3 of the fair value hierarchy described in Note 2 because significant judgments are required to determine fair value at the measurement date.

The Company has determined that an income approach (present value technique) that maximizes the use of observable market inputs is the preferred approach to measuring the fair value of our securities. Specifically, the Company used the discount rate adjustment technique described in Appendix B of Statement 157 to determine an indication of fair value.





---

**Table of Contents**

To calculate a price for our auction-rate securities, the Company calculates times to maturity, coupon rates, market required rates of return (discount rate) and a discount for lack of liquidity in the following manner:

The Company identifies the times to maturity of the auction-rate securities as the time at which principal is available to the investor. This can occur because the auction-rate security is paying a coupon that is above the required rate of return, and the Company treats the security as being called. It can also occur because the market has returned to normal and the Company treats the auctions as having recommenced. Lastly, and most frequently, the Company treats the principal as being returned as prepayment occurs and at the maturity of the security. The weighted average life used for each security representing time to maturity ranges from 5 to 8 years. The weighted average life measured across the entire auction-rate portfolio is approximately eight (8) years.

The Company calculates coupon rates based on estimated relationships between the maximum coupon rate (the coupon rate in event of a failure) and market interest rates. The representative coupon rates on September 30, 2008 ranged from 5.68% to 5.79%. The Company calculates appropriate discount rates for securities that include base interest rates, index spreads over the base rate, and security-specific spreads. These spreads include the possibility of changes in credit risk over time. At September 30, 2008, the spreads over the base rate for our securities applied to our securities ranged from 215 basis points to 448 basis points.

The Company believes that a market participant would require an adjustment to the required rate of return to adjust for the lack of liquidity. We believe it is not unreasonable to assume a 150 basis points adjustment to the required rate of return and a term of either three, four or five years to adjust for this lack of liquidity. The increase in the required rate of return decreases the prices of the securities. However, the assumption of a three, four or five-year term shortens the times to maturity and increases the prices of the securities. The Company has evaluated the impact of applying each term and the reasonableness of the range indicated by the results. The Company chose to use a four-year term to adjust for the lack of liquidity as we believe it is the point within the range that is most representative of fair value. The Company's conclusion is based in part on the fact that the fair values indicated by the results are reasonable in relation to each other given the nature of the securities and current market conditions.

At September 30, 2008, the fair value of our auction-rate securities, as determined by applying the above described discount rate adjustment technique, was approximately \$257.5 million, representing a 9.7%, or \$27.7 million discount from their original purchase price or par value. We believe we have appropriately reflected our best estimate of the assumptions that market participants would use in pricing the assets in a current transaction to sell the asset at the measurement date. Accordingly, the carrying value of our auction-rate securities were reduced by approximately \$27.7 million at September 30, 2008, reflecting the change in fair value, which the Company attributes to liquidity issues rather than credit issues. The Company assessed this decline in value to be temporary due to, the financial condition and near-term prospects of the underlying issuers, our intent and ability to retain our investment in the issuers for a period of time sufficient to allow for any anticipated recovery in market value and based on the extent to which fair value is less than par. Accordingly, we recorded a pre-tax \$27.7 million reduction in shareholders' equity in accumulated other comprehensive loss. The Company's carrying value of auction-rate securities at December 31, 2007 was at par value, which approximated fair value at that time. These securities are analyzed each reporting period for other-than-temporary impairment factors. Any future fluctuation in fair value related to these instruments that the Company judges to be temporary, including any recoveries of previous write-downs, would be recorded to accumulated other comprehensive income. If the Company determines that any future valuation adjustment was other-than-temporary, it would record a charge to earnings as appropriate.

In October 2008, UBS AG (UBS) made an offer (the Offer) of Auction Rate Securities Rights (the Rights) to the Company and other clients of UBS Securities LLC and UBS Financial Services Inc. (collectively, the UBS Entities), pursuant to which the Company is entitled to sell to UBS all auction-rate securities held by the Company as of February 13, 2008 in a UBS account (the Eligible Auction Rate Securities). The Rights permit the Company to require UBS to purchase the Eligible Auction Rate Securities for a price equal to original par value plus any accrued but unpaid dividends or interest beginning on June 30, 2010 and ending on July 2, 2012 (the Expiration Date). As of September 30, 2008, we had Eligible Auction Rate Securities with original par value of \$266.4 million, representing 93% of our total auction-rate securities portfolio at par. The remaining seven percent (7%), or \$18.8 million, of our auction-rate securities portfolio are not held in a UBS account and therefore are not subject to the Offer.

The Offer is being made pursuant to agreements in principle entered into by the UBS Entities with the Securities and Exchange Commission, the New York Attorney General, the Texas State Securities Board and other state regulatory agencies represented by North American Securities Administrators Association, and a settlement agreement with the Massachusetts Securities Division to settle investigations brought by each of these agencies against the UBS Entities relating to the sale and marketing of auction rate securities. The alleged conduct underlying these investigations suggested that the UBS Entities marketed auction rate securities as cash alternatives but failed to adequately disclose liquidity

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

risk. We may elect to accept the Offer any time prior to 5:00 p.m., New York City time, on November 14, 2008 (unless extended by UBS). In order to accept the Offer, we will be required to complete an acceptance form which releases UBS and its employees and agents from all claims except claims for consequential damages directly or indirectly relating to UBS's marketing and sale of auction rate securities.

**Table of Contents**

If the Company accepts the Offer, the Company would grant to the UBS Entities the sole discretion and right to sell or otherwise dispose of, and/or enter orders in the auction process with respect to the Eligible Auction Rate Securities on the Company's behalf until the Expiration Date, without prior notification, so long as the Company receives a payment of par value plus any accrued but unpaid dividends or interest upon any sale or disposition. In addition, if the Company accepts the Offer, the UBS Entities will offer no net cost loans to the Company, should the Company desire to borrow money prior to the commencement of the exercise period for the Rights. The Company may be eligible for no net cost loans for an amount up to 75% of the market value of the Eligible Auction-Rate Securities at the time of the loan, should the Company desire to borrow money prior to the commencement of the exercise period for the Rights. The loans will become fully payable as soon as UBS receives the proceeds from a purchase of the Eligible Auction Rate Securities. See Note 16 for further information.

The Company's financial assets measured at fair value on a recurring basis subject to the disclosure requirements of SFAS 157 at September 30, 2008, were as follows (in thousands):

	Fair Value Measurements at Reporting Date Using			Total
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
<b>Assets:</b>				
Money market funds	\$ 405,208	\$	\$	\$ 405,208
Auction-rate securities	11,300		246,168	257,468
Equity securities	23,800			23,800
<b>Total</b>	<b>\$ 440,308</b>	<b>\$</b>	<b>\$ 246,168</b>	<b>\$ 686,476</b>

Auction-rate securities included in Level 1 represent securities that were called by the issuer and settled subsequent to September 30, 2008 at amounts equal to our original par value investment. The following table presents changes to the Company's financial assets measured at fair value on a recurring basis using significant unobservable inputs (Level 3) as defined in SFAS 157 for the three months ended September 30, 2008 (in thousands):

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3) Auction-rate Securities
Balance at June 30, 2008	\$ 257,723
Transfers to Level 3	
Securities sold or redeemed	
Securities purchased	
Transfers in and/or (out) of Level 3	(11,300)
Unrealized loss included in other comprehensive income	(255)
<b>Balance at September 30, 2008</b>	<b>\$ 246,168</b>

The following table presents changes to the Company's financial assets measured at fair value on a recurring basis using significant unobservable inputs (Level 3) as defined in SFAS 157 for the nine months ended September 30, 2008 (in thousands):

	<b>Fair Value Measurements Using Significant Unobservable Inputs (Level 3) Auction-rate Securities</b>
Balance at December 31, 2007	\$
Transfers to Level 3	356,250
Securities sold or redeemed	(71,100)
Securities purchased	
Transfers in and/or (out) of Level 3	(11,300)
Unrealized loss included in other comprehensive income	(27,682)
Balance at September 30, 2008	\$ 246,168

**Table of Contents****4. MARKETABLE SECURITIES**

Marketable securities held by the Company as of September 30, 2008 and December 31, 2007 were as follows (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized (Losses)	Fair Value
<b>September 30, 2008:</b>				
Money market funds	\$ 405,208	\$	\$	\$ 405,208
<i>Total included in cash and cash equivalents</i>	405,208			405,208
Auction-rate securities	11,300			11,300
Equity securities	15,000	211		15,211
<i>Current marketable securities</i>	26,300	211		26,511
Auction-rate securities	273,850		(27,682)	246,168
Equity securities	5,000	3,589		8,589
<i>Long-term marketable securities</i>	278,850	3,589	(27,682)	254,757
<i>Total available-for-sale securities</i>	\$ 710,358	\$ 3,800	\$ (27,682)	\$ 686,476
<b>December 31, 2007:</b>				
Money market funds	\$ 299,261	\$	\$	\$ 299,261
<i>Total included in cash and cash equivalents</i>	299,261			299,261
Auction-rate securities	194,465	2		194,467
Variable-rate demand obligations	113,805			113,805
Municipal bond	5,078	36		5,114
<i>Current marketable securities</i>	313,348	38		313,386
Auction-rate securities	273,477			273,477
Equity securities	5,000	4,862		9,862
<i>Long-term marketable securities</i>	278,477	4,862		283,339
<i>Total available-for-sale securities</i>	\$ 891,086	\$ 4,900	\$	\$ 895,986

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. In an active market, 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 current 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

**Table of Contents**

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 Long-term Marketable Securities 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.

During the nine months ended September 30, 2008, we purchased \$15.0 million of equity securities consisting of investments in open-end mutual funds that invest in U.S. government securities and \$118.7 million of original par value auction-rate securities and variable rate demand obligations. In January 2008, the Company chose to reduce its exposure to auction-rate securities and ceased all purchases of auction-rate securities effective February 1, 2008, prior to when we began to experience failed auctions. During the nine months ended September 30, 2008, we sold \$113.8 million of original par value variable-rate demand obligations. During the same period, we also sold \$301.4 million of original par value auction-rate securities and a \$5.0 million original par value municipal bond. There were no realized holding gains or losses resulting from the sales of our available for sale securities during the nine months ended September 30, 2008.

Given the inactivity in the auction-rate securities market, the Company cannot predict when future auctions related to our existing auction-rate securities portfolio will be successful. As a result of the current illiquidity in the auction-rate securities markets and the long-term remaining duration of the underlying securities, we have classified these investments as long-term marketable securities in the Condensed Consolidated Balance Sheets at September 30, 2008 and December 31, 2007. Auction-rate securities classified as long-term at September 30, 2008 and December 31, 2007 were \$246.2 million and \$273.5 million, respectively. Since February 2008, when we began to experience failed auctions, and through October 29, 2008, we have divested, without a loss, \$82.4 million of our original par value auction-rate securities, either through successful auctions or mandatory tenders by the issuers. Of this \$82.4 million of original par value auction-rate securities, \$11.3 million was classified as short-term marketable securities at September 30, 2008. Further, we do not employ an asset management strategy or tax planning strategy that would require us to sell any of our existing securities at a loss, and none of our third-party investment advisors has discretion to make investment decisions or execute investment transactions without our consent. Furthermore, there have been no adverse changes in our business or industry that could require us to sell the securities at a loss in order to meet working capital requirements.

The underlying assets of our auction-rate securities are student loans. Student loans are insured by either the Federal Family Education Loan Program, or FFELP, or a combination of FFELP and other monoline insurers such as Ambac Assurance Corp., or AMBAC, and MBIA Insurance Corp, or MBIA. As of October 28, 2008, MBIA was rated Baa2 by Moody's and A- by Standard and Poor's. AMBAC was rated Aa3 by Moody's and AA by Standard and Poor's.

The following table sets forth the fair value of our long-term auction-rate securities by type of security and underlying credit rating as of September 30, 2008 (in thousands):

	Underlying Credit Rating(1)		Total
	AAA	AA	
<i>Underlying security:</i>			
Student loans	\$ 172,747	\$ 73,421	\$ 246,168
<i>Total auction-rate securities included in long-term marketable securities</i>	<i>\$ 172,747</i>	<i>\$ 73,421</i>	<i>\$ 246,168</i>

(1) Our auction-rate securities maintain split ratings. For purposes of this table, securities are categorized according to their lowest rating. As of September 30, 2008, the yields on our long-term auction-rate securities ranged from 3.12% to 14.00%. These yields represent the predetermined maximum reset rates that occur upon auction failures according to the specific terms within each security's prospectus. As of September 30, 2008, the weighted average yield for our long-term auction-rate securities was 8.36%. Total interest earned on our auction-rate securities during the nine months ended September 30, 2008 was \$11.4 million.

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, 2008		December 31, 2007	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Debt securities:				
Due in less than 1 year	\$	\$	\$ 5,078	\$ 5,114
Due in 1 to 5 years			4,500	4,500
Due in 5 to 10 years				
Due after 10 years	285,150	257,468	577,247	577,249
Equity securities	20,000	23,800	5,000	9,862
Money market funds	405,208	405,208	299,261	299,261
Total	\$ 710,358	\$ 686,476	\$ 891,086	\$ 895,986

**5. INVENTORIES**

Inventories are comprised of the following at September 30, 2008 and December 31, 2007, respectively (in thousands):

	September 30, 2008	December 31, 2007
Raw materials	\$ 7,424	\$ 8,670
Work-in-process	13,916	14,720
Finished goods	70,288	45,838
Total	\$ 91,628	\$ 69,228

**6. ACQUISITIONS, LICENSE AND COLLABORATION AGREEMENTS***Commercial Products**Novartis AG*

On March 4, 2008, we entered into a license and supply agreement, referred to as the Novartis Agreement, with and among Novartis AG and Novartis Consumer Health, Inc., referred to as Novartis, to obtain the exclusive U.S. marketing rights for the prescription medicine Voltaren® Gel (diclofenac sodium topical gel) 1%, referred to as Voltaren Gel or Licensed Product. Voltaren Gel received regulatory approval in October 2007 from the U.S. Food and Drug Administration ( FDA ), becoming the first topical prescription treatment for use in treating pain associated with osteoarthritis and the first new product approved in the U.S. for osteoarthritis since 2001. Voltaren Gel has been granted marketing exclusivity in the U.S. as a prescription medicine until at least October 2010.

Under the terms of the five-year Novartis Agreement, Endo made an upfront cash payment of \$85 million. Endo has agreed to pay royalties to Novartis AG on annual Net Sales of the Licensed Product, subject to certain thresholds as defined in the Novartis Agreement. In addition, Endo has agreed to make certain guaranteed minimum annual royalty payments of \$30 million per year payable in the fourth and fifth year of the Novartis Agreement, subject to certain limitations as defined in the Novartis Agreement. These guaranteed minimum royalties will be creditable against royalty payments on a Novartis Agreement year basis such that Endo's obligation with respect to each Novartis Agreement year is to pay the greater of (i) royalties payable based on annual net sales of the Licensed Product or (ii) the guaranteed minimum royalty for such Novartis Agreement year. Novartis is also eligible to receive a one-time milestone payment of \$25 million if annual net sales of Voltaren Gel exceed \$300 million in the U.S. The \$85 million upfront payment and the present value of the guaranteed minimum royalties have been capitalized as an intangible asset in the amount of \$129.0 million, representing the fair value of the exclusive license to market Voltaren Gel. We are amortizing this intangible asset over its estimated useful life of 5 years.

Endo shall be solely responsible to commercialize the Licensed Product during the term of the Novartis Agreement. With respect to each year during the term of the Novartis Agreement, Endo is required to expend a minimum amount of annual advertising and promotional expenses on the commercialization of the Licensed Product, subject to certain limitations as provided for under the Novartis Agreement. In addition, Endo will be required to perform a minimum number of face-to-face one-on-one discussions with physicians and other health care practitioners (referred to as details) for the purpose of promoting the Licensed Product within its approved indication during each year of the Novartis

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

Agreement, subject to certain provisions under the Novartis Agreement. Further, during the term of the Novartis Agreement, Endo will share in the costs of certain clinical studies and development activities initiated at the request of the FDA or as considered appropriate by Novartis and Endo.

During the term of the Novartis Agreement, Endo has agreed to purchase all of its requirements for the Licensed Product from Novartis. The price of product purchased under the Novartis Agreement is fixed for the first year and subject to annual changes based upon changes in the producer price index and raw materials as set forth in the Novartis Agreement. Endo has an existing long-term manufacturing and development agreement with Novartis whereby Novartis has agreed to manufacture certain of our commercial products and products in development.

## **Table of Contents**

Novartis has the exclusive right, at its sole discretion, to effect a switch of the Licensed Product from a prescription product to an over-the-counter (OTC) product in the United States, referred to as an OTC Switch, by filing an amendment or supplement to the Licensed Product New Drug Application or taking any other action necessary or advisable in connection therewith to effect the OTC Switch, and thereafter to commercialize such OTC product. Notwithstanding the foregoing, Novartis shall not launch an OTC equivalent product prior to a time specified in the Novartis Agreement, and Novartis shall not take any action that results in the loss of the prescription product status for the Licensed Product prior to such time. Novartis will notify Endo if it submits a filing to the FDA in respect of an OTC equivalent product. In the event that Novartis gains approval of an OTC equivalent product that results in the Licensed Product being declassified as a prescription product, then Novartis will make certain royalty payments to Endo on net sales of such OTC equivalent product in the United States by Novartis, its affiliates and their respective licensees or sublicensees as set forth in the Novartis Agreement, provided that, and subject to certain limitations and provisions as set forth in the Novartis Agreement. As a condition to the payment of any and all such royalties, net sales of the Licensed Product in the United States must have exceeded a certain threshold as defined in the Novartis Agreement prior to the launch of the OTC equivalent product by Novartis or its affiliates.

The initial term of the Novartis Agreement will expire on June 30, 2013. Endo has the option to extend the Novartis Agreement for two successive one (1) year terms (each referred to as a Renewal Term) beyond the initial term. The Novartis Agreement will remain in place after the first two Renewal Terms unless either party provides written notice of non-renewal to the other party at least six (6) months prior to the expiration of any Renewal Term after the first Renewal Term or the Novartis Agreement is otherwise terminated in accordance with its terms. Among other standard and customary termination rights granted under the Novartis Agreement, the Novartis Agreement can be terminated by either party upon reasonable written notice, if either party has committed a material breach that has not been remedied within ninety (90) days from the giving of written notice. Endo may terminate the Novartis Agreement by written notice upon the occurrence of several events, including the launch in the United States of a generic to the Licensed Product. Novartis may terminate the Novartis Agreement upon reasonable written notice (1) if Endo fails to deliver a set percentage of the minimum details in any given six (6)-month period under the Novartis Agreement; or (2) on or after the launch in the United States of an OTC equivalent product by Novartis, its affiliates or any third party that does not result in the declassification of the Licensed Product as a prescription product, following which net sales in any six-month period under the Novartis Agreement are less than a certain defined dollar amount.

### *Hind Healthcare Inc.*

In November 1998, Endo entered into a license agreement (referred to as the Hind License Agreement) with Hind Healthcare Inc., or Hind, for the sole and exclusive right to develop, use, market, promote and sell Lidoderm® in the United States. Under the terms of the Hind License Agreement, Endo paid Hind approximately \$10 million based upon the achievement of certain milestones and capitalized this amount as an intangible asset representing the fair value of these exclusive rights. In addition, Endo pays Hind nonrefundable royalties based on net sales of Lidoderm®. 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 nine months ended September 30, 2008 and 2007, we recorded \$62.0 million and \$55.1 million, respectively, for these royalties to Hind, which were recorded as a reduction to net sales. In March 2002, we extended this license with Hind to cover Lidoderm® in Canada and Mexico.

---

**Table of Contents**

*Penwest Pharmaceuticals Co.*

In September 1997, we entered into a collaboration agreement with Penwest Pharmaceuticals Co. to exclusively co-develop opioid analgesic products for pain management, using Penwest's patent-protected proprietary technology, for commercial sale worldwide. On April 2, 2002, we amended and restated this strategic alliance agreement between the parties (the 2002 Agreement) to provide, among other things, that this collaboration would cover only that opioid analgesic product currently under development by the parties, namely, oxymorphone ER, now known as Opana® ER. We had historically shared, on an equal basis, the costs of products developed under this agreement. On March 18, 2003, we received notice from Penwest that it was exercising its right under the agreement to cease funding its share of the development and pre-launch marketing costs of oxymorphone ER on account of their concern about their ability to access external capital funding opportunities in the future. Accordingly, we were responsible for funding 100% of these remaining costs until June 22, 2006, the date on which oxymorphone ER received FDA approval. In January 2007, the Company and Penwest entered into an amendment (the 2007 Amendment) to 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 certification period prior to when Opana® ER reached 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.

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 September 2008, the \$41 million royalty threshold was met. As a result, we began incurring royalties on the net sales of Opana® ER. Such royalties will be reduced by fifty percent (50%) until we recoup Penwest's share of the unfunded development costs of \$28 million, after which time royalties will be payable on annual net sales based on the royalty rates described above.

In July 2008, the Company and Penwest entered into an amendment (the 2008 Amendment) to the 2002 Agreement. Under the terms of the 2008 Amendment, Endo and Penwest agreed to restructure the 2002 Agreement to change the manner in which Endo reimburses Penwest for costs and fees incurred by Penwest in connection with any patent enforcement litigation.

*Vernalis Development Limited*

In July 2004, we entered into a license agreement and a loan agreement with Vernalis Development Limited, or Vernalis, under which Vernalis agreed to license exclusively to us rights to market Frova® (frovatriptan succinate) in North America. Launched in the U.S. in June 2002, Frova® is indicated for the acute treatment of migraine headaches in adults. Under the terms of the license agreement, we paid Vernalis an upfront fee of \$30 million and were required to make anniversary payments for the first two years at \$15 million in 2005 and 2006 (both \$15 million anniversary payments have been made). Under the loan agreement, we provided Vernalis with a loan of \$50 million in August 2004. We have capitalized the \$30 million up-front payment, the present value of the two \$15 million anniversary payments and the difference of \$6.2 million between the face amount of the loan and its present value at inception (See Note 8) as an intangible asset representing the fair value of the exclusive license to market Frova®. We are amortizing this intangible asset over its estimated useful life of 15 years.

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

Under the terms of the license agreement with Vernalis, we would have been required to make a \$40 million milestone payment upon FDA approval for the short-term prevention of menstrual migraine indication. 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> for the additional indication of short-term prevention of menstrual migraine. In April 2008, Endo notified the FDA of the withdrawal of the sNDA without prejudice to refiling as afforded under 21 CFR 314.65 for Frova<sup>®</sup> (frovatriptan succinate) 2.5 mg tablets. Frova<sup>®</sup> is approved and marketed for the acute treatment of migraine with or without aura in adults.

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

In addition, Vernalis could receive one-time milestone payments for the achievement of 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. Beginning on January 1, 2007, we began paying royalties to Vernalis based on the net sales of

**Table of Contents**

Frova<sup>®</sup>. We withheld 50% of those royalties and used the withholding to offset a portion of the unpaid accrued interest on the note receivable. The term of the license agreement is for the shorter of the time (i) that there are valid claims on the Vernalis patents covering Frova<sup>®</sup> or there is market exclusivity granted by a regulatory authority, whichever is longer, or (ii) until the date on which a generic version of Frova<sup>®</sup> is first offered, but in no event longer than 20 years. We can terminate the license agreement under certain circumstances, including upon one year written notice. In July 2007, Vernalis and Endo entered into Amendment No. 3 (Amendment No. 3) to the License Agreement dated July 14, 2004. Under Amendment No. 3, 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.

On July 1, 2005, we entered into a co-promotion agreement, as amended on December 22, 2005, with Vernalis. The co-promotion agreement, as amended, was related to the above described license agreement under which Vernalis agreed to exclusively license to us rights to market the product Frova<sup>®</sup> in North America. Pursuant to the license agreement, Vernalis had retained rights to co-promote Frova<sup>®</sup> in the United States and exercised its co-promotion option effective January 2006. Concurrent with the execution of Amendment No. 4 to the License Agreement (see below), the co-promotion agreement was terminated.

In February 2008, we entered into a termination agreement with Vernalis to terminate the existing loan agreement between the parties and to settle the outstanding note receivable. Concurrent with the termination agreement, we entered into Amendment No. 4 to the 2004 License Agreement between Vernalis and the Company (Amendment No. 4). In addition to amending certain specific terms and conditions of the License Agreement, Amendment No. 4 sets forth an annual minimum net sales threshold such that no royalties will be due on annual U.S. net sales of Frova<sup>®</sup> less than \$85 million. Prior to this amendment, royalties were payable by us to Vernalis on all net sales of Frova<sup>®</sup> in the United States. Now, once the annual minimum net sales amount is reached, royalty payments will be due only on the portion of annual net sales that exceed the \$85 million threshold. In summary, we received a cash payment from Vernalis of \$7 million and acquired an intangible asset representing a future royalty stream on the net sales of Frova<sup>®</sup> as consideration for the full settlement of the note receivable.

The fair value of the royalty stream that we acquired as a result of the settlement of the note receivable was calculated using the present value of expected future cash flows using a discount rate that we considered to be appropriate given the inherent risk in the timing and the amount of estimated cash flows. Our estimate of expected future cash flows is based on the royalty savings that we expect to realize as a result of Amendment No. 4 described above. Based upon our analysis, the fair value of the royalties that we would have otherwise been required to pay plus the \$7 million cash payment made by Vernalis to us in February 2008 is sufficient to recover the amounts owed to us.

Accordingly, we recorded the intangible asset on our books in an amount equal to the book value of the note receivable surrendered, after applying the \$7 million payment received from Vernalis, or \$46.7 million. We are amortizing this acquired intangible asset, into costs of sales, on a straight-line basis over its estimated useful life of nine (9) years. The nine-year estimated useful life is consistent with the period of time we currently expect to maximize use of the asset without the significant risk of generic competition for Frova<sup>®</sup>.

*ZARS Pharma*

On January 6, 2006, we entered into a license agreement with ZARS Pharma for the North American rights to Synera<sup>®</sup> (lidocaine 70 mg and tetracaine 70 mg) topical patch, referred to as the ZARS Agreement. Synera<sup>®</sup> is for use on intact skin to provide local dermal anesthesia in children and adults. Approved by the FDA on June 23, 2005, Synera<sup>®</sup> became commercially available in the second half of 2006. Under the terms of the ZARS Agreement, we paid ZARS an upfront fee of \$11 million in January 2006 and an additional \$8 million upon the first commercial shipment of the product in the second half of 2006. Both amounts were capitalized as an intangible asset representing the fair value of the marketing rights to Synera<sup>®</sup> acquired from ZARS. Following an impairment review of Synera<sup>®</sup>, we determined that the carrying amount of the recorded intangible asset was not fully recoverable. As a result, during 2006, we recorded a \$16.5 million impairment charge to write the unamortized portion of this intangible asset down to its fair value, determined using a discounted cash flow model. During the year ended December 31, 2007, as a result of the continued lack of commercial success of Synera<sup>®</sup>, we recorded an impairment charge of \$0.9 million related to the remaining unamortized portion of our ZARS intangible asset. Endo terminated the ZARS Agreement effective July 31, 2008.

*Products in development**RxKinetix, Inc.*

On October 12, 2006, the Company acquired all of the outstanding common stock of privately-held RxKinetix, Inc. RxKinetix specialized in developing new therapeutics focused on improving the quality of life for patients being treated for cancer. RxKinetix's most advanced product, now named EN3285, was, as of the acquisition date, 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.

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

In December 2007, the Company initiated the first of two phase III clinical trials of EN3285 for the prevention or delay of oral mucositis (OM). Endo had agreed to the trial design with the FDA under the Special Protocol Assessment (SPA) process. Under the



---

**Table of Contents**

terms of the SPA, Endo initiated a multicenter, double-blind, placebo-controlled trial in approximately 240 OM patients undergoing chemoradiation therapy for head and neck cancer. In March 2008, the first dosage of EN 3285 was administered to a patient enrolled in the clinical phase III trial, triggering a contingent purchase consideration payment in the amount of \$15 million that was made in March 2008. In April 2008, the FDA notified us that they were placing our studies on clinical hold pending the submission to the FDA of additional pre-clinical data. We are currently undertaking additional pre-clinical studies with the intent of addressing the FDA's comments.

*Orexo AB*

In August 2004, we entered into an agreement with Orexo AB, referred to as the Orexo Agreement, granting us the exclusive rights to develop and market Orexo AB's patented sublingual muco-adhesive fentanyl product (Rapinyl) in North America. Rapinyl is a sub-lingual, fast-dissolving tablet of fentanyl intended for the treatment of breakthrough cancer pain. Rapinyl is based on Orexo's unique patented technology for sublingual administration. The Orexo Agreement provided for us to make an up-front license fee payment of \$10 million, which we capitalized as an intangible asset representing the fair value of the exclusive right to market products utilizing Orexo's unique patented technology for sublingual administration. We were amortizing this intangible asset over its estimated useful life of 20 years. Our agreement with Orexo provided for us to make additional license fees and payments based on development and regulatory milestones, which total up to \$22.1 million, \$17.7 million of which has been recorded and included in research and development expense. Of this \$17.7 million expensed from the inception of the Orexo Agreement through September 30, 2008, \$0.8 million and \$5.2 million has been recorded during each of the nine months ended September 30, 2008 and 2007, respectively.

During the second quarter of 2008, the Company completed an in-depth review of its research and development (R&D) activities. The review included an analysis of the Company's R&D priorities, focus and available resources for current and future projects as well as the commercial potential for each product. As a result of this review, in July 2008 the Company decided to discontinue development of Rapinyl and terminate the Orexo Agreement in accordance with its terms. As a result of this decision, the Company recorded a pre-tax impairment of other intangible assets in the amount of \$8.1 million in the second quarter of 2008 to reduce the remaining balance of our Rapinyl intangible asset to zero and also recorded an impairment charge of approximately \$3.1 million related to the impairment of property and equipment that has been included in research and development expenses.

Pursuant to the terms the Orexo Agreement, we are required to pay a \$0.8 million termination fee to Orexo. In addition, we were required to continue all ongoing clinical trials related to Rapinyl for a maximum of six months from the date of our termination of the Orexo Agreement. On October 30, 2008, Endo entered into an early termination agreement effective October 31, 2008 pursuant to which we agreed to cease all involvement in the ongoing clinical trials of Rapinyl and to pay Orexo a lump sum fee. In exchange, Orexo has released Endo from certain claims under the Orexo Agreement. During the nine months ended September 30, 2008, the Company expensed \$3.8 million as research and development expense for all remaining costs associated with the Orexo Agreement. We are also required to transition the manufacturing process to Orexo or an agreed-upon third party, and supply manufactured product to Orexo or the agreed-upon third party during the transition period for up to a maximum of two years from the date of termination of the agreement. Orexo will pay us 125% of the cost for all manufactured product we provide during the transition period.

*ProEthic Pharmaceuticals, Inc.*

In March 2005, we entered into an agreement with ProEthic Pharmaceuticals, Inc. (now owned by and renamed Kowa Pharmaceuticals America Inc.) for the U.S. and Canadian rights to develop and commercialize a once-daily ketoprofen-containing topical patch. We refer to this agreement as the ProEthic Agreement. Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID) generally used for the treatment of inflammation and pain and currently available in the U.S. only in oral form. The ketoprofen patch is being developed for the localized treatment of acute pain associated with soft-tissue injuries. Under the terms of the ProEthic Agreement, in March 2005, we paid a \$10 million upfront fee that was expensed as research and development during the year ended December 31, 2005. We made a \$5 million milestone payment upon the achievement of a regulatory milestone that was expensed as research and development during the year ended December 31, 2006.

During the second quarter of 2008, the Company completed an in-depth review of its research and development activities. The review included an analysis of the Company's R&D priorities, focus and available resources for current and future projects as well as the commercial potential for each product. As a result of this review, in July 2008 the Company decided to discontinue development of the ketoprofen patch. There was no termination fee due to ProEthic as a result of terminating the ProEthic Agreement.

*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, referred to as the DURECT CHRONOGESIC® License Agreement, relating to the development and

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

commercialization of the CHRONOGESIC® product candidate in the U.S. and Canada. Amendment No. 4 provided 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

**Table of Contents**

terminate the DURECT CHRONOGESIC<sup>®</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. In April 2008, we terminated the DURECT CHRONOGESIC<sup>®</sup> License Agreement. Under the current terms of this license agreement, we were not responsible for any development costs for CHRONOGESIC<sup>®</sup> prior to May 1, 2008 so long as written notification of termination of the agreement was provided to DURECT by April 30, 2008. This return of CHRONOGESIC<sup>®</sup> rights has no effect on DURECT and Endo's collaboration with respect to the sufentanil transdermal patch (TRANSDUR<sup>®</sup>-Sufentanil) licensed by Endo from DURECT for the U.S. and Canada. There was no termination fee due to DURECT as a result of terminating the DURECT CHRONOGESIC<sup>®</sup> License Agreement.

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, referred to as the DURECT Sufentanil Agreement. The sufentanil patch, which is in clinical development, is intended to provide relief of moderate-to-severe chronic pain for up to seven days. We have assumed all remaining development and regulatory filing responsibility for this product, including the funding thereof. 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. In addition, the DURECT Sufentanil Agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. The DURECT Sufentanil Agreement will continue in effect until terminated. 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.*

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

*Alexza Pharmaceuticals, Inc.*

In December 2007, we entered into a license, development and supply agreement with Alexza Pharmaceuticals, Inc. (Alexza) for the exclusive development and commercialization rights in North America for Alexza's AZ-003 (Staccato<sup>®</sup> fentanyl). We refer to this agreement as the Alexza Agreement. Currently in Phase I clinical development, AZ-003, now named EN3294, is a hand-held delivery system that uses Alexza's proprietary Staccato<sup>®</sup> system inhalation technology to deliver fentanyl for the treatment of breakthrough pain. EN3294 is patent protected until 2022. Under the terms of the Alexza Agreement, Endo paid Alexza an upfront fee of \$10 million that was expensed as research and development during the year ended December 31, 2007, with additional payments of approximately \$40 million becoming due upon achievement of predetermined regulatory and commercial milestones. Endo will also pay royalties to Alexza on net sales of EN3294. Endo has assumed responsibility for, and funding of, all remaining clinical trial development and regulatory filings. Alexza will manufacture the product for Endo and will be responsible for completing development of the device.

*Other*

In December 2007, we entered into a license, development and supply agreement with an undisclosed third party collaborative partner for the exclusive clinical development and commercialization rights in Canada and the United States for a certain technology to be utilized in our various product development activities. Under the terms of this agreement, the collaborative partner will be responsible for development efforts to conduct pharmaceutical formulation development and will manufacture any such product or products which obtain FDA approval. Endo will be responsible for conducting clinical development activities and for all development costs incurred to obtain regulatory approval. Pursuant to this agreement, we expensed upfront fees of \$18.9 million as research and development during the year ended December 31, 2007. During the nine months ended September 30, 2008, we expensed a \$2 million milestone payment as research and development expense. Additional payments of approximately 74.8 million euros may become due upon achievement of predetermined regulatory and commercial milestones. Endo will also make payments to the collaboration partner based on net sales of any such product or products commercialized under this agreement.



**Table of Contents**

We have also entered into certain other collaboration agreements with third parties for the development of pain management and other products. In future periods, we may incur up to approximately \$3.8 million of expense pursuant to these agreements. These agreements require us to share in the development costs of such products and grant marketing rights to us for such products.

We have also licensed from universities and other companies rights to certain technologies or intellectual property generally in the field of pain management. We are generally required to make upfront payments as well as other payments upon successful completion of regulatory or sales milestones. In addition, these agreements generally require us to pay royalties on sales of the products arising from these agreements. These agreements generally permit Endo to terminate the agreement with no significant continuing obligation.

In July 2008, the Company made a \$20 million investment in a privately-held company focused on the development of an innovative treatment for certain types of cancer. In exchange for our \$20 million payment, we received an equity interest in the privately-held company and the rights to negotiate an exclusive worldwide development and commercialization arrangement with respect to a certain technology for use in a specified indication. The Company's \$20 million payment resulted in an ownership interest of less than 20% of the outstanding voting stock of the privately-held company. In addition, Endo does not have the ability to exert significant influence over the privately-held company. Accordingly, Endo is accounting for this investment under the cost method.

**7. GOODWILL AND OTHER INTANGIBLES**

Our goodwill and other intangible assets consist of the following at September 30, 2008 and December 31, 2007, respectively (in thousands):

	September 30, 2008	December 31, 2007
Goodwill	\$ 181,079	\$ 181,079
Amortizable intangibles:		
Licenses	\$ 257,757	\$ 92,100
Patents	3,200	3,200
	260,957	95,300
Less accumulated amortization	(45,219)	(24,351)
Other Intangibles, net	\$ 215,738	\$ 70,949

Changes in the gross carrying amount of licenses for the year ended December 31, 2007 and the nine months ended September 30, 2008, are as follows:

(in thousands)	Gross carrying amount
Balance at December 31, 2006	\$ 94,621
Synera® impairment	(2,521)
<i>Balance at December 31, 2007</i>	<i>92,100</i>
Vernalis note receivable termination	46,667
Novartis license acquisition	128,990
Rapinyl impairment (Note 6)	(10,000)
<i>Balance at September 30, 2008</i>	<i>\$ 257,757</i>

Estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2007 is as follows (in thousands):

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

2008	\$ 31,859
2009	\$ 36,297
2010	\$ 36,297
2011	\$ 36,297
2012	\$ 36,297

**8. 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 succinate) in North America. Under the

**Table of Contents**

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, plc from Vernalis in connection with Vernalis' reacquisition of the North American rights to Frova<sup>®</sup>. 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 was 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 would have been 8% per annum. The difference of \$6.2 million between the face amount of the note and its present value at inception had been treated as additional consideration paid to acquire the license rights and was included in other intangibles, net.

In February 2008, we entered into a termination agreement with Vernalis to terminate the existing loan agreement between the parties and to settle the outstanding note receivable. Concurrent with the termination agreement, we entered into Amendment No. 4 to the License Agreement dated July 14, 2004 between Vernalis and the Company (Amendment No. 4). In addition to amending certain specific terms and conditions of the License Agreement, Amendment No. 4 sets forth an annual minimum net sales threshold such that no royalties will be due on annual net sales less than \$85 million. Prior to this amendment, royalties were payable by the Company on all net sales of Frova<sup>®</sup> in the United States. Once the annual minimum net sales amount is reached, royalty payments will be due on the portion of annual net sales that exceed the threshold. Pursuant to the termination agreement, Vernalis also made a cash payment to the Company of \$7 million.

Our analysis of the fair value of the royalty stream that we acquired as a result of the settlement of the note receivable was performed using the present value of expected future cash flows using a discount rate that we considered to be appropriate given the inherent risk in the timing and the amount of estimated cash flows. Our estimate of expected future cash flows is based on the royalty savings that we expect to realize as a result of Amendment No. 4. These royalty savings are based upon revenue projections of Frova<sup>®</sup> through 2018. Net sales of Frova<sup>®</sup> were \$38.1 million, \$40.6 million and \$52.4 million for the years ended December 31, 2005, 2006 and 2007, respectively, representing a compound annual growth rate of approximately seventeen (17) percent. Our probability weighted model analyzes two scenarios, one having revenue growth through 2015 and the other assuming declines in revenue beginning in 2009 due to potential generic competition in the migraine market.

Based upon our analysis, the fair value of the royalties that we would have otherwise been required to pay plus the \$7 million cash payment made by Vernalis to us in February 2008 was sufficient to cover the amounts Vernalis owed to us. Therefore, we concluded that an impairment charge was not required upon settlement in February 2008.

**9. COMPREHENSIVE INCOME**

Comprehensive income includes the following components for the three and nine months ended September 30, 2008 and 2007 (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2008	2007	2008	2007
Net income	\$ 68,246	\$ 59,147	\$ 186,799	\$ 176,842
Other comprehensive income:				
Unrealized gain (loss) on securities, net of tax	1,647	1,544	(28,303)	986
Total comprehensive income	\$ 69,893	\$ 60,691	\$ 158,496	\$ 177,828

**10. STOCKHOLDERS' EQUITY***Stock-Based Compensation***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

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

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, 2008, stock options, restricted stock awards and restricted stock units have been granted under the Stock Incentive Plans.



**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 \$4.8 million and \$13.7 million during the three and nine months ended September 30, 2008 and \$3.7 million and \$10.9 million during the three and nine months ended September 30, 2007. 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, 2008 and 2007 (in thousands).

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Selling, general and administrative expenses	\$ 4,388	\$ 3,320	\$ 12,642	\$ 9,694
Research and development expenses	367	387	1,071	1,246
<b>Total stock-based compensation expense</b>	<b>\$ 4,755</b>	<b>\$ 3,707</b>	<b>\$ 13,713</b>	<b>\$ 10,940</b>

As of September 30, 2008, the total remaining unrecognized compensation cost related to non-vested stock-based compensation awards amounted to \$43.9 million. This expected cost does not include the impact of any future stock-based compensation awards.

**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. 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, 2004, and 2007 Stock Incentive Plans for the nine months ended September 30, 2008 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding, January 1, 2008	4,336,052	\$ 24.24		
Granted	1,345,093	\$ 24.93		
Exercised	(94,657)	\$ 12.94		
Forfeited	(812,206)	\$ 28.06		
Expired	(55,831)	\$ 29.38		
Outstanding, September 30, 2008	4,718,451	\$ 23.94	5.68	\$ 6,297,052
Vested and expected to vest, September 30, 2008	4,471,948	\$ 23.77	5.50	\$ 6,297,042
Exercisable, September 30, 2008	2,633,798	\$ 21.23	3.31	\$ 6,296,851

The total intrinsic value of options exercised during the nine months ended September 30, 2008 and 2007 was \$1.1 million and \$9.2 million, respectively. The weighted-average grant date fair value of the stock options granted in the nine months ended September 30, 2008 and 2007 was \$9.54 per option and \$15.18 per option, respectively, determined using the following assumptions:

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

	2008	2007
Average expected term (years)	4.92	5.50
Risk-free interest rate	2.82%	4.63%
Dividend yield	0.00	0.00
Expected volatility	39%	48%

**Table of Contents**

The weighted average remaining requisite service period of the non-vested stock options was 2.6 years.

**Restricted Stock Awards**

During the nine months ended September 30, 2008, the Company granted restricted stock awards to non-employee directors of the Company. 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, 2008, is presented below:

	Number of Shares	Weighted Average Fair Value Per Share	Aggregate Intrinsic Value
Non-vested, January 1, 2008	13,572	\$ 29.84	
Granted		\$	
Forfeited	(6,786)	\$ 29.84	
Vested	(1,131)	\$ 29.84	\$
Nonvested, September 30, 2008	5,655	\$ 29.84	

The weighted average remaining requisite service period of the non-vested restricted stock was approximately 5 months.

**Restricted Stock Units**

During the nine months ended September 30, 2008, the Company granted restricted stock units to employees and non-employee directors of the Company as part of their annual stock compensation award. We recognize expense for our restricted stock units using the straight-line method over the requisite service period. The total value of compensation expense for restricted stock unit is equal to the closing price of Endo shares on the date of grant.

A summary of our restricted stock units as of September 30, 2008, is presented below:

	Number of Shares	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding, January 1, 2008			
Granted	639,396		
Forfeited	(81,585)		
Vested			
Outstanding, September 30, 2008	557,811	1.98	\$ 11,156,220
Vested and expected to vest, September 30, 2008	473,552	1.88	\$ 9,471,040

The weighted average remaining requisite service period of the non-vested restricted stock units was 3.27 years.

**Share Repurchase Program**

In April 2008, our Board of Directors approved a share repurchase program, authorizing the Company to repurchase in the aggregate up to \$750 million of shares of its outstanding common stock. Purchases under this program may be made from time to time in open market purchases, privately-negotiated transactions, accelerated stock repurchase transactions or otherwise, as determined by Endo.

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

This program does not obligate Endo to acquire any particular amount of common stock. The pace of repurchase activity will depend on factors such as levels of cash generation from operations, cash requirements for investment in the Company's business, repayment of future debt, if any, current stock price, market conditions and other factors. The share repurchase program may be suspended, modified or discontinued at any time and is set to expire in April 2010.

As described in Note 15, we entered into a privately-negotiated \$325.0 million accelerated share repurchase agreement as part of our broader share repurchase program described above. Pursuant to the accelerated share repurchase agreement, we purchased approximately 11.9 million shares of our common stock on April 15, 2008. On August 14, 2008, Endo received approximately 1.4 million additional shares of our common stock based on the volume-weighted average price of our common stock during a specified averaging period set forth by the accelerated share repurchase agreement. In addition to the accelerated share repurchase,

## Table of Contents

beginning in April 2008, we made open market purchases of our common stock as part of our broader share repurchase program. As of September 30, 2008, we purchased approximately 3.9 million shares of our common stock on the open market for a total purchase price of approximately \$88.7 million.

### *Amendment to the Company's Amended and Restated Certificate of Incorporation*

At our 2008 Annual Meeting held on June 26, 2008, our stockholders approved an amendment to the Company's Amended and Restated Certificate of Incorporation which increased the total number of shares of common stock, \$0.01 par value, that the Company is authorized to issue from 175,000,000 to 350,000,000.

## **11. RELATED PARTY TRANSACTIONS**

**Tax Sharing Agreement.** On July 14, 2000, Endo Pharma LLC was formed in connection with our acquisition of 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 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 were 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, 2008, all 36 million of these stock options had been exercised into shares of our common stock held by Endo Pharma LLC.

During the year ended December 31, 2007, the final 75,259 shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised. We were obligated, under our amended tax sharing agreement, to pay to Endo Pharma LLC an additional tax benefit amount of approximately \$0.7 million. 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 were paid during the nine months ended September 30, 2008, and the remaining tax benefit amount attributable to 2007 was paid in October 2008. This represents the final tax sharing payment due to Endo Pharma LLC.

As of September 30, 2008, there were no options remaining to be granted under the Endo Pharma LLC stock option plans.

## **12. 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., Mallinckrodt Inc., Almac Pharma Services and Sharp Corporation. 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 \$20 million of product in 2008 and approximately \$21 million per year thereafter through December 31, 2010. Either party may terminate this agreement on three-years' notice, effective at any time after the initial five-year term. Either party may also terminate this agreement on account of a material breach by the other.

### *Teikoku Seiyaku Co., Ltd.*

Under the terms of our agreement with Teikoku, a Japanese manufacturer, Teikoku 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. The agreement contains certain provisions requiring Teikoku to qualify an additional manufacturing site, at our request, should we meet certain defined purchasing levels for a defined period of time. On April 24, 2007, we amended this agreement. The material components of the Amended Agreement are as follows:

We have agreed to purchase a minimum number of patches per year through 2012, representing the noncancelable portion of the Amended Agreement.

## Table of Contents

Teikoku has agreed to fix the supply price of Lidoderm® for a 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, we have used prices currently existing under the Amended Agreement, and estimated our minimum purchase requirement to be approximately \$32 million per year through 2012. The minimum purchase requirement shall remain in effect subsequent to 2012, except that Endo has the right to terminate the Amended Agreement after 2012, if we fail to meet the annual minimum requirement.

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 Lidoderm®.

The Amended Agreement will expire on December 31, 2021, unless terminated in accordance with its terms. Either party may terminate this Agreement, upon thirty (30) days written notice, in the event that Endo fails to purchase the annual minimum quantity for each year after 2012 (e.g., 2013 through 2021) upon thirty (30) days written notice. Notwithstanding the foregoing, 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 our agreement with Mallinckrodt, Mallinckrodt manufactures and supplies to us narcotic active drug substances, in bulk form, and raw materials for inclusion in our controlled substance pharmaceutical products. There is no minimum annual purchase commitment under this agreement. However, 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.

### *Almac Pharma Services*

Under the terms of our agreement with Almac Pharma Services (Almac), a European manufacturer, Almac manufactures Frova® at its Ireland facility for commercial sale by us in the United States. The agreement with Almac will expire on January 1, 2010, unless terminated sooner in accordance with its terms and can be extended beyond January 1, 2010 upon mutual agreement by both parties. If no agreement as to any extension or termination is reached six months prior to the end of the term, then the agreement will automatically renew for a period of twelve months. Almac has agreed to fix the supply price of Frova® for a period of time after which the price will be adjusted at future dates certain based on a price index defined in the agreement, subject to an annual maximum increase.

### *Sharp Corporation*

Under the terms of our agreement with Sharp Corporation (Sharp), a U.S. manufacturer, Sharp performs certain services for Endo including the packaging and labeling of Lidoderm® at its facility in Allentown, Pennsylvania, for commercial sale by us in the United States. The Sharp agreement will expire on March 1, 2011, subject to renewal for additional one-year periods upon mutual agreement by both parties. Endo has the right to terminate the Sharp agreement at any time upon ninety (90) days written notice.

### *Ventiv Commercial Services, LLC*

On May 15, 2008, we entered into a services agreement with Ventiv Commercial Services, LLC ( Ventiv ), referred to as the Ventiv Agreement. Under the terms of the Ventiv Agreement, Ventiv will provide to Endo certain sales and marketing services through a contracted field force of approximately 275 sales representatives and other sales management positions, collectively referred to as the Ventiv Field Force. The Ventiv Field Force will promote primarily Voltaren® Gel and will be required to perform a minimum number of face-to-face one-on-one discussions with physicians and other health care practitioners for the purpose of promoting Voltaren® Gel and other Endo products within their respective approved indications during each year of the Ventiv Agreement, subject to certain provisions.

Under the terms of the Ventiv Agreement, we incurred a one-time implementation fee that we recognized in selling, general, and administrative expense in the second quarter of 2008. In addition, each month we are required to pay Ventiv a monthly fixed fee during the term of the Ventiv Agreement based on a pre-approved budget. Included in the fixed monthly fee are certain costs such as the Ventiv sales representative and

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

district manager salaries, Ventiv field force travel, and office and other expenses captured on routine expense reports, as well as a fixed management fee. If the Ventiv Agreement is terminated prior to the completion of the first twelve months of Detailing (as defined in the Ventiv Agreement), Endo is obligated to pay Ventiv the remaining unpaid portion of the fixed management fee. During the term of the Ventiv Agreement, Ventiv will also be eligible to earn a performance-based bonus equal to the fixed management fee during each year of the Ventiv Agreement. This performance-based bonus is payable upon the achievement of certain conditions, including the number of Voltaren® Gel tubes sold and the number of Details achieved.



## **Table of Contents**

The Ventiv Agreement is effective April 1, 2008 and will expire on June 30, 2010. Among other standard and customary termination rights granted under the Ventiv Agreement, we may terminate the Ventiv Agreement at our sole discretion at any time upon 120 days' written prior notice to Ventiv, at which time we may be required to pay Ventiv a termination fee of up to \$1 million. The Ventiv Agreement can also be terminated by either party upon reasonable written notice, if either party has committed a material breach that has not been remedied within thirty (30) days from the giving of written notice.

### *General*

In addition to the manufacturing, services, 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 and (2) Kunitz and Associates Inc. for assistance with 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.

### **Milestones and Royalties**

See Note 6 for a complete description of future milestone and royalty commitments pursuant to our acquisitions, license and collaboration agreements.

### **Employment Agreements**

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

### **Research Contracts**

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

### **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 contingent amounts have been accrued with respect to any of these unsettled legal proceedings as of September 30, 2008.

#### *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.

#### *Pricing Litigation*

A number of cases brought by local and state government entities are pending that allege generally that our wholly-owned subsidiary, Endo Pharmaceuticals Inc. (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*

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

*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*

**Table of Contents**

*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. 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, are pending in the 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. That case was removed to federal court, transferred to the MDL, and then remanded to the court in which it was originally filed.

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. That case was transferred to the MDL.

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 EPI, and EPI 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.

*Paragraph IV Certifications on Opana® ER*

On December 14, 2007, the Company received a notice from IMPAX advising of the FDA's apparent acceptance for substantive review, as of November 23, 2007, of IMPAX's amended ANDA for a generic version of Opana® ER. IMPAX stated in its letter that the FDA requested IMPAX to provide notification to us and Penwest of any Paragraph IV certifications submitted with its ANDA, as required under section 355(j) of the Federal Food, Drug and Cosmetics Act, or the FDCA Act. Accordingly, IMPAX's letter included notification that it had filed Paragraph IV certifications with respect to Penwest's U.S. Patent Nos. 7,276,250, 5,958,456 and 5,662,933, which cover the formulation of Opana® ER. These patents are listed in the FDA's Orange Book and expire in 2022, 2013 and 2013, respectively. The Company's Opana® ER product has new dosage form exclusivity that prevents final approval of any ANDA by the FDA until the exclusivity expires on June 22, 2009. In addition, because IMPAX's application referred to patents owned by Penwest and contained a Paragraph IV certification under section 355(j) of the FDCA Act, we believe IMPAX's notice triggered the 45-day period under the FDCA Act in which we and Penwest could file a patent infringement action and trigger the automatic 30-month stay of approval. Subsequently, on January 25, 2008, the Company and our partner Penwest filed a

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

lawsuit against IMPAX in the United States District Court for the District of Delaware in connection with IMPAX's ANDA. The lawsuit alleges infringement of certain Orange Book-listed U.S. patents that cover the Opana® ER formulation. Additionally, the lawsuit previously filed by the Company and Penwest on November 15, 2007 against IMPAX remains pending. We cannot predict the outcome of this litigation.

---

**Table of Contents**

On June 16, 2008, the Company received a notice from IMPAX that it had filed an amended ANDA containing Paragraph IV certifications for the 7.5 mg, 15 mg and 30 mg strengths of oxymorphone hydrochloride extended release tablets. The notice covers Penwest's U.S. Patent Nos. 7,276,250, 5,958,456 and 5,662,933. Subsequently, on July 25, 2008, the Company and our partner Penwest filed a lawsuit against IMPAX in the United States District Court for the District of Delaware in connection with IMPAX's ANDA. The lawsuit alleges infringement of certain Orange Book-listed U.S. patents that cover the Opana® ER formulation. Additionally, the lawsuits previously filed by the Company and Penwest on s against IMPAX remain pending. We cannot predict the outcome of this litigation.

In February 2008, we along with our partner Penwest, received a notice from Actavis South Atlantic LLC, or Actavis, advising of the filing by Actavis of an ANDA containing a Paragraph IV certification under 21 U.S.C. Section 355(j) for a generic version of Opana® ER (oxymorphone hydrochloride extended-release tablets CII). The Actavis Paragraph IV certification notice refers to Penwest's U.S. Patent Nos. 5,128,143, 5,662,933, 5,958,456 and 7,276,250, which cover the formulation of Opana® ER. These patents are listed in the FDA's Orange Book and expire in 2008, 2013, 2013 and 2023, respectively. In addition to 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. Subsequently, on March 28, 2008, we and Penwest filed a lawsuit against Actavis in the U.S. District Court for the District of New Jersey in connection with Actavis's ANDA. The lawsuit alleges infringement of an Orange Book-listed U.S. patents that covers the Opana® ER formulation. On May 5, 2008, Actavis filed an answer and counterclaims, asserting claims for declaratory judgment that the patents listed in the Orange Book are invalid, not infringed and/or unenforceable, as well as a claim of unfair competition against Endo and Penwest. Endo has filed a motion to dismiss or stay the unfair competition claim, which is pending. We cannot predict the outcome of this litigation. We intend, and we have been advised by Penwest that they too intend, to pursue all available legal and regulatory avenues in defense of Opana® ER, including enforcement of our intellectual property rights and approved labeling.

On or around June 2, 2008, the Company received a notice from Actavis that it had filed an amended ANDA containing Paragraph IV certifications for the 7.5 mg and 15 mg dosage strengths of oxymorphone hydrochloride extended release tablets. On or around July 2, 2008, the Company received a notice from Actavis that it had filed an amended ANDA containing Paragraph IV certifications for the 30 mg dosage strength. Both notices cover Penwest's U.S. Patent Nos. 5,128,143, 7,276,250, 5,958,456 and 5,662,933. On July 11, 2008, the Company and Penwest, filed suit against Actavis in the United States District Court for the District of New Jersey. The lawsuit alleges infringement of an Orange Book-listed U.S. patent that covers the Opana® ER formulation. We cannot predict the outcome of this litigation. We intend, and we have been advised by Penwest that they too intend, to pursue all available legal and regulatory avenues in defense of Opana®ER, including enforcement of our intellectual property rights and approved labeling.

On July 14, 2008, the Company received a notice from Sandoz, Inc. or Sandoz, advising of the filing by Sandoz of an ANDA containing a Paragraph IV certification under 21 U.S.C. Section 355(j) with respect to oxymorphone hydrochloride extended-release oral tablets in 5 mg, 10 mg, 20 mg and 40 mg dosage strengths. The Sandoz Paragraph IV certification notice refers to Penwest's U.S. Patent Nos. 5,662,933, 5,958,456 and 7,276,250, which cover the formulation of Opana® ER. These patents are listed in the FDA's Orange Book and expire in 2013, 2013 and 2023, respectively. In addition to 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. Subsequently, on August 22, 2008, the Company and our partner Penwest filed a lawsuit against Sandoz in the United States District Court for the District of Delaware in connection with Sandoz's ANDA. The lawsuit alleges infringement of certain Orange Book-listed U.S. patents that cover the Opana® ER formulation. We cannot predict the outcome of this litigation. We intend, and we have been advised by Penwest that they too intend, to pursue all available legal and regulatory avenues in defense of Opana® ER, including enforcement of our intellectual property rights and approved labeling.

On September 12, 2008, the Company received a notice from Barr Laboratories, Inc. or Barr, advising of the filing by Barr of an ANDA containing a Paragraph IV certification under 21 U.S.C. Section 355(j) with respect to oxymorphone hydrochloride extended-release oral tablets in a 40 mg dosage strength. On September 15, 2008, the Company received a notice from Barr that it had filed an ANDA containing a Paragraph IV certification under 21 U.S.C. Section 355(j) with respect to oxymorphone hydrochloride extended-release oral tablets in 5 mg, 10 mg, and 20 mg dosage strengths.

Both notices refer to Penwest's U.S. Patent Nos. 5,662,933, 5,958,456 and 7,276,250, which cover the formulation of Opana® ER. These patents are listed in the FDA's Orange Book and expire in 2013, 2013 and 2023, respectively. In addition to 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. Subsequently, on October 20, 2008, the Company and our partner Penwest filed a lawsuit against Barr in the United States District Court for the District of Delaware in connection with Barr's ANDA. The lawsuit alleges infringement of certain Orange Book-listed U.S. patents that cover the Opana® ER formulation. We cannot predict the outcome of this litigation. We intend, and we have been advised by Penwest that they too intend, to pursue all available legal and regulatory avenues in defense of Opana® ER, including enforcement of our intellectual property rights and approved labeling.

*LecTec Corporation v. Chattem, Inc., et al.*

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

On July 25, 2008, the LecTec Corporation filed a complaint in the Eastern District of Texas against the Company and several other pharmaceutical companies alleging that each of the defendants sells product that infringes one or more claims of patents owned by LecTec. The Company's product Lidoder<sup>®</sup> is identified in the complaint. The complaint alleges that Lidoder<sup>®</sup> infringes U.S. Patents 5,536,263 and 5,741,510. On September 30, 2008, the Company filed an answer denying infringement and alleging that the patents are invalid. The Company intends to contest this case vigorously. However, we cannot predict the timing or outcome of this litigation.

**Table of Contents***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.

**13. EARNINGS PER SHARE**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
<b>Numerator:</b>				
Net income available to common stockholders	\$ 68,246	\$ 59,147	\$ 186,799	\$ 176,842
<b>Denominator:</b>				
For basic per share data weighted average shares	119,439	133,915	125,498	133,835
Effect of dilutive stock options	515	696	514	656
For diluted per share data weighted average shares	119,954	134,611	126,012	134,491
Basic earnings per share	\$ 0.57	\$ 0.44	\$ 1.49	\$ 1.32
Diluted earnings per share	\$ 0.57	\$ 0.44	\$ 1.48	\$ 1.31

**14. 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.

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 accrued \$2.2 million in interest and penalties. The total amount of unrecognized tax benefits as of January 1, 2007 was \$7.7 million.

The Company and its subsidiaries are routinely examined by various taxing authorities, which have proposed adjustments to tax for issues such as certain tax credits and the deductibility of certain expenses. As discussed below, various issues pertaining to tax years after 2002 have been effectively settled during the nine months ended September 30, 2008. While it is possible that one or more of the open examinations may be resolved within the next twelve months, it is not anticipated that the resolution of these items will have a significant impact on our unrecognized tax benefits balance. In addition, the expiration of statutes of limitations for various jurisdictions is expected to reduce the unrecognized tax benefits balance by an insignificant amount.

The Company files income tax returns in the U.S. federal jurisdiction, and various state and foreign jurisdictions. The Company is subject to U.S. federal, state and local, and non-U.S. income tax examinations by tax authorities. 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. The Company's U.S. federal income tax returns for tax years 2003 through 2005 are currently under routine examination by the IRS. The Company believes that it has adequately provided under FIN 48 for all open tax years by tax jurisdiction.

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

During the nine months ended September 30, 2008, certain issues were effectively settled with taxing authorities for various tax years after 2002. Accordingly, the Company reversed approximately \$7.0 million of previously recorded unrecognized tax benefits



**Table of Contents**

incurred since the adoption of FIN 48, of which \$1.5 million pertained to interest and penalties. The total amount of unrecognized tax benefits as of September 30, 2008 is \$10.9 million (including interest and penalties). In addition to the aforementioned decrease in the amount of unrecognized tax benefits during the nine months ended September 30, 2008, we recorded additional unrecognized tax benefits, interest and penalties that relate to other uncertain income tax positions we previously identified at January 1, 2007. The change in the total amount of unrecognized benefits did not have a material impact on the Company's results of operations for the nine months ended September 30, 2008 or our financial position as of September 30, 2008. Any future adjustments to our uncertain tax position liability will impact 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.

**15. CONVERTIBLE SENIOR SUBORDINATED NOTES DUE 2015**

In April 2008, we issued \$379.5 million in aggregate principal amount of 1.75% Convertible Senior Subordinated Notes due April 15, 2015 (the Convertible Notes) in a private offering for resale to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended.

We received proceeds of approximately \$371.5 million from the issuance, net of the initial purchaser's discount. The initial purchaser's discount, as well as certain other estimated costs of the offering, has been recorded as a contra-liability account applied to the face amount of the Convertible Notes and are being amortized to interest expense utilizing the effective interest method. Interest is payable semi-annually in arrears on each April 15 and October 15 beginning on October 15, 2008. We recognized \$3.7 million of interest expense for the nine months ended September 30, 2008. The Convertible Notes will mature on April 15, 2015, unless earlier converted or repurchased by us.

Holders of the Convertible Notes may convert their notes based on a conversion rate of 34.2466 shares of our common stock per \$1,000 principal amount of notes (the equivalent of \$29.20 per share), subject to adjustment upon certain events, only under the following circumstances as described in the Indenture for the Convertible Notes (the Indenture): (1) during specified periods, if the price of our common stock reaches specified thresholds; (2) if the trading price of the Convertible Notes is below a specified threshold; (3) at any time after October 15, 2014; or (4) upon the occurrence of certain corporate transactions. We will be permitted to deliver cash, shares of Endo common stock or a combination of cash and shares, at our election, to satisfy any future conversions of the notes. It is our current intention to settle the principal amount of any conversion consideration in cash.

In connection with a Fundamental Change as defined in the Indenture, we also will deliver upon conversion of the notes additional shares of common stock as described in the Indenture. In addition, if we undergo a Fundamental Change before maturity of the Convertible Notes, we may be required to repurchase for cash all or a portion of the Convertible Notes at a repurchase price of 100% of the principal amount of the notes being repurchased, plus accrued and unpaid interest, including additional amounts, if any, up to but excluding the date of purchase. As of October 29, 2008, none of the conditions allowing holders of the Convertible Notes to convert had been met. In accordance with SFAS 128, *Earnings Per Share* (SFAS 128), the shares that are contingently convertible have not been included in our diluted earnings per share calculation for the three or nine months ended September 30, 2008 as they are anti-dilutive.

The notes and the shares of common stock underlying the notes have not been registered under the Securities Act of 1933, as amended (the Securities Act), or any applicable state securities laws, and will be offered only to qualified institutional buyers pursuant to Rule 144A promulgated under the Securities Act. Unless so registered, the notes may not be offered or sold in the United States except pursuant to an exemption from the registration requirements of the Securities Act and applicable state securities laws.

Concurrently with the issuance of the Convertible Notes, we entered into a privately-negotiated convertible note hedge transaction with affiliates of the initial purchasers. Pursuant to the hedge transaction we purchased common stock call options intended to reduce the potential dilution to our common stock upon conversion of the Convertible Notes by effectively increasing the initial conversion price of the notes to \$40.00 per share, representing a 61.1% conversion premium over the closing price of our common stock on April 9, 2008 of \$24.85 per share. The call options allow us to purchase up to approximately 13.0 million shares of our common stock at an initial strike price of \$29.20 per share. The call options expire on April 15, 2015 and must be net-share settled. The cost of the call option was approximately \$107.6 million. In addition, we sold warrants to affiliates of certain of the initial purchasers whereby they have the option to purchase up to approximately 13.0 million shares of our common stock at an initial strike price of \$40.00 per share. The warrants expire on various dates from July 14, 2015 through October 6, 2015 and must be net-share settled. We received approximately \$50.4 million in cash proceeds from the sale of these warrants.

In addition to entering into the convertible note hedge transaction and the warrant transaction, we entered into a privately-negotiated accelerated share repurchase agreement with the same counterparty, as part of our broader share repurchase program described in Note 10. We used

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

approximately \$57 million representing a portion of the net proceeds from the Convertible Notes offering to pay the cost of the convertible note hedge transaction, taking into account the proceeds from the warrant transaction, and

**Table of Contents**

used the balance of the net proceeds or approximately \$314 million, together with approximately \$11 million of cash on hand, to repurchase a variable number of shares of our common stock pursuant to the accelerated share repurchase agreement entered into as part of our broader share repurchase program. Pursuant to the accelerated share repurchase agreement, the counterparty delivered 11.9 million shares of our common stock to the Company on the day that the note offering closed, April 15, 2008. On August 14, 2008, Endo received approximately 1.4 million additional shares of our common stock based on the volume-weighted average price of our common stock during a specified averaging period set forth by the accelerated share repurchase agreement.

The Company has reserved previously authorized shares of common stock for issuance pursuant to the aforementioned Convertible Notes transaction, the convertible note hedge transaction, the warrant transaction and the accelerated share repurchase transaction.

Paragraph 11(a) of SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, provides that contracts issued or held by an entity that are both (1) indexed to the entities own common stock and (2) classified in stockholders' equity in its statement of financial position are not considered to be derivative financial instruments under SFAS No. 133 if the provisions of EITF Issue 00-19 are met.

We accounted for the call options, warrants, and accelerated share repurchase agreement in accordance with the guidance in EITF Issue 00-19. The call options, warrants, and accelerated share repurchase agreement meet the requirements of EITF Issue 00-19 to be accounted for as equity instruments. The cost of the call options and the proceeds related to the sale of the warrants are included in additional paid-in capital in our condensed consolidated balance sheet as of September 30, 2008. The common stock acquired through the accelerated share repurchase agreement has been included in treasury stock in our condensed consolidated balance sheet as of September 30, 2008.

In accordance with SFAS No. 128, the Convertible Notes, call options, and warrants have not been considered for purposes of the diluted net income per share calculation as their effect would be anti-dilutive. Should our common stock price exceed the conversion price of the notes or the strike price of the warrants, we will include the effect of the additional shares that may be issued in our diluted net income per share calculation using the treasury stock method.

**16. SUBSEQUENT EVENTS**

On October 3, 2008, the Emergency Economic Stabilization Act of 2008, referred to as the Act, was signed into law with its objective to promote the stability of the United States financial system. The Act authorizes the Treasury Secretary to purchase up to \$700 billion of troubled assets from financial institutions. In addition to other important provisions, the Act also authorizes the Securities and Exchange Commission (SEC) to suspend mark-to-market accounting for any issuer or for any class or category of transaction if the SEC determines it is necessary or in the public interest or consistent with the protection of investors. In addition, the tax credit for research and development, or R&D tax credit, was reinstated and extended through fiscal year 2009. We expect the effect of the reinstatement of the R&D tax credit to lower our income tax expense in the fourth quarter of 2008 by approximately \$2.0 million to \$2.5 million.

In October 2008, UBS AG (UBS) made an offer (the Offer) of Auction Rate Securities Rights (the Rights) to the Company and other clients of UBS Securities LLC and UBS Financial Services Inc. (collectively, the UBS Entities), pursuant to which the Company is entitled to sell to UBS all auction-rate securities held by the Company as of February 13, 2008 in a UBS account (the Eligible Auction Rate Securities). The Rights permit the Company to require UBS to purchase the Eligible Auction Rate Securities for a price equal to original par value plus any accrued but unpaid dividends or interest beginning on June 30, 2010 and ending on July 2, 2012 (the Expiration Date). As of September 30, 2008, we had Eligible Auction Rate Securities with original par value of \$266.4 million, representing 93% of our total auction-rate securities portfolio at par. The remaining seven percent (7%), or \$18.8 million, of our auction-rate securities portfolio is not held in a UBS account and therefore is not subject to the Offer.

The Offer is being made pursuant to agreements in principle entered into by the UBS Entities with the Securities and Exchange Commission, the New York Attorney General, the Texas State Securities Board and other state regulatory agencies represented by North American Securities Administrators Association, and a settlement agreement with the Massachusetts Securities Division to settle investigations brought by each of these agencies against the UBS Entities relating to the sale and marketing of auction rate securities. The alleged conduct underlying these investigations suggested that the UBS Entities marketed auction rate securities as cash alternatives but failed to adequately disclose liquidity risk. We may elect to accept the Offer any time prior to 5:00 p.m., New York City time, on November 14, 2008 (unless extended by UBS). In order to accept the Offer, we will be required to complete an acceptance form which releases UBS and its employees and agents from all claims except claims for consequential damages directly or indirectly relating to UBS's marketing and sale of auction rate securities.

If the Company accepts the Offer, the Company would grant to the UBS Entities the sole discretion and right to sell or otherwise dispose of, and/or enter orders in the auction process with respect to the Eligible Auction Rate Securities on the Company's behalf until the Expiration Date, without prior notification, so long as the Company receives a payment of par value plus any accrued but unpaid dividends or interest upon any

sale or disposition.

**Table of Contents**

In addition, if the Company accepts the Offer, the UBS Entities will offer no net cost loans to the Company, should the Company desire to borrow money prior to the commencement of the exercise period for the Rights. The Company may be eligible for no net cost loans for an amount up to 75% of the market value of the Eligible Auction-Rate Securities at the time of the loan, should the Company desire to borrow money prior to the commencement of the exercise period for the Rights. The loans will become fully payable as soon as UBS receives the proceeds from a purchase of the Eligible Auction Rate Securities.

The Offer made by UBS in October 2008, represents a substantive change in facts and circumstances occurring after September 30, 2008, that could change the Company's view about whether it intends to hold the impaired securities until their anticipated recovery. Accordingly, the Offer and our decision whether or not to ultimately accept it, could affect the Company's intent in the fourth quarter of 2008. The Company is required to evaluate its intent as of the reporting date using facts and circumstances that existed as of that date. As such, the Offer was not a factor considered in the Company's assessment of whether, at September 30, 2008, the Company had the intent and ability to hold its impaired securities until their anticipated recovery.

If the Company accepts the Offer, an enforceable legal right by and between the Company and UBS would exist. At that time, the commitment made by UBS to purchase the Eligible Auction-Rate Securities during the exercise period of the Rights will likely be considered a free standing put option between UBS and the Company which the Company will have to recognize as an asset, measured at its fair value, with the resultant gain recognized in earnings during the fourth quarter of 2008. The existence of the put option would not affect the separate determination of the fair value of the auction-rate securities. Currently, the Company has determined that the decline in fair value of its auction-rate securities is temporary for several reasons, including our intent and ability to hold the securities until their anticipated recovery. If we accept the Offer, the Company may no longer have the intent to hold the securities until their anticipated recovery. Accordingly, any decline in fair value will likely be considered an other-than-temporary impairment charge recognized in earnings during the fourth quarter of 2008 and measured as the amount of unrealized loss in accumulated other comprehensive income related to the auction-rate securities as of the date we accept the Offer.

**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, 2007 (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**

The Company is 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 \$21.5 billion in 2007. This represents an approximately 4% compounded annual growth rate since 2003. Our primary area of focus within this market is analgesics and, specifically, opioid analgesics. In 2007, analgesics were the third most prescribed medication in the United States with over 273 million prescriptions written for this classification. Opioid analgesics is a segment that comprised approximately 80% of the analgesic prescriptions for 2007. Total U.S. sales for the opioid analgesic segment were \$8.2 billion in 2007, representing a compounded annual growth rate of 6% since 2003.

We have a portfolio of branded products that includes established brand names such as Lidoderm®, Opana® ER and Opana®, Percocet® and Frova®. Branded products comprised approximately 92% of our net sales in 2007, with 65% of our net sales coming from Lidoderm®. In addition, in March 2008 Endo launched Voltaren® Gel, Endo's newly licensed topical prescription product for use in treating pain associated with osteoarthritis. Our non-branded generic portfolio, which accounted for 8% of net sales in 2007, currently consists of products primarily focused in pain management. 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.

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



---

## **Table of Contents**

Through a dedicated sales force of approximately 700 sales representatives and an additional 275 contract sales representatives throughout 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 Company Developments*

On September 2, 2008, the Company announced the resignation of Executive Vice President and Chief Financial Officer, Charles A. Rowland, Jr. The Company has engaged an executive search firm to assist in the search for a new chief financial officer.

On August 11, 2008, Dr. Sandeep Gupta was hired as Senior Vice President, Discovery and Early Development. Prior to joining Endo, Dr. Gupta served as head of drug discovery and pharmacology at Forest Laboratories. Dr. Gupta joined Forest in 1998 after nearly a decade in academia, including faculty positions at the University of Pennsylvania's Department of Surgery and the Boston University School of Medicine. Dr. Gupta graduated with a BS in Pharmacy from Banaras Hindu University in India in 1982 and earned his Doctorate in Pharmacology from Northeastern University in 1989. He is a member of the American Diabetes Association, the European Association for the Study of Diabetes and the American Urological Association.

In July 2008, Joyce N. LaViscount elected to pursue an operational role as the Company's Vice President, Sales Operations and resigned her position as the Company's Chief Accounting Officer, effective August 1, 2008. Ms. LaViscount's employment contract has been amended accordingly. In connection with this change, the Company decided to eliminate the Chief Accounting Officer position and Edward J. Sweeney, age 39, assumed the responsibilities as the principal accounting officer of the Company. Mr. Sweeney is Vice President, Controller and joined the Company in March 2004 as Director, Financial Reporting and was named Vice President, Controller in June 2007. Prior to joining the Company, Mr. Sweeney was a senior manager at Ernst & Young LLP, where he worked from September 1991 through March 2004. Mr. Sweeney is a licensed certified public accountant in the Commonwealth of Pennsylvania and holds a BS degree in accounting from St. Joseph's University.

On July 14, 2008, the Company received a notice from Sandoz, Inc. or Sandoz, advising of the filing by Sandoz of an ANDA containing a Paragraph IV certification under 21 U.S.C. Section 355(j) with respect to oxymorphone hydrochloride extended-release oral tablets in 5 mg, 10 mg, 20 mg and 40 mg dosage strengths. The Sandoz Paragraph IV certification notice refers to Penwest's U.S. Patent Nos. 5,662,933, 5,958,456 and 7,276,250, which cover the formulation of Opana® ER. These patents are listed in the FDA's Orange Book and expire in 2013, 2013 and 2023, respectively. In addition to 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. Subsequently, on August 22, 2008, the Company and our partner Penwest filed a lawsuit against Sandoz in the United States District Court for the District of Delaware in connection with Sandoz's ANDA. The lawsuit alleges infringement of certain Orange Book-listed U.S. patents that cover the Opana® ER formulation. We cannot predict the outcome of this litigation. We intend, and we have been advised by Penwest that they too intend, to pursue all available legal and regulatory avenues in defense of Opana® ER, including enforcement of our intellectual property rights and approved labeling.

During the second quarter of 2008, the Company completed an in-depth review of its research and development (R&D) activities. The review included an analysis of the Company's R&D priorities, focus and available resources for current and future projects as well as the commercial potential for each product. As a result of this review, the Company decided to discontinue development of Rapinyl®, the sub-lingual, fast-dissolving tablet of fentanyl intended for treatment of breakthrough cancer pain, and Topical Ketoprofen Patch being studied for the treatment of acute pain associated with soft-tissue injuries. Endo is working closely with development partners Orexo AB and ProEthic Pharmaceuticals (now owned by and renamed Kowa Pharmaceuticals America Inc.) to facilitate a smooth transition of work as Endo transfers these activities. As a result of these decisions, the Company recorded impairment charges totaling \$11.2 million to write-down all of the balance of its Rapinyl® intangible asset and other long-lived assets.





## **Table of Contents**

Endo currently intends to continue its development of the Transdermal Sufentanil Patch for the relief of moderate-to-severe chronic pain, Staccato® fentanyl that uses Alexza's proprietary Staccato® system inhalation technology to deliver fentanyl for the treatment of breakthrough pain, and Oral Rinse for the prevention or delay of severe oral mucositis. There can be no assurance that these development projects will progress and if they do, that they will be successful.

Endo also completed a review of operations to assess its core competencies and cost infrastructure. As a result of this review, the Company has begun an initiative to improve the efficiency of its business operations and reduce expenses. In addition to reductions in staff which resulted in a pre-tax second quarter charge of \$6.4 million, the Company is changing its business structure and reducing its utilization of outside consultants to create a more efficient operating model. With these changes, the Company's operating priorities will be to increase sales of branded products, pursue new business opportunities, and support its most promising R&D programs and its generics business.

In July 2008, the Company and Penwest entered into an amendment (the 2008 Amendment) to the 2002 Agreement. Under the terms of the amendment, Endo and Penwest agreed to restructure the 2002 Agreement to change the manner in which Endo reimburses Penwest for costs and fees incurred by Penwest in connection with patent enforcement litigation.

In May 2008, we entered into a services agreement with Ventiv Commercial Services, LLC ( Ventiv ), pursuant to which Ventiv will provide certain sales and marketing services, namely the promotion of Voltaren® Gel and other Endo products. The Ventiv Agreement will expire on June 30, 2010 unless earlier terminated in accordance with its terms.

In April 2008, the FDA notified us that they were placing our Oral Rinse studies on clinical hold pending the submission to the FDA of additional pre-clinical data. We are currently evaluating possible approaches to addressing this FDA correspondence.

In April 2008, David A. Lee, M.D., Ph.D. resigned his position as Chief Scientific Officer to devote more time to pursue his philanthropic activities. Dr. Lee, who had been working part-time for the Company for over a year, has agreed at the Company's request to remain with the Company as a senior strategic adviser primarily to continue to support the Company's activities in the area of public affairs.

In April 2008, Company director Michel de Rosen informed the Board of Directors that he did not intend to stand for re-election upon the expiration of his term at the 2008 Annual Meeting of Stockholders so that he may devote more time to his new position as Chief Executive Officer of Saint-Gobain Desjonqueres in France, a position he has held since March 31, 2008. Mr. de Rosen served as a director of the Company until the expiration of his term at the 2008 Annual Meeting of Stockholders held on June 26, 2008. The Board nominated Joseph C. Scodari at the 2008 Annual Meeting of Stockholders to fill the vacancy left by Mr. de Rosen's departure. Mr. Scodari, 55, was most recently Worldwide Chairman, Pharmaceuticals Group, of Johnson & Johnson and a Member of Johnson & Johnson's Executive Committee from March 1, 2005 until March 1, 2008. He joined Johnson & Johnson in 1999 as President of Centocor, Inc. when Johnson & Johnson acquired Centocor. At the time of that acquisition, Mr. Scodari had been the President and Chief Operating Officer of Centocor and a member of Centocor's Board of Directors since December 1997. At the 2008 Annual Meeting of Stockholders on June 26, 2008, the Company stockholders elected Mr. Scodari a director of the Company.

In April 2008, we reached an agreement with the D. E. Shaw group, pursuant to which Endo's Board of Directors nominated William F. Spengler at the 2008 Annual Meeting of Stockholders to serve as a member of the Company's Board of Directors. The D. E. Shaw group, which owns approximately 13.2 million shares of the Company's common stock, agreed to vote all of its shares in favor of the election of each of the Board's nominees. The Board of Directors increased to eight members, effective June 26, 2008. Mr. Spengler, 53, was named Executive Vice President and Chief Financial Officer of Smith and Wesson Holding Corporation on September 30, 2008. He was until February 2008 Executive Senior Vice President and Chief Financial Officer at MGI Pharmaceuticals Inc., an oncology- and acute care- focused bio-pharmaceutical company, where he had worked since 2005. Prior to joining MGI Pharma, Mr. Spengler was Executive Vice President and Chief Financial Officer at Guilford Pharmaceuticals Inc. from July 2004 to October 2005. As a condition to the agreement, the D. E. Shaw group has agreed not to solicit proxies from the Company's stockholders in connection with the election of directors or other matters until and, subject to certain other agreements, through the Company's 2009 Annual Meeting of Stockholders. At the 2008 Annual Meeting of Stockholders, the Company stockholders elected Mr. Spengler a director of the Company. Mr. Spengler also serves on the Audit Committee of the Board of Directors of the Company.

In April 2008, our Board of Directors approved a share repurchase program, authorizing the Company to repurchase in the aggregate up to \$750 million of shares of its outstanding common stock. Purchases under this program may be made from time to time in open market purchases, privately-negotiated transactions, accelerated stock repurchase transactions or otherwise, as determined by Endo. This program does not obligate Endo to acquire any particular amount of common stock. The pace of repurchase activity depends on factors such as levels of cash generation from operations, cash requirements for investment in the Company's business, repayment of future debt, if any, current stock price, market conditions and other factors. The share repurchase program may be suspended, modified or discontinued at any time and is set to expire in two years.



## **Table of Contents**

In April 2008, we entered into a privately-negotiated \$325.0 million accelerated share repurchase agreement as part of our broader share repurchase program described above. Pursuant to the accelerated share repurchase agreement, we purchased approximately 11.9 million shares of our common stock on April 15, 2008. On August 14, 2008, Endo received approximately 1.4 million additional shares of our common stock based on the volume-weighted average price of our common stock during a specified averaging period set forth by the accelerated share repurchase agreement. In addition to the accelerated share repurchase, beginning in April 2008 we made open market purchases of our common stock as part of our broader share repurchase program. As of September 30, 2008, we purchased approximately 3.9 million shares of our common stock on the open market for a total purchase price of approximately \$88.7 million.

In April 2008, we issued \$379.5 million in aggregate principal amount of 1.75% Convertible Senior Subordinated Notes due April 15, 2015 (the Convertible Notes ) in a private offering for resale to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933. The Convertible Notes will mature on April 15, 2015, unless earlier converted or repurchased by us.

Concurrently with the issuance of the Convertible Notes, we entered into a privately-negotiated convertible note hedge transaction with affiliates of the initial purchasers. Pursuant to the hedge transaction we purchased common stock call options intended to reduce the potential dilution to our common stock upon conversion of the Convertible Notes. The call options expire on April 15, 2015 and must be net-share settled. The cost of the call option was approximately \$107.6 million. In addition, we sold warrants to affiliates of certain of the initial purchasers whereby they have the option to purchase up to approximately 13.0 million shares of our common stock at an initial strike price of \$40.00 per share. The warrants expire on various dates from July 14, 2015 through October 6, 2015 and must be net-share settled.

In April 2008, Ivan Gergel, M.D. was hired as Executive Vice President, Research & Development. Dr. Gergel has responsibility for all of the Company's research and development activities, including direct supervision of clinical research, pre-clinical R&D, medical affairs, marketed product development support, regulatory affairs, project management and drug safety and surveillance. From May 19, 2005 until March 31, 2008, Dr. Gergel had been Senior Vice President of Scientific Affairs and President of the Forest Research Institute of Forest Laboratories Inc., managing over 900 physicians, scientists and staff at the Research Institute. Prior to that, Dr. Gergel served as Vice President and Chief Medical Officer at Forest and Executive Vice President of the Forest Research Institute. He joined Forest in 1998 as Executive Director of Clinical Research following nine years at SmithKline Beecham and was named Vice President of Clinical Development and Clinical Affairs in 1999. Dr. Gergel received his MD from The Royal Free Medical School of The University of London and an MBA from the Wharton School.

In April 2008, we notified the U.S. Food and Drug Administration (FDA) of the withdrawal of the supplemental new drug application (sNDA) without prejudice to refiling as afforded under 21 CFR 314.65 for Frova® (frovatriptan succinate) 2.5 mg tablets. This sNDA was 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.

In April 2008, upon written notice to DURECT, we terminated the DURECT CHRONOGESIC™ License Agreement. Under the current terms of this license agreement, we were not responsible for any development costs for CHRONOGESIC prior to May 1, 2008 so long as written notification of termination of the agreement is provided to DURECT by April 30, 2008. This return of CHRONOGESIC rights has no effect on DURECT and Endo's collaboration with respect to the sufentanil transdermal patch (TRANSDUR -Sufentanil) licensed by Endo from DURECT for the U.S. and Canada. There was no fee due to DURECT as a result of terminating the DURECT CHRONOGESIC™ License Agreement.

In March 2008, we announced the appointment of David P. Holveck to the position of President and Chief Executive Officer of the Registrant and its wholly owned subsidiary, Endo Pharmaceuticals Inc., effective April 1, 2008. Mr. Holveck was appointed to the Board of Directors effective March 25, 2008. Prior to joining Endo, Mr. Holveck, was President of Johnson & Johnson Development Corporation and Vice President, Corporate Development of Johnson & Johnson, a pharmaceutical company, since March 2004. Mr. Holveck joined Johnson & Johnson as a company Group Chairman in 1999, following the acquisition of Centocor, Inc., a biotechnology company, by Johnson & Johnson. Mr. Holveck was Chief Executive Officer of Centocor, Inc. at the time of the acquisition. Mr. Holveck joined Centocor in 1983 and progressed through various executive positions. In 1992, he assumed the role of President and Chief Operating Officer and later that year was named President and Chief Executive Officer. Prior to joining Centocor, he had held positions at General Electric Company, Corning Glass Works and Abbott Laboratories. Mr. Holveck is a member of the Board of Trustees for the Fund for West Chester University, the Board of Directors of the Eastern Technology Council and Cleveland Clinic's Industrial Advisory Board. Effective April 7, 2008, Mr. Holveck was appointed to the board of directors of Light Sciences Oncology, Inc., and effective April 14, 2008, he was appointed to the board of directors of Tengion Inc. In connection with Mr. Holveck's appointment as President and Chief Executive Officer of the Company, he has entered into an executive employment agreement, effective as of April 1, 2008.

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

In March 2008, we entered into a licensing agreement with Novartis to obtain the exclusive U.S. marketing rights for the prescription medicine Voltaren® Gel (diclofenac sodium topical gel) 1%. Voltaren® Gel received regulatory approval in October 2007 from the U.S. Food and Drug Administration, becoming the first topical prescription treatment for use in treating pain associated with osteoarthritis and the first new product approved in the U.S. for osteoarthritis since 2001. Voltaren® Gel has been granted

**Table of Contents**

marketing exclusivity in the U.S. as a prescription medicine until at least October 2010. Voltaren® Gel, which is a nonsteroidal anti-inflammatory (NSAID) medication, is indicated for use in treating pain associated with osteoarthritis in joints amenable to topical treatment, such as the knees and those of the hands. Clinical trials have demonstrated Voltaren® Gel to be highly effective in treating osteoarthritis pain in the hands and knees, which are the body's most commonly affected joints. Voltaren® Gel delivers effective pain relief with a favorable safety profile as its systemic absorption is on average 6% of the systemic exposure from a comparable dose of an oral form of diclofenac sodium. Voltaren® Gel will compete in the emerging topical NSAID market, which is expected to grow given the aging U.S. population. Of the estimated 84 million NSAID and Cox-II prescriptions written annually in the U.S., about 40% are osteoarthritis-related. The dollar value of this market is approximately \$3.3 billion, with roughly half of the value coming from NSAIDs and the remainder from Cox-IIs. The Company estimates U.S. peak annual sales for Voltaren® Gel in treating osteoarthritis pain in the range of \$250-300 million. The Company commercialized Voltaren® Gel without delay, initially using one of its two specialty sales forces, consisting of 160 representatives, prior to executing a full physician launch in late May with an additional 275 contract sales representatives targeting primary care physicians who treat patients with osteoarthritis.

In February 2008, we amended our license agreement with Vernalis dated July 14, 2004. In addition to amending certain specific terms and conditions of the license agreement, this amendment sets forth an annual minimum net sales threshold that must be achieved prior to any royalties becoming due. Once the annual minimum net sales threshold is reached, royalty payments will be due on the portion of annual net sales that exceed the threshold. In addition, both parties agreed to terminate the co-promotion agreement effective in February 2008. Also in February 2008, we entered into a termination agreement with Vernalis to terminate the existing loan agreement between the parties. Pursuant to the termination agreement, payment of our outstanding note receivable was satisfied by a cash payment from Vernalis of \$7 million and by way of a reduction in royalties payable to Vernalis pursuant to the amended license agreement as described above.

In February 2008, we along with our partner Penwest, received a notice from Actavis South Atlantic LLC, or Actavis, advising of the filing by Actavis of an ANDA containing a Paragraph IV certification under 21 U.S.C. Section 355(j) for a generic version of Opana® ER (oxymorphone hydrochloride extended-release tablets CII). The Actavis Paragraph IV certification notice refers to Penwest's U.S. Patent Nos. 5,128,143, 5,662,933, 5,958,456 and 7,276,250, which cover the formulation of Opana® ER. These patents are listed in the FDA's Orange Book and expire in 2008, 2013, 2013 and 2023, respectively. In addition to 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. Subsequently, on March 28, 2008, we and Penwest filed a lawsuit against Actavis in the U.S. District Court for the District of New Jersey in connection with Actavis's ANDA. The lawsuit alleges infringement of an Orange Book-listed U.S. patents that covers the Opana® ER formulation. On May 5, 2008, Actavis filed an answer and counterclaims, asserting claims for declaratory judgment that the patents listed in the Orange Book are invalid, not infringed and/or unenforceable, as well as a claim of unfair competition against Endo and Penwest. Endo has filed a motion to dismiss or stay the unfair competition claim, which is pending. We cannot predict the outcome of this litigation. We intend, and we have been advised by Penwest that they too intend, to pursue all available legal and regulatory avenues in defense of Opana® ER, including enforcement of our intellectual property rights and approved labeling.

On or around June 2, 2008, the Company received a notice from Actavis that it had filed an amended ANDA containing Paragraph IV certifications for the 7.5 mg and 15 mg dosage strengths of oxymorphone hydrochloride extended release tablets. On or around July 2, 2008, the Company received a notice from Actavis that it had filed an amended ANDA containing Paragraph IV certifications for the 30 mg dosage strength. Both notices cover Penwest's U.S. Patent Nos. 5,128,143, 7,276,250, 5,958,456 and 5,662,933. On July 11, 2008, the Company and Penwest, filed suit against Actavis in the United States District Court for the District of New Jersey. The lawsuit alleges infringement of an Orange Book-listed U.S. patent that covers the Opana® ER formulation. We cannot predict the outcome of this litigation. We intend, and we have been advised by Penwest that they too intend, to pursue all available legal and regulatory avenues in defense of Opana®ER, including enforcement of our intellectual property rights and approved labeling.

In January 2008, Peter A. Lankau resigned as President and Chief Executive Officer of the Company effective March 1, 2008. Mr. Lankau also resigned from the Company's board of directors effective January 28, 2008.

On December 14, 2007, the Company received a notice from IMPAX advising of the FDA's apparent acceptance for substantive review, as of November 23, 2007, of IMPAX's amended ANDA for a generic version of Opana® ER. IMPAX stated in its letter that the FDA requested IMPAX to provide notification to us and Penwest of any Paragraph IV certifications submitted with its ANDA, as required under section 355(j) of the Federal Food, Drug and Cosmetics Act, or the FDCA Act. Accordingly, IMPAX's letter included notification that it had filed Paragraph IV certifications with respect to Penwest's U.S. Patent Nos. 7,276,250, 5,958,456 and 5,662,933, which cover the formulation of Opana® ER. These patents are listed in the FDA's Orange Book and expire in 2022, 2013 and 2013, respectively. The Company's Opana® ER product has new dosage form exclusivity that prevents final approval of any ANDA by the FDA until the exclusivity expires on June 22, 2009. In addition, because IMPAX's application referred to patents owned by Penwest and contained a Paragraph IV certification under section 355(j) of the FDCA Act, we believe IMPAX's notice triggered the 45-day period under the FDCA Act in which we and Penwest could file a patent infringement action and trigger the automatic 30-month stay of approval. Subsequently, on January 25, 2008, the Company and our partner Penwest filed a lawsuit against IMPAX in the United States District Court for the District of Delaware in connection with IMPAX's ANDA. The lawsuit alleges

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

infringement of certain Orange Book-listed U.S. patents that cover the Opana® ER formulation. Additionally, the lawsuit previously filed by the Company and Penwest on November 15, 2007 against IMPAX remains pending. We cannot predict the outcome of this litigation.

---

**Table of Contents**

On June 16, 2008, the Company received a notice from IMPAX that it had filed an amended ANDA containing Paragraph IV certifications for the 7.5 mg, 15 mg and 30 mg strengths of oxymorphone hydrochloride extended release tablets. The notice covers Penwest's U.S. Patent Nos. 7,276,250, 5,958,456 and 5,662,933. Subsequently, on July 25, 2008, the Company and our partner Penwest filed a lawsuit against IMPAX in the United States District Court for the District of Delaware in connection with IMPAX's ANDA. The lawsuit alleges infringement of certain Orange Book-listed U.S. patents that cover the Opana® ER formulation. Additionally, the lawsuits previously filed by the Company and Penwest on s against IMPAX remain pending. We cannot predict the outcome of this litigation.

**Critical Accounting Estimates Application of Critical Accounting Policies**

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 related to inventories and related inventory reserves, the valuation of long-lived 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.

We consider an accounting estimate to be critical if: (1) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made, and (2) changes in the estimate that are reasonably likely to occur from period to period, or use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition or results of operations. 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 three years, our wholesaler customers, as well as others in the industry, began modifying their business models from arrangements where they derive profits from price arbitrage, 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 five 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, 2008, we received information from our five largest 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.

## **Table of Contents**

### *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, 2008, favorable adjustments for prior periods sales deduction accruals amounted to approximately \$5.1 million.

### *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 an 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;

---

**Table of Contents**

managed care rebates; and

Medicaid and Medicare Part D rebates.

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*

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

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.

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. 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;

---

**Table of Contents**

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.

***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 value. The Company reviews impairments associated with these investments in accordance with Emerging Issues Task Force (EITF) 03-1 and FSP SFAS 115-1 and 124-1, The Meaning of Other-Than-Temporary-Impairment and Its Application to Certain Investments, to determine the classification of the impairment as temporary or other-than-temporary. A temporary impairment results in an unrealized loss being recorded in the other comprehensive income. An impairment that is viewed as other-than-temporary would be recognized in net income. 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 recognized any such other-than-temporary impairment in any of the periods presented.

The cost of securities sold is based on the specific identification method. Generally, 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. Auction-rate securities that are currently illiquid as a result of an inactive market are generally classified as non-current assets as the Company cannot predict when future auctions related to these securities will be successful. 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 and other income, net.

As of September 30, 2008, the Company holds certain assets that are required to be measured at fair value on a recurring basis, including money market funds and available-for-sale securities. The Company's available-for-sale securities include auction-rate securities which consist of municipal bonds with an auction reset feature, the underlying assets of which are student loans that are backed substantially by the federal government and have underlying credit ratings of AA or better. Further, the issuers have been making interest payments promptly. We do not own any collateralized debt obligations or other types of mortgage-backed securities that have recently traded at significant discounts to their par amount.

Auction-rate securities 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.). In an active market, auction-rate securities are bought and sold at each reset date through a competitive bidding process, often referred to as a "Dutch auction". Auctions are successful when the supply and demand of securities are in balance. Financial institutions brokering the auctions would also participate in the auctions to balance the supply and demand. Beginning in the second half of 2007, auctions began to fail for specific securities and in mid-February 2008 auction failures became common, prompting market participants, including financial institutions, to cease or limit their exposure to the auction-rate market. Given the current negative liquidity conditions in the global credit markets, the auction-rate securities market has become inactive. Consequently, our auction-rate securities are currently illiquid through the normal auction process. As a result of the inactivity in the market, quoted market prices and other observable data are not available or their utility is limited. Prior to February 2008, the Company was able to determine the fair value of the auction-rate securities using a market approach valuation technique based on successful auctions of our securities or based on quoted prices in active markets for identical auction-rate securities without any adjustment (Level 1 of the fair value hierarchy).

Since mid-February 2008, the market for auction-rate securities has seen a dramatic decrease in the volume of trades relative to historical levels. At September 30, 2008, (the measurement date), the Company determined that the market for its auction-rate securities was inactive. That determination was made considering that there are very few observable transactions for the auction-rate securities or similar securities, the prices for transactions that have occurred are not current, and the observable prices for those transactions to the extent they exist vary substantially either over time or among market makers, thus reducing the potential usefulness of those observations. In addition, the current lack of liquidity prevents the Company from comparing our securities directly to securities with quoted market prices. Consequently, while we have appropriately considered those observable inputs, ultimately, our auction-rate securities will be classified within Level 3 of the fair value hierarchy described in Note 2 to the Condensed Consolidated Financial Statements in Part I Item I of this Report because significant judgments are required to determine fair value at the measurement date.



---

**Table of Contents**

The Company has determined that an income approach (present value technique) that maximizes the use of observable market inputs is the preferred approach to measuring the fair value of our securities. Specifically, the Company used the discount rate adjustment technique described in Appendix B of Statement 157 to determine an indication of fair value.

To calculate a price for our auction-rate securities, the Company calculates times to maturity, coupon rates, market required rates of return (discount rate) and a discount for lack of liquidity in the following manner:

The Company identifies the times to maturity of the auction-rate securities as the time at which principal is available to the investor. This can occur because the auction-rate security is paying a coupon that is above the required rate of return, and the Company treats the security as being called. It can also occur because the market has returned to normal and the Company treats the auctions as having recommenced. Lastly, and most frequently, the Company treats the principal as being returned as prepayment occurs and at the maturity of the security. The weighted average life used for each security representing time to maturity ranges from 5 to 8 years. The weighted average life measured across the entire auction-rate portfolio is approximately eight (8) years.

The Company calculates coupon rates based on estimated relationships between the maximum coupon rate (the coupon rate in event of a failure) and market interest rates. The representative coupon rates on September 30, 2008 ranged from 5.68% to 5.79%. The Company calculates appropriate discount rates for securities that include base interest rates, index spreads over the base rate, and security-specific spreads. These spreads include the possibility of changes in credit risk over time. At September 30, 2008, the spreads over the base rate for our securities applied to our securities ranged from 215 basis points to 448 basis points.

The Company believes that a market participant would require an adjustment to the required rate of return to adjust for the lack of liquidity. We believe it is not unreasonable to assume a 150 basis points adjustment to the required rate of return and a term of either three, four or five years to adjust for this lack of liquidity. The increase in the required rate of return decreases the prices of the securities. However, the assumption of a three, four or five-year term shortens the times to maturity and increases the prices of the securities. The Company has evaluated the impact of applying each term and the reasonableness of the range indicated by the results. The Company chose to use a four-year term to adjust for the lack of liquidity as we believe it is the point within the range that is most representative of fair value. The Company's conclusion is based in part on the fact that the fair values indicated by the results are reasonable in relation to each other given the nature of the securities and current market conditions.

At September 30, 2008, the fair value of our auction-rate securities, as determined by applying the above described discount rate adjustment technique, was approximately \$257.5 million, representing a 9.7%, or \$27.7 million discount from their original purchase price or par value. Had the Company chosen to apply a three or five year term with respect to the liquidity adjustment, the resultant discount to the original purchase price or par value would have been \$21.7 million and \$31.9 million, respectively. We believe we have appropriately reflected our best estimate of the assumptions that market participants would use in pricing the assets in a current transaction to sell the asset at the measurement date. Accordingly, the carrying value of our auction-rate securities were reduced by approximately \$27.7 million at September 30, 2008, reflecting the change in fair value, which the Company attributes to liquidity issues rather than credit issues. The Company assessed this decline in value to be temporary due to, the financial condition and near-term prospects of the underlying issuers, our intent and ability to retain our investment in the issuers for a period of time sufficient to allow for any anticipated recovery in market value and based on the extent to which fair value is less than par. Accordingly, we recorded a pre-tax \$27.7 million reduction in shareholders' equity in accumulated other comprehensive loss. The Company's carrying value of auction-rate securities at December 31, 2007 was at par value, which approximated fair value at that time. These securities are analyzed each reporting period for other-than-temporary impairment factors. Any future fluctuation in fair value related to these instruments that the Company judges to be temporary, including any recoveries of previous write-downs, would be recorded to accumulated other comprehensive income. If the Company determines that any future valuation adjustment was other-than-temporary, it would record a charge to earnings as appropriate.

Given the inactivity in the auction-rate securities market, the Company cannot predict when future auctions related to our existing auction-rate securities portfolio will be successful. As a result of the current illiquidity in the auction-rate securities markets and the long-term remaining duration of the underlying securities, we have classified these investments as long-term marketable securities in the Condensed Consolidated Balance Sheets at September 30, 2008 and December 31, 2007. Auction-rate securities classified as long-term at September 30, 2008 and December 31, 2007 were \$246.2 million and \$273.5 million, respectively. Since February 2008, when we began to experience failed auctions, and through October 29, 2008, we have divested, without a loss, \$82.4 million of our original par value auction-rate securities, either through successful auctions or mandatory tenders by the issuers. Of this \$82.4 million of original par value auction-rate securities, \$11.3 million was classified as short-term marketable securities at September 30, 2008. Further, we do not employ an asset management strategy or tax planning

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

strategy that would require us to sell any of our existing securities at a loss, and none of our third-party investment advisors has discretion to make investment decisions or execute investment transactions without our consent. Furthermore, there have been no adverse changes in our business or industry that could require us to sell the securities at a loss in order to meet working capital requirements. Furthermore, there have been no

---

## **Table of Contents**

adverse changes in our business or industry that could require us to sell the securities at a loss in order to meet working capital requirements. Of course, there can be no assurance that our current belief that the securities will recover their value will not change, at which time an other-than-temporary impairment could occur. An other-than-temporary impairment would be recorded in the statement of operations.

### ***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.

### ***Valuation of Long-lived Assets***

Long-lived assets, including property, plant and equipment, 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 undiscounted future cash flows of the product and the carrying value is not considered recoverable, impairment exists. An impairment loss is measured as the excess of the asset's carrying value over its fair value, generally based on a discounted future cash flow method, independent appraisals or preliminary offers from prospective buyers. 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.

During the nine months ended September 30, 2008, as a result of our decision to discontinue the development of Rapinyl, we recorded impairment charges of \$8.1 million related to the remaining unamortized portion of our Rapinyl intangible asset, and \$3.1 million to write off certain other assets related to the development of Rapinyl. In addition, during the nine months ended September 30, 2008, we recorded impairment charges totaling \$1.5 million related to the abandonment of certain long-lived assets.

During the year ended December 31, 2007, as a result of the continued lack of commercial success of Synera™, we recorded an impairment charge of \$0.9 million related to the remaining unamortized portion of our ZARS intangible asset.

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 five to twenty years, with a weighted average useful life of approximately 7.7 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 our acquisition of Algos Pharmaceutical Corporation are stated at cost, less accumulated amortization, and are amortized using the straight-line method over their estimated useful lives of seventeen years.

### ***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. We recognize deferred taxes by the asset and liability method of accounting for income taxes. Under the asset and liability method, deferred income taxes are recognized for differences between the financial statement and tax bases of assets and liabilities at enacted statutory tax rates in effect for the years in which the differences are expected to reverse. Significant judgment is required in determining income tax provisions and evaluating tax positions. Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized. The factors used to assess the likelihood of realization are the Company's forecast of future taxable income and available tax planning strategies that could be implemented to realize the net deferred tax assets. Failure to achieve forecasted taxable income in applicable tax jurisdictions could affect the ultimate realization of deferred tax assets and could result in an increase in the Company's effective tax rate on future earnings.



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

On a periodic basis, we evaluate the realizability of our deferred tax assets and liabilities and will adjust such amounts in light of changing facts and circumstances, including but not limited to future projections of taxable income, tax legislation, rulings by relevant tax authorities, tax planning strategies and the progress of ongoing tax audits. Settlement of filing positions that may be challenged by tax authorities could impact the income tax position in the year of resolution.

**Table of Contents**

At September 30, 2008, we had \$169.0 million of gross deferred tax assets, which included the effects of accrued expenses and reserves of \$66.4 million, differences between book basis and tax basis interest expense of \$39.0 million, federal net operating loss and state net operating losses of \$9.8 million, capital loss carryforwards of \$10.8 and other items of \$43.0 million. Deferred tax assets attributable to state net operating losses (NOLs) and capital loss carryforwards are offset by valuation allowances of \$1.5 million and \$10.8 million, respectively. The realization of certain of these future state NOL benefits is not considered more likely than not as they were acquired in connection with our purchase of RxKinetix in 2006 (now known as Endo Pharmaceuticals Colorado LLC). The realization of these state NOL benefits and capital loss carryforward benefits is not considered more likely than not as we do not anticipate sufficient Colorado state taxable income or future capital gain income to use these benefits. At September 30, 2008, the Company had \$28.3 million in capital loss carryforwards, for tax purposes, which expire in 2009. Also, at September 30, 2008, the Company had \$21.5 million in federal NOLs and \$69.6 million in state NOLs which expire at various intervals between 2010 and 2026. In assessing the realizability of deferred tax assets, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period in which those temporary differences become deductible or the NOLs and capital loss carryforwards can be utilized. We believe that for other than certain state NOLs and capital loss carryforwards we will generate sufficient future taxable income to fully realize our deferred tax assets.

On January 1, 2007, the Company adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48). 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.

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. As of January 1, 2007, the Company accrued \$2.2 million in interest and penalties. The total amount of unrecognized tax benefits as of January 1, 2007 was \$7.7 million. The additional unrecognized tax benefits incurred during 2007 and 2008 relate to the uncertain income tax positions previously identified at January 1, 2007.

The total amount of unrecognized tax benefits as of September 30, 2008 is \$10.9 million (including interest and penalties). During the nine months ended September 30, 2008, certain issues were effectively settled with taxing authorities for various tax years after 2002. Accordingly, the Company reversed approximately \$7.0 million of previously recorded unrecognized tax benefits incurred since the adoption of FIN 48, of which \$1.5 million pertained to interest and penalties. The change 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, 2008, or our financial position as of September 30, 2008. 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.

On October 3, 2008, the Emergency Economic Stabilization Act of 2008 (the Act) was signed into law with its objective to promote the stability of the US financial system. The Act authorizes the Treasury Secretary to purchase up to \$700 billion of troubled assets from financial institutions. In addition to other important provisions, the Act also authorizes the Securities and Exchange Commission (SEC) to suspend mark-to-market accounting for any issuer or for any class or category of transaction if the SEC determines it is necessary or in the public interest or consistent with the protection of investors. In addition, the tax credit for research and development, or R&D tax credit, was reinstated and extended through fiscal year 2009. We expect the effect of the reinstatement of the R&D tax credit to lower our income tax expense in the fourth quarter of 2008 by approximately \$2.0 million to \$2.5 million.

**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.



**Table of Contents*****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 year ended December 31, 2005. 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 years ended December 31, 2007 and 2006 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 expected 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. 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 measurement 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, 2008, the total remaining unrecognized compensation cost related to all non-vested stock-based compensation awards amounted to \$43.9 million. The weighted average remaining requisite service period of the non-vested stock options, restricted stock and restricted stock units was 2.6 years, 5 months and 3.27 years, respectively. This unrecognized compensation cost does not include the impact of any future stock-based compensation awards.

***Convertible Senior Subordinated Notes Due 2015***

In April 2008, we issued \$379.5 million in aggregate principal amount of 1.75% Convertible Senior Subordinated Notes due April 15, 2015 (the Convertible Notes) in a private offering for resale to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. We received proceeds of approximately \$371.5 million from the issuance, net of the initial purchaser's discount. The initial purchaser's discount, as well as certain other estimated costs of the offering, has been recorded as a contra-liability account applied to the face amount of the Convertible Notes and are being amortized to interest expense on an effective interest rate basis. The Convertible Notes will mature on April 15, 2015, unless earlier converted or repurchased by us. See Note 15 to Condensed Consolidated Financial Statements in Part I Item I of this Report for further details of the transaction.

We accounted for the issuance of the Convertible Notes in accordance with the guidance in EITF Issue 90-19, *Convertible Bonds with Issuer Option to Settle for Cash upon Conversion* and EITF Issue 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*. Accordingly, we have recorded the Convertible Notes as long-term debt in our condensed consolidated balance sheet as of September 30, 2008.

Concurrently with the issuance of the Convertible Notes, we entered into a privately-negotiated convertible note hedge transaction with affiliates of the initial purchasers. Pursuant to the hedge transaction we purchased common stock call options intended to reduce the potential dilution to our common stock upon conversion of the Convertible Notes. The cost of the call option was approximately \$107.6 million. In addition, we sold warrants to affiliates of certain of the initial purchasers whereby they have the option to purchase up to approximately 13.0 million shares of our common stock at an initial strike price of \$40.00 per share. See Note 15 to Condensed Consolidated Financial Statements in Part I Item I of this Report for further details.

In addition to entering into the convertible note hedge transaction and the warrant transaction, we entered into a privately-negotiated accelerated share repurchase agreement with the same counterparty, as part of our broader share repurchase program described in Note 10 to the Condensed

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

Consolidated Financial Statements in Part I Item I of this Report. We used approximately \$57 million representing a portion of the net proceeds from the Convertible Notes offering to pay the cost of the convertible note hedge

**Table of Contents**

transaction, taking into account the proceeds from the warrant transaction, and used the balance of the net proceeds or approximately \$314 million, together with approximately \$11 million of cash on hand, to repurchase a variable number of shares of our common stock pursuant to the accelerated share repurchase agreement entered into as part of our broader share repurchase program. See Note 10 to the Condensed Consolidated Financial Statements in Part I Item I of this Report for further details.

In connection with hedging the transactions described above, our counterparty or its affiliates may purchase Endo common stock and enter into various derivative transactions with respect to our common stock at, and possibly after, the pricing of the notes and may purchase or sell Endo common stock in secondary market transactions following the pricing of the notes. These activities could have the effect of increasing, or preventing a decline in, the price of our common stock concurrently with and possibly following the pricing of the notes. The counterparty or its affiliates are likely to modify their respective hedge positions from time to time prior to conversion or maturity of the notes by purchasing and selling shares of our common stock, other Endo securities or other instruments they may wish to use in connection with such hedging.

Paragraph 11(a) of SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities, provides that contracts issued or held by an entity that are both (1) indexed to the entities own common stock and (2) classified in stockholders' equity in its statement of financial position are not considered to be derivative financial instruments under SFAS No. 133 if the provisions of EITF Issue 00-19 are met.

We accounted for the call options, warrants, and accelerated share repurchase agreement in accordance with the guidance in EITF Issue 00-19. The call options, warrants, and accelerated share repurchase agreement meet the requirements of EITF Issue 00-19 to be accounted for as equity instruments. The cost of the call options and the proceeds related to the sale of the warrants are included in additional paid-in capital in our condensed consolidated balance sheet as of September 30, 2008. The common stock acquired through the accelerated share repurchase agreement has been included in treasury stock in our condensed consolidated balance sheet as of September 30, 2008.

We are required to monitor the Convertible Notes, call options, warrants and accelerated share repurchase agreement for compliance with the provisions of EITF Issue 00-19 and paragraph 11(a) of SFAS No. 133 on a quarterly basis. Should the issuance of the Convertible Notes, the purchase of the call options, the sale of the warrants, or the accelerated repurchase of common stock fail to qualify under the provisions of EITF 00-19 or paragraph 11(a) of SFAS No. 133, we would be required to recognize derivative instruments in connection with the transaction, include the effects of the transaction in assets or liabilities instead of equity, and recognize changes in the fair values of the assets or liabilities as they occur in the consolidated net income until the provisions of EITF Issue 00-19 and paragraph 11(a) of SFAS No. 133 are met.

In accordance with SFAS No. 128, Earnings Per Share, the Convertible Notes, call options, and warrants have not been considered for purposes of the diluted net income per share calculation as their effect would be anti-dilutive. Should our common stock price exceed the conversion price of the notes or the strike price of the warrants, we will include the effect of the additional shares that may be issued in our diluted net income per share calculation using the treasury stock method.

**Results of Operations for the Three and Nine Months Ended September 30, 2008 Compared to the Three and Nine Months Ended September 30, 2007**

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, impairment long-lived assets, separation benefits, 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, 2008 increased by \$47.3 million or 18%, and \$132.2 million or 17%, respectively, compared to the same periods of 2007. This increase in net sales is primarily driven by increased net sales of Lidoderm® as well as increased net sales of Opana® ER and Opana. For the three months ended September 30, 2008, the total sales growth of 18% was primarily driven by increased sales volume of 26%, which was partially offset by price decreases of 8%. The price decrease was primarily driven by contracting strategy across our product categories. For the nine months ended September 30, 2008, increased sales volume contributed 16% of the total sales growth of 17%, while price increases contributed the remaining 1% of the total sales growth.

**Table of Contents**

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, 2008 and 2007 (dollars in thousands):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2008		2007		2008		2007	
	\$	%	\$	%	\$	%	\$	%
Lidoderm®	\$ 194,138	61	\$ 174,326	64	\$ 559,712	61	\$ 496,926	63
Opana® ER and Opana®	41,496	13	23,998	9	128,171	14	78,274	10
Percocet®	31,371	10	31,644	12	96,553	11	91,183	12
Frova®	14,306	5	13,465	5	41,247	5	38,365	5
Voltaren® Gel	10,299	3			11,296	1		
Other brands	2,748	1	2,707	1	8,031	1	7,837	1
<b>Total brands</b>	<b>294,358</b>	<b>93</b>	<b>246,140</b>	<b>91</b>	<b>845,010</b>	<b>93</b>	<b>712,585</b>	<b>91</b>
<b>Total generics</b>	<b>22,410</b>	<b>7</b>	<b>23,330</b>	<b>9</b>	<b>68,190</b>	<b>7</b>	<b>68,441</b>	<b>9</b>
<b>Total net sales</b>	<b>\$ 316,768</b>	<b>100</b>	<b>\$ 269,470</b>	<b>100</b>	<b>\$ 913,200</b>	<b>100</b>	<b>\$ 781,026</b>	<b>100</b>

*Lidoderm®*. Net sales of Lidoderm® for the three months ended September 30, 2008 increased by \$19.8 million or 11% over the comparable period in 2007. Net sales of Lidoderm® for the nine months ended September 30, 2008 increased by \$62.8 million or 13% over the comparable period in 2007. The increase is primarily attributable to continued prescription growth of the product during both the third quarter and nine months ended September 30, 2008. We believe the continued growth of Lidoderm® is driven by the product's proven clinical effectiveness combined with our continued promotional activities positioning Lidoderm® as the only prescription analgesic patch specifically designed to effectively relieve the localized pain of post-herpetic neuralgia (PHN) with low risk of systemic side effects and drug-to-drug interactions. We believe we also are benefiting from our educational programs designed to improve our target audience's understanding regarding the localized pain of PHN. In addition, our managed care efforts are focused on Medicare Part D, which consists predominately of elderly patients who are at greater risk for PHN. Medicare Part D has also served to raise overall awareness among formulary decision-makers resulting in an ongoing assessment of how best to secure access for patients. As expected, we recognize that the growth of this product is beginning to slow as it matures and competition in the topical pain market increases.

*Opana® ER and Opana®*. Net sales of Opana® ER and Opana® for the three months ended September 30, 2008 increased by \$17.5 million or 73% over the comparable period in 2007. Net sales of Opana® ER and Opana® for the nine months ended September 30, 2008 increased by \$49.9 million or 64% over the comparable periods in 2007. 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. 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.

*Percocet®*. Net sales of Percocet® for the three months ended September 30, 2008 decreased by \$0.3 million or 1% over the comparable period in 2007. Net sales of Percocet® for the nine months ended September 30, 2008 increased by \$5.4 million or 6% over the comparable period in 2007. The increase is primarily attributable to improved pricing during the nine months ended September 30, 2008.

*Frova®*. Net sales of Frova® for the three months ended September 30, 2008 increased by \$0.9 million or 6% over the comparable period in 2007. Net sales of Frova® for the nine months ended September 30, 2008 increased by \$2.9 million or 8% over the comparable 2007 period. 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.

*Voltaren® Gel*. Net sales of Voltaren® Gel for the three and nine months ended September 30, 2008 were \$10.3 million and \$11.3 million, respectively. The Company launched Voltaren® Gel in March 2008.

*Generics*. Net sales of our generic products for the three months ended September 30, 2008 decreased by \$0.9 million or 4% over the comparable period in 2007. Net sales of our generic products for the nine months ended September 30, 2008 were relatively unchanged when compared to the same period in 2007. Generic competition with all of our products may continue to have a material impact on our results of operations and cash flows in the future.





**Table of Contents****Gross Margin, Costs and Expenses**

The following table sets forth costs and expenses for the three and nine months ended September 30, 2008 and 2007:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	2007	% Change	2008	2007	% Change
	(in thousands)			(in thousands)		
Costs of sales	\$ 71,027	\$ 51,009	39%	\$ 190,554	\$ 155,324	23%
Selling, general and administrative	116,249	109,833	6%	357,775	292,419	22%
Research and development	22,165	28,290	(22)%	82,244	83,663	(2)%
Impairment of long-lived assets			0%	8,083		100%
<b>Total costs and expenses</b>	<b>\$ 209,441</b>	<b>\$ 189,132</b>	<b>11%</b>	<b>\$ 638,656</b>	<b>\$ 531,406</b>	<b>20%</b>

**Costs of Sales and Gross Margin.** Costs of sales for the three months ended September 30, 2008 increased by \$20.0 million or 39% over the comparable period in 2007. Costs of sales for the nine months ended September 30, 2008 increased by \$35.2 million or 23% over the comparable period in 2007. Costs of sales as a percent of net sales for the three months ended September 30, 2008 increased to 22% from 19% in the comparable period in 2007. Costs of sales as a percent of net sales for the nine months ended September 30, 2008 increased to 21% from 20% in the comparable period in 2007. These increases in costs of sales are primarily due to the increase in amortization expense in 2008. In 2008, the Company recorded intangible assets totaling \$175.7 million, \$46.7 million of which resulted from the settlement of our note receivable with Vernalis, and the remaining \$129.0 million resulted from our licensing arrangement with Novartis AG for Voltaren. The additional increase in costs of sales as a percentage of net sales for the three months ended September 30, 2008 compared to the same period of 2007 is due to an overall price decrease of 8%. Gross profit margins for the three months ended September 30, 2008 decreased to 78% from 81% in the comparable 2007 period. Gross profit margins for the nine months ended September 30, 2008 decreased to 79% from 80% in the comparable 2007.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses for the three months ended September 30, 2008 increased by 6% to \$116.2 million from the comparable 2007 period. Selling, general and administrative expenses for the nine months ended September 30, 2008 increased by 22% to \$357.8 million from the comparable 2007 period. These increases are primarily due to an increase in sales and promotional efforts in 2008 over the comparable 2007 periods due to our continued investment in our commercial business and our infrastructure to support our key on-market products and pipeline. Selling, general and administrative expenses in 2008 include the impact of the 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, as well as certain costs incurred during the nine months ended September 30, 2008 to obtain an additional 275 contract sales representatives for the launch of Voltaren® Gel. In addition, during the nine months ended September 30, 2008, we recognized \$10.5 million in separation benefits provided to former employees. These increases have been partially offset by cost reduction initiatives and headcount reduction completed in July 2008.

**Research and Development Expenses.** Research and development expenses for the three months ended September 30, 2008 decreased to \$22.2 million from \$28.3 million in the comparable period in 2007. Research and development expenses for the nine months ended September 30, 2008 decreased to \$82.2 million from \$83.7 million in the comparable 2007 period. Research and development expense reflects the Company's ongoing commitment to clinical research as well as the impact of the Company's external collaborations. The reduction in expense for the three and nine months ended September 30, 2008 when compared to the same periods in 2007 is primarily attributable to our decision to discontinue the development of Rapinyl™ and the ketoprofen patch in July 2008. This was partially offset by a \$3.1 million charge recorded during the nine months ended September 30, 2008 related to the disposal of long lived assets as a result of our decision to discontinue the development of Rapinyl™. In addition, during the nine months ended September 30, 2008 we recorded a \$3.8 million charge associated with research and development commitments we incurred as a result of our decision to discontinue the development of Rapinyl™.

**Impairment of Other Intangible Assets**

As a result of our decision to discontinue the development of Rapinyl™ we recorded an impairment charge in the amount of \$8.1 million in the second quarter of 2008 to write-off the remaining balance of our Rapinyl™ intangible asset.

**Interest Expense**

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

Interest expense for the three months and nine months ended September 30, 2008 was \$2.8 million and \$5.5 million, respectively. These changes are primarily due to interest recognized on our 1.75% Convertible Senior Subordinated Notes issued in April 2008.

*Interest and Other Income*

Interest and other income for the three months ended September 30, 2008 decreased to \$5.0 million from \$9.8 million in the comparable 2007 period. For the nine months ended September 30, 2008, interest and other income decreased to \$21.3 million from \$25.1 million in the comparable 2007 period. The changes in interest and other income are a result of the fluctuations in the amount of cash invested in interest-bearing accounts, including our money market funds and auction-rate securities and the yields on those investments. As a result of the current environment in the global credit markets, beginning in January 2008, the Company chose to reduce its exposure to auction rate securities and ceased all purchases of auction-rate securities effective February 1, 2008, prior to when we began to experience failed auctions. In March 2008, the Board of Directors approved an amended investment policy which seeks to preserve the value of capital,

**Table of Contents**

consistent with maximizing return on the Company's investment, while maintaining adequate liquidity. As a result, yields on our interest-bearing accounts have generally been lower than yields earned on the same or similar investments during the comparable periods of 2007.

***Income Tax***

Income tax for the three months ended September 30, 2008 increased to \$41.3 million from \$30.9 million in the comparable 2007 period. Income tax expense for the nine months ended September 30, 2008 increased to \$103.5 million from \$97.8 million in the comparable 2007 period. The net increase in income tax expense for the three and nine months ended September 30, 2008 is primarily the result of an increase in income before income tax and an increase in the Company's effective tax rate. Our effective tax rate for the three months ended September 30, 2008 increased to 37.7% from 34.3% in the comparable period of 2007, while our effective rate for the nine months ended September 30, 2008 increased to 35.7% from 35.6% in the comparable period of 2007. The increase in the effective income tax rate is primarily related to the absence of the federal R&D tax credit as of September 30, 2008 and a lower amount of tax exempt interest. For the nine months ended September 30, 2008, these increases were partially offset by the reversal of approximately \$7.0 million of previously recorded unrecognized tax benefits incurred since the adoption of FIN 48, of which \$1.5 million pertained to interest and penalties. As of September 30, 2008, the federal R&D tax credit had expired for taxable years beginning after December 31, 2007. On October 3, 2008, the Emergency Economic Stabilization Act of 2008 (the Act) was signed into law. Under the provisions of the Act the tax credit for research and development, or federal R&D tax credit, was reinstated and extended through fiscal year 2009. For the three months and nine months ended September 30, 2008, the effective tax rate appropriately did not reflect a benefit for the federal R&D tax credit. We expect this benefit to be recognized in the fourth quarter of 2008.

***2008 Outlook***

We estimate our 2008 net sales to be between \$1.245 billion and \$1.280 billion. Of course, there can be no assurance that the Company will achieve these results. Our estimate is based on the continued growth of our branded product portfolio, primarily driven by prescription demand for Lidoderm® and Opana® ER and Opana®, as well as the launch of Voltaren® Gel, our newly licensed topical prescription product for use in treating pain associated with osteoarthritis. We expect gross profit margins to decline slightly over the remainder of 2008 as a result of royalties we expect to incur on our net sales of Opana® ER in the fourth quarter of 2008. We expect selling, general and administrative expenses for the remainder of 2008 to include additional incremental costs in support of the Voltaren® Gel launch. As a result of the completed business review, we are in the process of changing our business structure to reduce our utilization of outside consultants and create a more efficient operating model. We expect the anticipated benefit from these changes to slightly offset the increased expenses we expect to incur over the remainder of 2008 relating to the additional launch costs. R&D expenses are expected to remain stable for the remainder of 2008 despite our decision to discontinue developing two of our late-stage development products. While we expect some benefit to the R&D expense line over the longer term as a result of these decisions, we have contractual and other obligations requiring us to complete ongoing clinical trials and are also required to transition these products back to the respective collaborative partners. In addition, as a result of the completion of the R&D review we are in the process of expanding on and building certain core competencies that will affect the R&D spend going forward.

***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, capital expenditures, and debt service payments.

Cash, cash equivalents and current marketable securities were approximately \$659.5 million at September 30, 2008 compared to \$663.7 million at December 31, 2007. The Company continues to maintain a sufficient level of working capital, which was approximately \$699.1 million at September 30, 2008, increasing from \$668.5 million at December 31, 2007. In 2008 and future periods, the Company expects cash generated by its U.S. operations, together with existing cash, cash equivalents, and liquid marketable securities, to be sufficient to cover cash needs for working capital for operations, licenses, milestone payments, capital expenditures and debt service payments.

Cash and cash equivalents at September 30, 2008 and December 31, 2007 primarily consisted of bank deposits, time deposits and money market funds. Cash equivalents are primarily highly liquid investments with original maturities of three months or less at the time of purchase and are recorded at cost, which approximates fair value. Current marketable securities at September 30, 2008 consisted of investments in open-end mutual funds that invest in U.S. government securities and certain auction rate securities that have been called by the issuer and settled at original par value subsequent to September 30, 2008.

During the nine months ended September 30, 2008, we purchased \$15.0 million of equity securities consisting of investments in open-end mutual funds that invest in U.S. government securities and \$118.7 million of original par value auction-rate securities and variable rate demand obligations. In January 2008, the Company chose to reduce its exposure to auction-rate securities and ceased all purchases of auction-rate securities effective February 1, 2008, prior to when we began to experience failed auctions. During the nine months ended September 30, 2008,

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

we sold \$113.8 million of original par value variable-rate demand obligations. During the same period, we also sold \$301.4 million of original par value auction-rate securities and a \$5.0 million original par value municipal bond. There were no realized holding gains or losses resulting from the sales of our available for sale securities during the nine months ended September 30, 2008.

**Table of Contents**

Given the inactivity in the auction-rate securities market, the Company cannot predict when future auctions related to our existing auction-rate securities portfolio will be successful. As a result of the current illiquidity in the auction-rate securities markets and the long-term remaining duration of the underlying securities, we have classified these investments as long-term marketable securities in the Condensed Consolidated Balance Sheets at September 30, 2008 and December 31, 2007. Auction-rate securities classified as long-term at September 30, 2008 and December 31, 2007 were \$246.2 million and \$273.5 million, respectively. Since February 2008, when we began to experience failed auctions, and through October 29, 2008, we have divested, without a loss, \$82.4 million of our original par value auction-rate securities, either through successful auctions or mandatory tenders by the issuers. Of this \$82.4 million of original par value auction-rate securities, \$11.3 million was classified as short-term marketable securities at September 30, 2008. Further, we do not employ an asset management strategy or tax planning strategy that would require us to sell any of our existing securities at a loss, and none of our third-party investment advisors has discretion to make investment decisions or execute investment transactions without our consent. Furthermore, there have been no adverse changes in our business or industry that could require us to sell the securities at a loss in order to meet working capital requirements. Of course, there can be no assurance that our current belief that the securities will recover their value will not change, at which time an other-than-temporary impairment could occur. An other-than-temporary impairment would be recorded in the statement of operations.

As of October 29, 2008, all of our auction-rate securities in which we invest remain with AA and AAA underlying ratings. Specifically, 70% of our auction-rate securities are AAA rated and 30% are AA rated. The underlying assets of our auction-rate securities are student loans. Student loans are insured by either the Federal Family Education Loan Program, or FFELP, or a combination of FFELP and other monoline insurers such as Ambac Assurance Corp., or AMBAC, and MBIA Insurance Corp., or MBIA. As of October 28, 2008, MBIA was rated Baa2 by Moody's and A- by Standard and Poor's. AMBAC was rated Aa3 by Moody's and AA by Standard and Poor's. Although our auction-rate securities continue to pay interest according to their stated terms, based on valuation models, the carrying value of our auction-rate securities were reduced by approximately \$27.7 million at September 30, 2008, reflecting the change in fair value, which the Company attributes to liquidity issues rather than credit issues. The Company assessed this decline in value to be temporary due to, the financial condition and near-term prospects of the underlying issuers, our intent and ability to retain our investment in the issuers for a period of time sufficient to allow for any anticipated recovery in market value and based on the extent to which fair value is less than par. Accordingly, we recorded a pre-tax \$27.7 million reduction in shareholders' equity in accumulated other comprehensive loss. The Company's carrying value of auction-rate securities at December 31, 2007 was at par value, which approximated fair value. These securities are analyzed each reporting period for other-than-temporary impairment factors.

Of course, there can be no assurance that our current belief that the securities will recover their value will not change, at which time an other-than-temporary impairment could occur. An other-than-temporary impairment would be recorded in the statement of operations. If uncertainties in the credit and capital markets continue, these markets deteriorate further or we experience any additional cover rating downgrades on any investments in our portfolio (including on our auction-rate securities), we may incur additional impairments in future periods, which could negatively affect our financial condition, cash flow or reported earnings. Any of these events could materially affect our results of operations and our financial condition. In the event we need to access these funds, we could be required to sell these securities at an amount below our original purchase value. However, based on our ability to access our cash and cash equivalents and our other liquid investments, and our expected operating cash flows, we do not expect to be required to sell these securities at a loss. However, there can be no assurance that we will not have to sell these securities at a loss.

The following table sets forth the fair value of our long-term auction-rate securities by type of security and underlying credit rating as of September 30, 2008 (in thousands):

	Underlying Credit Rating(1)		Total
	AAA	AA	
<i>Underlying security:</i>			
Student loans	\$ 172,747	\$ 73,421	\$ 246,168
<i>Total auction-rate securities included in long-term marketable securities</i>	<i>\$ 172,747</i>	<i>\$ 73,421</i>	<i>\$ 246,168</i>

(1) Our auction-rate securities maintain split ratings. For purposes of this table, securities are categorized according to their lowest rating. We believe our exposure to loss is limited, despite the current illiquidity in the marketplace. We do not own any collateralized debt obligations or other types of mortgage-backed securities that have traded at significant discounts to their par amount. In addition, the underlying credit ratings of our securities are AA or better and issuers have been making interest payments promptly. Since February 2008 when we began to

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

experience failed auctions, and through October 29, 2008, we have divested, without a loss, \$82.4 million of our original par value auction-rate securities, either through successful auctions or mandatory tenders by the issuers. Of this \$82.4 million of original par value securities, \$11.3 million was classified as short-term marketable securities at September 30, 2008.

---

**Table of Contents**

Further, we do not employ an asset management strategy or tax planning strategy that would require us to sell any of our existing securities at a loss, and none of our third-party investment advisors have discretion to make investment decisions or execute investment transactions without our consent. Furthermore, there have been no adverse changes in our business or industry that could require us to sell the securities at a loss in order to meet working capital requirements.

In October 2008, UBS AG ( UBS ) made an offer (the Offer ) of Auction Rate Securities Rights (the Rights ) to the Company and other clients of UBS Securities LLC and UBS Financial Services Inc. (collectively, the UBS Entities ), pursuant to which the Company is entitled to sell to UBS all auction-rate securities held by the Company as of February 13, 2008 in a UBS account (the Eligible Auction Rate Securities ). The Rights permit the Company to require UBS to purchase the Eligible Auction Rate Securities for a price equal to original par value plus any accrued but unpaid dividends or interest beginning on June 30, 2010 and ending on July 2, 2012 (the Expiration Date ). As of September 30, 2008, we had Eligible Auction Rate Securities with original par value of \$266.4 million, representing 93% of our total auction-rate securities portfolio at par. The remaining seven percent (7%), or \$18.8 million, of our auction-rate securities portfolio is not held in a UBS account and therefore is not subject to the Offer.

The Offer is being made pursuant to agreements in principle entered into by the UBS Entities with the Securities and Exchange Commission, the New York Attorney General, the Texas State Securities Board and other state regulatory agencies represented by North American Securities Administrators Association, and a settlement agreement with the Massachusetts Securities Division to settle investigations brought by each of these agencies against the UBS Entities relating to the sale and marketing of auction rate securities. The alleged conduct underlying these investigations suggested that the UBS Entities marketed auction rate securities as cash alternatives but failed to adequately disclose liquidity risk. We may elect to accept the Offer any time prior to 5:00 p.m., New York City time, on November 14, 2008 (unless extended by UBS). In order to accept the Offer, we will be required to complete an acceptance form which releases UBS and its employees and agents from all claims except claims for consequential damages directly or indirectly relating to UBS 's marketing and sale of auction rate securities.

If the Company accepts the Offer, the Company would grant to the UBS Entities the sole discretion and right to sell or otherwise dispose of, and/or enter orders in the auction process with respect to the Eligible Auction Rate Securities on the Company 's behalf until the Expiration Date, without prior notification, so long as the Company receives a payment of par value plus any accrued but unpaid dividends or interest upon any sale or disposition.

In addition, if the Company accepts the Offer, the UBS Entities will offer no net cost loans to the Company, should the Company desire to borrow money prior to the commencement of the exercise period for the Rights. The Company may be eligible for no net cost loans for an amount up to 75% of the market value of the Eligible Auction-Rate Securities at the time of the loan, should the Company desire to borrow money prior to the commencement of the exercise period for the Rights. The loans will become fully payable as soon as UBS receives the proceeds from a purchase of the Eligible Auction Rate Securities.

The Offer made by UBS in October 2008, represents a substantive change in facts and circumstances occurring after September 30, 2008, that could change the Company 's view about whether it intends to hold the impaired securities until their anticipated recovery. Accordingly, the Offer and our decision whether or not to ultimately accept it, could affect the Company 's intent in the fourth quarter of 2008. The Company is required to evaluate its intent as of the reporting date using facts and circumstances that existed as of that date. As such, the Offer was not a factor considered in the Company 's assessment of whether, at September 30, 2008, the Company had the intent and ability to hold its impaired securities until their anticipated recovery.

If the Company accepts the Offer, an enforceable legal right by and between the Company and UBS would exist. At that time, the commitment made by UBS to purchase the Eligible Auction-Rate Securities during the exercise period of the Rights will likely be considered a free standing put option between UBS and the Company which the Company will have to recognize as an asset, measured at its fair value, with the resultant gain recognized in earnings during the fourth quarter of 2008. The existence of the put option would not affect the separate determination of the fair value of the auction-rate securities. Currently, the Company has determined that the decline in fair value of its auction-rate securities is temporary for several reasons, including our intent and ability to hold the securities until their anticipated recovery. If we accept the Offer, the Company may no longer have the intent to hold the securities until their anticipated recovery. Accordingly, any decline in fair value will likely be considered an other-than-temporary impairment charge recognized in earnings during the fourth quarter of 2008 and measured as the amount of unrealized loss in accumulated other comprehensive income related to the auction-rate securities as of the date we accept the Offer.



**Table of Contents**

**Net Cash Provided by Operating Activities.** Net cash provided by operating activities was \$228.1 million for the nine months ended September 30, 2008, compared to \$287.4 million for the nine months ended September 30, 2007. Significant components of our operating cash flows for the nine months ended September 30, 2008 and 2007 are as follows:

	<b>Nine Months Ended September 30, 2008</b>		<b>2007</b>	
<b>Cash Flow Data-Operating Activities:</b>				
Net income	\$ 186,799		\$ 176,842	
Depreciation and amortization	32,367		12,996	
Stock-based compensation	13,713		10,940	
Impairment of long-lived assets	12,680			
Interest earned on available-for-sale securities	(3,069)		(3,477)	
Changes in assets and liabilities which (used) provided cash:	(6,979)		77,859	
Other, net	(7,402)		12,271	
<b>Net cash provided by operating activities</b>	<b>\$ 228,109</b>		<b>\$ 287,431</b>	

Net cash provided by operating activities decreased to \$228.1 million for the nine months ended September 30, 2008, from \$287.4 million for the comparable 2007 period. This decrease is primarily a result of (1) a \$68.2 million decrease in the cash flow impact of accounts receivable as a result of the significant collections during the nine months ended September 30, 2007 for 2006 sales of our generic oxycodone ER product which we ceased selling as of December 31, 2006; and (2) a \$10.0 million increase in cash outflows from inventory purchases during the nine months ended September 30, 2008. This was partially offset by a \$15.0 million decrease in income tax payments during the nine months ended September 30, 2008 compared to the same period in 2007.

**Net Cash Provided by/used in Investing Activities.** Net cash provided by investing activities was \$153.5 million for the nine months ended September 30, 2008 compared to net cash used in investing activities of \$630.6 million during the same period of 2007. During the nine months ended September 30, 2008, we collected \$3.3 million in principal payments from Vernalis on our note receivable and \$420.8 million from the sale of available-for-sale securities. These cash inflows were partially offset by the purchase of \$134.2 million of available-for-sale securities, an \$85 million upfront payment to Novartis AG to obtain the exclusive U.S. marketing rights for the prescription medicine Voltaren® Gel, a \$20 million investment in a privately-held company that is focused on the development of an innovative treatment for certain types of cancer, and \$16.5 million for capital expenditures. During 2008, the first dosage of EN 3285 was administered to a patient enrolled in a clinical phase III trial. Accordingly, in March 2008, we paid \$15 million in additional contingent purchase price consideration to the former shareholders of RxKinetix. 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. 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 an existing equity method investee. These out flows were partially offset by sales of available-for-sale securities of \$63.0 million.

**Net Cash Used in Financing Activities.** Net cash used in financing activities increased to \$99.0 million for the nine months ended September 30, 2008 from \$10.0 million for the nine months ended September 30, 2007. In connection with the April 2008 issuance of our 1.75% Convertible Senior Subordinated Notes, we received proceeds of approximately \$371.5 million, net of the original purchaser's discount. Concurrently with the issuance of the Convertible Notes, we entered into a privately-negotiated convertible note hedge transaction with affiliates of the initial purchasers. The cost of the call option was approximately \$107.6 million. In addition, we sold warrants to affiliates of certain of the initial purchasers whereby they have the option to purchase up to approximately 13.0 million shares of our common stock at an initial strike price of \$40.00 per share. We received approximately \$50.4 million in cash proceeds from the sale of these warrants. In addition to entering into the convertible note hedge transaction and the warrant transaction, we entered into a privately-negotiated accelerated share repurchase agreement with the same counterparty, as part of our broader share repurchase program. We used approximately \$57 million representing a portion of the net proceeds from the Convertible Notes offering to pay the cost of the convertible note hedge transaction, taking into account the proceeds from the warrant transaction, and used the balance of the net proceeds or approximately \$314 million, together with approximately \$11 million of cash on hand, to repurchase a variable number of shares of our common stock pursuant to the accelerated share repurchase agreement entered into as part of our broader share repurchase program. Pursuant to the accelerated share repurchase agreement, the counterparty delivered 11.9 million shares of our common stock to the Company on the day that the note offering closed, April 15, 2008. On August 14, 2008, Endo received approximately 1.4 million additional shares of our common stock based on the volume weighted average price of our common stock during a specified averaging period set forth by the accelerated share repurchase agreement. In addition to the accelerated share repurchase,

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

beginning in April 2008 we made open market purchases of our common stock as part of our broader share repurchase program. As of September 30, 2008, we purchased approximately 3.9 million shares of our common stock on the open market for a total purchase price of approximately \$88.7 million.

**Table of Contents**

**Working Capital.** Working capital increased to \$699.1 million as of September 30, 2008 from \$668.5 million as of December 31, 2007. The components of our working capital as of September 30, 2008 and December 31, 2007 are below:

	September 30, 2008	December 31, 2007
Total current assets	\$ 1,090,321	\$ 1,065,447
Less: Total current liabilities	391,173	396,958
<b>Working capital</b>	<b>\$ 699,148</b>	<b>\$ 668,489</b>

Working capital increased primarily as a result of the overall impact of cash flow from operations. This was partially offset by the impact of (1) an \$85 million upfront payment to Novartis AG to obtain the exclusive U.S. marketing rights for the prescription medicine Voltaren® Gel; (2) a \$20 million investment in a privately-held company; and (3) a net cash outflow in the amount of \$99.4 associated with certain financing activities including the convertible note offering, note hedge, sale of common stock warrants and the accelerated share repurchase.

**Convertible Senior Subordinated Notes due 2015.** As discussed in Note 15 to the Condensed Consolidated Financial Statements in Part I, Item I of this Report, in April 2008, we issued \$379.5 million in aggregate principal amount of 1.75% Convertible Senior Subordinated Notes due April 15, 2015 (the Convertible Notes) in a private offering for resale to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The initial purchasers of the Convertible Notes had the option to purchase up to an additional \$34.5 million in principal amount of notes from us to cover over-allotments, which was exercised in full and is included in the aggregate principal amount of \$379.5 million.

We received proceeds of approximately \$371.5 million from the issuance, net of the initial purchaser's discount. The initial purchaser's discount, as well as certain other estimated costs of the offering, has been recorded as a contra-liability account applied to the face amount of the Convertible Notes and are being amortized to interest expense on an effective interest rate basis. Interest is payable semi-annually in arrears on each April 15 and October 15 beginning on October 15, 2008. We recognized \$3.7 million of interest expense for the nine months ended September 30, 2008. The Convertible Notes will mature on April 15, 2015, unless earlier converted or repurchased by us.

Concurrently with the issuance of the Convertible Notes, we entered into a privately-negotiated convertible note hedge transaction with affiliates of the initial purchasers. Pursuant to the hedge transaction we purchased common stock call options intended to reduce the potential dilution to our common stock upon conversion of the Convertible Notes by effectively increasing the initial conversion price of the notes to \$40.00 per share, representing a 61.1% conversion premium over the closing price of our common stock on April 9, 2008 of \$24.85 per share. The call options allow us to purchase up to approximately 13.0 million shares of our common stock at an initial strike price of \$29.20 per share. The call options expire on April 15, 2015 and must be net-share settled. The cost of the call option was approximately \$107.6 million. In addition, we sold warrants to affiliates of certain of the initial purchasers whereby they have the option to purchase up to approximately 13.0 million shares of our common stock at an initial strike price of \$40.00 per share. The warrants expire on various dates from July 14, 2015 through October 6, 2015 and must be net-share settled. We received approximately \$50.4 million in cash proceeds from the sale of these warrants.

In addition to entering into the convertible note hedge transaction and the warrant transaction, we entered into a privately-negotiated accelerated share repurchase agreement with the same counterparty, as part of our broader share repurchase program described in Note 10 to the Condensed Consolidated Financial Statements in Part I Item I of this Report. We used approximately \$57 million representing a portion of the net proceeds from the Convertible Notes offering to pay the cost of the convertible note hedge transaction, taking into account the proceeds from the warrant transaction, and used the balance of the net proceeds or approximately \$314 million, together with approximately \$11 million of cash on hand, to repurchase a variable number of shares of our common stock pursuant to the accelerated share repurchase agreement entered into as part of our broader share repurchase program. Pursuant to the accelerated share repurchase agreement, the counterparty delivered 11.9 million shares of our common stock to the Company on the day that the note offering closed, April 15, 2008. On August 14, 2008, Endo received approximately 1.4 million additional shares of our common stock based on the volume-weighted average price of our common stock during a specified averaging period set forth by the accelerated share repurchase agreement.

**Tax Sharing Agreement.** On July 14, 2000, Endo Pharma LLC was formed in connection with our acquisition of 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 former members of management have an interest. Upon the exercise of these stock options, only currently

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

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 were 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, 2008, all 36 million of these stock options had been exercised into shares of our common stock held by Endo Pharma LLC.

---

## **Table of Contents**

During the year ended December 31, 2007, the final 75,259 shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised. We were obligated, under our amended tax sharing agreement, to pay to Endo Pharma LLC an additional tax benefit amount of approximately \$0.7 million. 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 were paid during the nine months ended September 30, 2008, and the remaining tax benefit amount attributable to 2007 was paid in October 2008. This represents the final tax sharing payment due to Endo Pharma LLC.

As of September 30, 2008, there were no options remaining to be granted under the Endo Pharma LLC stock option plans.

## **ACQUISITIONS, LICENSE AND COLLABORATION AGREEMENTS**

### *Commercial Products*

#### *Novartis AG*

On March 4, 2008, we entered into a license and supply agreement, referred to as the Novartis Agreement, with and among Novartis AG and Novartis Consumer Health, Inc., referred to as Novartis, to obtain the exclusive U.S. marketing rights for the prescription medicine Voltaren<sup>®</sup> Gel (diclofenac sodium topical gel) 1%, referred to as Voltaren Gel or Licensed Product. Voltaren Gel received regulatory approval in October 2007 from the U.S. Food and Drug Administration ( FDA ), becoming the first topical prescription treatment for use in treating pain associated with osteoarthritis and the first new product approved in the U.S. for osteoarthritis since 2001. Voltaren Gel has been granted marketing exclusivity in the U.S. as a prescription medicine until at least October 2010.

Under the terms of the five-year Novartis Agreement, Endo made an upfront cash payment of \$85 million. Endo has agreed to pay royalties to Novartis AG on annual Net Sales of the Licensed Product, subject to certain thresholds as defined in the Novartis Agreement. In addition, Endo has agreed to make certain guaranteed minimum annual royalty payments of \$30 million per year payable in the fourth and fifth year of the Novartis Agreement, subject to certain limitations as defined in the Novartis Agreement. These guaranteed minimum royalties will be creditable against royalty payments on a Novartis Agreement year basis such that Endo's obligation with respect to each Novartis Agreement year is to pay the greater of (i) royalties payable based on annual net sales of the Licensed Product or (ii) the guaranteed minimum royalty for such Novartis Agreement year. Novartis is also eligible to receive a one-time milestone payment of \$25 million if annual net sales of Voltaren Gel exceed \$300 million in the U.S. The \$85 million upfront payment and the present value of the guaranteed minimum royalties have been capitalized as an intangible asset in the amount of \$129.0 million, representing the fair value of the exclusive license to market Voltaren Gel. We are amortizing this intangible asset over its estimated useful life of 5 years.

Endo shall be solely responsible to commercialize the Licensed Product during the term of the Novartis Agreement. With respect to each year during the term of the Novartis Agreement, Endo is required to expend a minimum amount of annual advertising and promotional expenses on the commercialization of the Licensed Product, subject to certain limitations as provided for under the Novartis Agreement. In addition, Endo will be required to perform a minimum number of face-to-face one-on-one discussions with physicians and other health care practitioners (referred to as details) for the purpose of promoting the Licensed Product within its approved indication during each year of the Novartis Agreement, subject to certain provisions under the Novartis Agreement. Further, during the term of the Novartis Agreement, Endo will share in the costs of certain clinical studies and development activities initiated at the request of the FDA or as considered appropriate by Novartis and Endo.

During the term of the Novartis Agreement, Endo has agreed to purchase all of its requirements for the Licensed Product from Novartis. The price of product purchased under the Novartis Agreement is fixed for the first year and subject to annual changes based upon changes in the producer price index and raw materials as set forth in the Novartis Agreement. Endo has an existing long-term manufacturing and development agreement with Novartis whereby Novartis has agreed to manufacture certain of our commercial products and products in development.

Novartis has the exclusive right, at its sole discretion, to effect a switch of the Licensed Product from a prescription product to an over-the-counter (OTC) product in the United States, referred to as an OTC Switch, by filing an amendment or supplement to the Licensed Product New Drug Application or taking any other action necessary or advisable in connection therewith to effect the OTC Switch, and thereafter to commercialize such OTC product. Notwithstanding the foregoing, Novartis shall not launch an OTC equivalent product prior to a time specified in the Novartis Agreement, and Novartis shall not take any action that results in the loss of the prescription product status for the Licensed Product prior to such time. Novartis will notify Endo if it submits a filing to the FDA in respect of an OTC equivalent product. In the event that Novartis gains approval of an OTC equivalent product that results in the Licensed Product being declassified as a prescription product, then Novartis will make certain royalty payments to Endo on net sales of such OTC equivalent product in the United States by Novartis, its affiliates and their respective licensees or sublicensees as set forth in the Novartis Agreement, provided that, and subject to certain limitations

and provisions as set forth in the Novartis Agreement. As a condition to the payment of any and all such royalties, net sales of the Licensed Product in the United States must have exceeded a certain threshold as defined in the Novartis Agreement prior to the launch of the OTC equivalent product by Novartis or its affiliates.

---

**Table of Contents**

The initial term of the Novartis Agreement will expire on June 30, 2013. Endo has the option to extend the Novartis Agreement for two successive one (1) year terms (each referred to as a Renewal Term) beyond the initial term. The Novartis Agreement will remain in place after the first two Renewal Terms unless either party provides written notice of non-renewal to the other party at least six (6) months prior to the expiration of any Renewal Term after the first Renewal Term or the Novartis Agreement is otherwise terminated in accordance with its terms. Among other standard and customary termination rights granted under the Novartis Agreement, the Novartis Agreement can be terminated by either party upon reasonable written notice, if either party has committed a material breach that has not been remedied within ninety (90) days from the giving of written notice. Endo may terminate the Novartis Agreement by written notice upon the occurrence of several events, including the launch in the United States of a generic to the Licensed Product. Novartis may terminate the Novartis Agreement upon reasonable written notice (1) if Endo fails to deliver a set percentage of the minimum details in any given six (6)-month period under the Novartis Agreement; or (2) on or after the launch in the United States of an OTC equivalent product by Novartis, its affiliates or any third party that does not result in the declassification of the Licensed Product as a prescription product, following which net sales in any six-month period under the Novartis Agreement are less than a certain defined dollar amount.

*Hind Healthcare Inc.*

In November 1998, Endo entered into a license agreement (referred to as the Hind License Agreement) with Hind Healthcare Inc., or Hind, for the sole and exclusive right to develop, use, market, promote and sell Lidoderm® in the United States. Under the terms of the Hind License Agreement, Endo paid Hind approximately \$10 million based upon the achievement of certain milestones and capitalized this amount as an intangible asset representing the fair value of these exclusive rights. In addition, Endo pays Hind nonrefundable royalties based on net sales of Lidoderm®. 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 nine months ended September 30, 2008 and 2007, we recorded \$62.0 million and \$55.1 million, respectively, for these royalties to Hind, which were recorded as a reduction to net sales. In March 2002, we extended this license with Hind to cover Lidoderm® in Canada and Mexico.

*Penwest Pharmaceuticals Co.*

In September 1997, we entered into a collaboration agreement with Penwest Pharmaceuticals Co. to exclusively co-develop opioid analgesic products for pain management, using Penwest's patent-protected proprietary technology, for commercial sale worldwide. On April 2, 2002, we amended and restated this strategic alliance agreement between the parties (the 2002 Agreement) to provide, among other things, that this collaboration would cover only that opioid analgesic product currently under development by the parties, namely, oxymorphone ER, now known as Opana® ER. We had historically shared, on an equal basis, the costs of products developed under this agreement. On March 18, 2003, we received notice from Penwest that it was exercising its right under the agreement to cease funding its share of the development and pre-launch marketing costs of oxymorphone ER on account of their concern about their ability to access external capital funding opportunities in the future. Accordingly, we were responsible for funding 100% of these remaining costs until June 22, 2006, the date on which oxymorphone ER received FDA approval. In January 2007, the Company and Penwest entered into an amendment (the 2007 Amendment) to 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 certification period prior to when Opana® ER reached 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.

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

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.



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

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 September 2008, the \$41

**Table of Contents**

million royalty threshold was met. As a result, we began incurring royalties on the net sales of Opana<sup>®</sup> ER. Such royalties will be reduced by fifty percent (50%) until we recoup Penwest's share of the unfunded development costs of \$28 million, after which time royalties will be payable on annual net sales based on the royalty rates described above.

In July 2008, the Company and Penwest entered into an amendment (the 2008 Amendment) to the 2002 Agreement. Under the terms of the 2008 Amendment, Endo and Penwest agreed to restructure the 2002 Agreement to change the manner in which Endo reimburses Penwest for costs and fees incurred by Penwest in connection with any patent enforcement litigation.

*Vernalis Development Limited*

In July 2004, we entered into a license agreement and a loan agreement with Vernalis Development Limited, or Vernalis, under which Vernalis agreed to license exclusively to us rights to market Frova<sup>®</sup> (frovatriptan succinate) in North America. Launched in the U.S. in June 2002, Frova<sup>®</sup> is indicated for the acute treatment of migraine headaches in adults. Under the terms of the license agreement, we paid Vernalis an upfront fee of \$30 million and were required to make anniversary payments for the first two years at \$15 million in 2005 and 2006 (both \$15 million anniversary payments have been made). Under the loan agreement, we provided Vernalis with a loan of \$50 million in August 2004. We have capitalized the \$30 million up-front payment, the present value of the two \$15 million anniversary payments and the difference of \$6.2 million between the face amount of the loan and its present value at inception (See Note 8) as an intangible asset representing the fair value of the exclusive license to market Frova<sup>®</sup>. We are amortizing this intangible asset over its estimated useful life of 15 years.

Under the terms of the license agreement with Vernalis, we would have been required to make a \$40 million milestone payment upon FDA approval for the short-term prevention of menstrual migraine indication. 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> for the additional indication of short-term prevention of menstrual migraine. In April 2008, Endo notified the FDA of the withdrawal of the sNDA without prejudice to refiling as afforded under 21 CFR 314.65 for Frova<sup>®</sup> (frovatriptan succinate) 2.5 mg tablets. Frova<sup>®</sup> is approved and marketed for the acute treatment of migraine with or without aura in adults.

In addition, Vernalis could receive one-time milestone payments for the achievement of 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. Beginning on January 1, 2007, we began paying royalties to Vernalis based on the net sales of Frova<sup>®</sup>. We withheld 50% of those royalties and used the withholding to offset a portion of the unpaid accrued interest on the note receivable. The term of the license agreement is for the shorter of the time (i) that there are valid claims on the Vernalis patents covering Frova<sup>®</sup> or there is market exclusivity granted by a regulatory authority, whichever is longer, or (ii) until the date on which a generic version of Frova<sup>®</sup> is first offered, but in no event longer than 20 years. We can terminate the license agreement under certain circumstances, including upon one year's written notice. In July 2007, Vernalis and Endo entered into Amendment No. 3 (Amendment No. 3) to the License Agreement dated July 14, 2004. Under Amendment No. 3, 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.

On July 1, 2005, we entered into a co-promotion agreement, as amended on December 22, 2005, with Vernalis. The co-promotion agreement, as amended, was related to the above described license agreement under which Vernalis agreed to exclusively license to us rights to market the product Frova<sup>®</sup> in North America. Pursuant to the license agreement, Vernalis had retained rights to co-promote Frova<sup>®</sup> in the United States and exercised its co-promotion option effective January 2006. Concurrent with the execution of Amendment No. 4 to the License Agreement (see below), the co-promotion agreement was terminated.

In February 2008, we entered into a termination agreement with Vernalis to terminate the existing loan agreement between the parties and to settle the outstanding note receivable. Concurrent with the termination agreement, we entered into Amendment No. 4 to the 2004 License Agreement between Vernalis and the Company (Amendment No. 4). In addition to amending certain specific terms and conditions of the License Agreement, Amendment No. 4 sets forth an annual minimum net sales threshold such that no royalties will be due on annual U.S. net sales of Frova<sup>®</sup> less than \$85 million. Prior to this amendment, royalties were payable by us to Vernalis on all net sales of Frova<sup>®</sup> in the United States. Now, once the annual minimum net sales amount is reached, royalty payments will be due only on the portion of annual net sales that exceed the \$85 million threshold. In summary, we received a cash payment from Vernalis of \$7 million and acquired an intangible asset representing a future royalty stream on the net sales of Frova<sup>®</sup> as consideration for the full settlement of the note receivable.

The fair value of the royalty stream that we acquired as a result of the settlement of the note receivable was calculated using the present value of expected future cash flows using a discount rate that we considered to be appropriate given the inherent risk in the timing and the amount of estimated cash flows. Our estimate of expected future cash flows is based on the royalty savings that we expect to realize as a result of Amendment No. 4 described above. Based upon our analysis, the fair value of the royalties that we would have otherwise been required to pay

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

plus the \$7 million cash payment made by Vernalis to us in February 2008 is sufficient to recover the amounts owed to us.

Accordingly, we recorded the intangible asset on our books in an amount equal to the book value of the note receivable surrendered, after applying the \$7 million payment received from Vernalis, or \$46.7 million. We are amortizing this acquired intangible asset, into costs of sales, on a straight-line basis over its estimated useful life of nine (9) years. The nine-year estimated useful life is consistent with the period of time we currently expect to maximize use of the asset without the significant risk of generic competition for Frova®.

**Table of Contents***ZARS Pharma*

On January 6, 2006, we entered into a license agreement with ZARS Pharma for the North American rights to Synera<sup>®</sup> (lidocaine 70 mg and tetracaine 70 mg) topical patch, referred to as the ZARS Agreement. Synera<sup>®</sup> is for use on intact skin to provide local dermal anesthesia in children and adults. Approved by the FDA on June 23, 2005, Synera<sup>®</sup> became commercially available in the second half of 2006. Under the terms of the ZARS Agreement, we paid ZARS an upfront fee of \$11 million in January 2006 and an additional \$8 million upon the first commercial shipment of the product in the second half of 2006. Both amounts were capitalized as an intangible asset representing the fair value of the marketing rights to Synera<sup>®</sup> acquired from ZARS. Following an impairment review of Synera<sup>®</sup>, we determined that the carrying amount of the recorded intangible asset was not fully recoverable. As a result, during 2006, we recorded a \$16.5 million impairment charge to write the unamortized portion of this intangible asset down to its fair value, determined using a discounted cash flow model. During the year ended December 31, 2007, as a result of the continued lack of commercial success of Synera<sup>®</sup>, we recorded an impairment charge of \$0.9 million related to the remaining unamortized portion of our ZARS intangible asset. Endo terminated the ZARS Agreement effective July 31, 2008.

*Products in development**RxKinetix, Inc.*

On October 12, 2006, the Company acquired all of the outstanding common stock of privately-held RxKinetix, Inc. RxKinetix specialized in developing new therapeutics focused on improving the quality of life for patients being treated for cancer. RxKinetix's most advanced product, now named EN3285, was, as of the acquisition date, 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.

In December 2007, the Company initiated the first of two phase III clinical trials of EN3285 for the prevention or delay of oral mucositis (OM). Endo had agreed to the trial design with the FDA under the Special Protocol Assessment (SPA) process. Under the terms of the SPA, Endo initiated a multicenter, double-blind, placebo-controlled trial in approximately 240 OM patients undergoing chemoradiation therapy for head and neck cancer. In March 2008, the first dosage of EN 3285 was administered to a patient enrolled in the clinical phase III trial, triggering a contingent purchase consideration payment in the amount of \$15 million that was made in March 2008. In April 2008, the FDA notified us that they were placing our studies on clinical hold pending the submission to the FDA of additional pre-clinical data. We are currently undertaking additional pre-clinical studies with the intent of addressing the FDA's comments.

*Orexo AB*

In August 2004, we entered into an agreement with Orexo AB, referred to as the Orexo Agreement, granting us the exclusive rights to develop and market Orexo AB's patented sublingual muco-adhesive fentanyl product (Rapinyl<sup>®</sup>) in North America. Rapinyl<sup>®</sup> is a sub-lingual, fast-dissolving tablet of fentanyl intended for the treatment of breakthrough cancer pain. Rapinyl<sup>®</sup> is based on Orexo's unique patented technology for sublingual administration. The Orexo Agreement provided for us to make an up-front license fee payment of \$10 million, which we capitalized as an intangible asset representing the fair value of the exclusive right to market products utilizing Orexo's unique patented technology for sublingual administration. We were amortizing this intangible asset over its estimated useful life of 20 years. Our agreement with Orexo provided for us to make additional license fees and payments based on development and regulatory milestones, which total up to \$22.1 million, \$17.7 million of which has been recorded and included in research and development expense. Of this \$17.7 million expensed from the inception of the Orexo Agreement through September 30, 2008, \$0.8 million and \$5.2 million has been recorded during each of the nine months ended September 30, 2008 and 2007, respectively.

During the second quarter of 2008, the Company completed an in-depth review of its research and development (R&D) activities. The review included an analysis of the Company's R&D priorities, focus and available resources for current and future projects as well as the commercial potential for each product. As a result of this review, in July 2008 the Company decided to discontinue development of Rapinyl<sup>®</sup> and terminate the Orexo Agreement in accordance with its terms. As a result of this decision, the Company recorded a pre-tax impairment of other intangible assets in the amount of \$8.1 million in the second quarter of 2008 to reduce the remaining balance of our Rapinyl<sup>®</sup> intangible asset to zero and also recorded an impairment charge of approximately \$3.1 million related to the impairment of property and equipment that has been included in research and development expenses.

Pursuant to the terms the Orexo Agreement, we are required to pay a \$0.8 million termination fee to Orexo. In addition, we were required to continue all ongoing clinical trials related to Rapinyl<sup>®</sup> for a maximum of six months from the date of our termination of the Orexo Agreement. On October 30, 2008, Endo entered into an early termination agreement effective October 31, 2008 pursuant to which we agreed to cease all involvement in the ongoing clinical trials



## **Table of Contents**

of Rapinyl and to pay Orexo a lump sum fee. In exchange, Orexo has released Endo from certain claims under the Orexo Agreement. We are also required to transition the manufacturing process to Orexo or an agreed-upon third party, and supply manufactured product to Orexo or the agreed-upon third party during the transition period for up to a maximum of two years from the date of termination of the agreement. Orexo will pay us 125% of the cost for all manufactured product we provide during the transition period.

### *ProEthic Pharmaceuticals, Inc.*

In March 2005, we entered into an agreement with ProEthic Pharmaceuticals, Inc. (now owned by and renamed Kowa Pharmaceuticals America Inc.) for the U.S. and Canadian rights to develop and commercialize a once-daily ketoprofen-containing topical patch. We refer to this agreement as the ProEthic Agreement. Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID) generally used for the treatment of inflammation and pain and currently available in the U.S. only in oral form. The ketoprofen patch is being developed for the localized treatment of acute pain associated with soft-tissue injuries. Under the terms of the ProEthic Agreement, in March 2005, we paid a \$10 million upfront fee that was expensed as research and development during the year ended December 31, 2005. We made a \$5 million milestone payment upon the achievement of a regulatory milestone that was expensed as research and development during the year ended December 31, 2006.

During the second quarter of 2008, the Company completed an in-depth review of its research and development activities. The review included an analysis of the Company's R&D priorities, focus and available resources for current and future projects as well as the commercial potential for each product. As a result of this review, in July 2008 the Company decided to discontinue development of the ketoprofen patch. There was no termination fee due to ProEthic as a result of terminating the ProEthic Agreement.

### *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, referred to as the DURECT CHRONOGESIC<sup>®</sup> License Agreement, relating to the development and commercialization of the CHRONOGESIC<sup>®</sup> product candidate in the U.S. and Canada. Amendment No. 4 provided Endo with the right to terminate the DURECT CHRONOGESIC<sup>®</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>®</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>®</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. In April 2008, we terminated the DURECT CHRONOGESIC<sup>®</sup> License Agreement. Under the current terms of this license agreement, we were not responsible for any development costs for CHRONOGESIC<sup>®</sup> prior to May 1, 2008 so long as written notification of termination of the agreement was provided to DURECT by April 30, 2008. This return of CHRONOGESIC<sup>®</sup> rights has no effect on DURECT and Endo's collaboration with respect to the sufentanil transdermal patch (TRANSDUR<sup>®</sup>-Sufentanil) licensed by Endo from DURECT for the U.S. and Canada. There was no termination fee due to DURECT as a result of terminating the DURECT CHRONOGESIC<sup>®</sup> License Agreement.

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, referred to as the DURECT Sufentanil Agreement. The sufentanil patch, which is in clinical development, is intended to provide relief of moderate-to-severe chronic pain for up to seven days. We have assumed all remaining development and regulatory filing responsibility for this product, including the funding thereof. 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. In addition, the DURECT Sufentanil Agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. The DURECT Sufentanil Agreement will continue in effect until terminated. 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.*

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

---

**Table of Contents***Alexza Pharmaceuticals, Inc.*

In December 2007, we entered into a license, development and supply agreement with Alexza Pharmaceuticals, Inc. (Alexza) for the exclusive development and commercialization rights in North America for Alexza's AZ-003 (Staccato® fentanyl). We refer to this agreement as the Alexza Agreement. Currently in Phase I clinical development, AZ-003, now named EN3294, is a hand-held delivery system that uses Alexza's proprietary Staccato® system inhalation technology to deliver fentanyl for the treatment of breakthrough pain. EN3294 is patent protected until 2022. Under the terms of the Alexza Agreement, Endo paid Alexza an upfront fee of \$10 million that was expensed as research and development during the year ended December 31, 2007, with additional payments of approximately \$40 million becoming due upon achievement of predetermined regulatory and commercial milestones. Endo will also pay royalties to Alexza on net sales of EN3294. Endo has assumed responsibility for, and funding of, all remaining clinical trial development and regulatory filings. Alexza will manufacture the product for Endo and will be responsible for completing development of the device.

*Other*

In December 2007, we entered into a license, development and supply agreement with an undisclosed third party collaborative partner for the exclusive clinical development and commercialization rights in Canada and the United States for a certain technology to be utilized in our various product development activities. Under the terms of this agreement, the collaborative partner will be responsible for development efforts to conduct pharmaceutical formulation development and will manufacture any such product or products which obtain FDA approval. Endo will be responsible for conducting clinical development activities and for all development costs incurred to obtain regulatory approval. Pursuant to this agreement, we expensed upfront fees of \$18.9 million as research and development during the year ended December 31, 2007. During the nine months ended September 30, 2008, we expensed a \$2 million milestone payment as research and development expense. Additional payments of approximately 74.8 million euros may become due upon achievement of predetermined regulatory and commercial milestones. Endo will also make payments to the collaboration partner based on net sales of any such product or products commercialized under this agreement.

We have also entered into certain other collaboration agreements with third parties for the development of pain management and other products. In future periods, we may incur up to approximately \$3.8 million of expense pursuant to these agreements. These agreements require us to share in the development costs of such products and grant marketing rights to us for such products.

We have also licensed from universities and other companies rights to certain technologies or intellectual property generally in the field of pain management. We are generally required to make upfront payments as well as other payments upon successful completion of regulatory or sales milestones. In addition, these agreements generally require us to pay royalties on sales of the products arising from these agreements. These agreements generally permit Endo to terminate the agreement with no significant continuing obligation.

In July 2008 the Company made a \$20 million investment in a privately-held company focused on the development of an innovative treatment for certain types of cancer. In exchange for our \$20 million payment, we received an equity interest in the privately-held company and the rights to negotiate an exclusive worldwide development and commercialization arrangement with respect to a certain technology for use in a specified indication. The Company's \$20 million payment resulted in an ownership interest of less than 20% of the outstanding voting stock of the privately-held company. In addition, Endo does not have the ability to exert significant influence over the privately-held company. Accordingly, Endo is accounting for this investment under the cost method.

**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.

**Growth Opportunities.** We continue to evaluate growth opportunities including strategic investments, licensing arrangements, acquisitions of product rights or technologies, and strategic alliances and promotional arrangements which could require significant capital resources. 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. While we continue to focus on evaluating and pursuing opportunities to deepen and broaden our penetration of the pain market, we remain opportunistic, selectively pursuing promising leads in other therapeutic areas with the potential to provide innovative solutions. Endo's growth strategy includes consideration of earlier stage opportunities. We will also selectively pursue opportunities to invest in our generics





**Table of Contents**

business. Endo's management team and our Board of Directors continue to examine the best use of the Company's strong balance sheet and liquidity, including consideration of opportunities in the evolving pharmaceutical marketplace 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® pain franchise, Voltaren® Gel for use in treating pain associated with osteoarthritis and Frova® for the acute treatment of migraine headaches in adults.

**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, 2007 (in thousands):

Contractual Obligations	Total	2008	Payment Due by Period				Thereafter
			2009	2010	2011	2012	
Operating Lease Obligations	\$ 37,094	\$ 8,292	\$ 7,618	\$ 4,704	\$ 3,246	\$ 2,724	\$ 10,510
Capital Lease Obligations	1,182	983	120	79			
Minimum Purchase Commitments to Novartis	62,000	20,000	21,000	21,000			
Estimated Tax Sharing Payments Due to Endo Pharma LLC	685	685					
Minimum Royalty Obligation Due to Hind	2,000	500	500	500	500		
Minimum Purchase Commitments to Teikoku(1)	160,000	32,000	32,000	32,000	32,000	32,000	
Limited Partnership Commitment(2)	2,000	2,000					
Milestone Payment(3)	15,000	15,000					
Minimum Voltaren® Royalty Obligations Due to Novartis AG (4)	60,000				15,000	30,000	15,000
Other Commitments(5)	3,333	3,333					
<b>Total</b>	<b>\$ 343,294</b>	<b>\$ 82,793</b>	<b>\$ 61,238</b>	<b>\$ 58,283</b>	<b>\$ 50,746</b>	<b>\$ 64,724</b>	<b>\$ 25,510</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 minimum number of patches per year through 2012, representing the noncancelable portion of the Amended Agreement. The minimum purchase requirement shall remain in effect subsequent to 2012, except that Endo has the right to terminate the Amended Agreement after 2012, if we fail to meet the annual minimum requirement. 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. During the year ended December 31, 2007, we invested an additional \$5.3 million in this partnership, bringing our cumulative cash investment to \$8.0 million as of December 31, 2007 leaving a commitment balance of \$2.0 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 the first dosage being administered to a patient in a clinical phase III trial of EN3285, 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. In December 2007, the Company initiated the first of two phase III clinical trials of EN3285 for the prevention or delay of oral mucositis (OM). In March 2008, the first dosage of EN 3285 was administered to a patient enrolled in the clinical phase III trial. Accordingly, we paid the \$15 million estimated amount due seller in March 2008.
- (4)

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

Under the terms of the five-year Novartis Agreement, Endo made an up-front cash payment of \$85 million. Endo has agreed to pay royalties to Novartis AG on annual Net Sales of the Licensed Product, subject to certain thresholds all as defined in the Novartis Agreement. In addition, Endo has agreed to make certain guaranteed minimum annual royalty payments beginning in the fourth year of the Novartis Agreement, subject to certain limitations as defined in the Novartis Agreement. These guaranteed minimum royalties will be creditable against royalty payments on a Novartis Agreement year basis such that Endo's obligation with respect to each Novartis Agreement year is to pay the greater of (i) royalties payable based on annual net sales of the Licensed Product or (ii) the guaranteed minimum royalty for such Agreement year.

- (5) In June 2007, we agreed to provide funding for certain tenant improvements to be made at a building at the Company's corporate headquarters in Chadds Ford, Pennsylvania. The payments were to be made in two equal installments, the first of which was paid in July 2007 with the remainder paid in March 2008 upon completion of the building. Also included in this balance is our fixed obligation payable to Ventiv during the first twelve months of Detailing under the Ventiv Agreement.

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 sheets and, 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 14 to the Condensed Consolidated Financial Statements in Part I Item I of this Report, on January 1, 2007, we adopted FIN 48 and recorded a \$7.7 million non-current liability representing the Company's unrecognized tax benefits with respect to our uncertain tax positions. As of September 30, 2008, our liability for unrecognized tax benefits amounted to \$10.9 million (including interest and penalties). 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.

**Litigation.** As discussed in Note 12. Commitments and Contingencies-Legal Proceedings, included in the consolidated financial statements in Part I, Item 1 of this Report, we are subject to various patent, product liability, government investigations and other legal proceedings in the ordinary course of business. Contingent accruals are recorded when we determine 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. Although we do not currently possess sufficient information to reasonably estimate the amounts of liabilities, if any, to be recorded upon future completion of litigation or investigations, and neither the timing nor the amount of the ultimate costs associated with such litigation or investigations can be determined, they could be material to our consolidated results of operations, financial condition or operating cash flows in the periods recognized or paid.

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 contingent amounts have been accrued with respect to any of these unsettled legal proceedings at September 30, 2008.

### *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.

### *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.

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

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 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. 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.

**Table of Contents**

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, are pending in the 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. That case was removed to federal court, transferred to the MDL, and then remanded to the court in which it was originally filed.

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. That case was transferred to the MDL.

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 EPI, and EPI 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.

*Paragraph IV Certifications on Opana® ER*

On December 14, 2007, the Company received a notice from IMPAX advising of the FDA's apparent acceptance for substantive review, as of November 23, 2007, of IMPAX's amended ANDA for a generic version of Opana® ER. IMPAX stated in its letter that the FDA requested IMPAX to provide notification to us and Penwest of any Paragraph IV certifications submitted with its ANDA, as required under section 355(j) of the Federal Food, Drug and Cosmetics Act, or the FDCA Act. Accordingly, IMPAX's letter included notification that it had filed Paragraph IV certifications with respect to Penwest's U.S. Patent Nos. 7,276,250, 5,958,456 and 5,662,933, which cover the formulation of Opana® ER. These patents are listed in the FDA's Orange Book and expire in 2022, 2013 and 2013, respectively. The Company's Opana® ER product has new dosage form exclusivity that prevents final approval of any ANDA by the FDA until the exclusivity expires on June 22, 2009. In addition, because IMPAX's application referred to patents owned by Penwest and contained a Paragraph IV certification under section 355(j) of the FDCA Act, we believe IMPAX's notice triggered the 45-day period under the FDCA Act in which we and Penwest could file a patent infringement action and trigger the automatic 30-month stay of approval. Subsequently, on January 25, 2008, the Company and our partner Penwest filed a lawsuit against IMPAX in the United States District Court for the District of Delaware in connection with IMPAX's ANDA. The lawsuit alleges infringement of certain Orange Book-listed U.S. patents that cover the Opana® ER formulation. Additionally, the lawsuit previously filed by the Company and Penwest on November 15, 2007 against IMPAX remains pending. We cannot predict the outcome of this litigation.

On June 16, 2008, the Company received a notice from IMPAX that it had filed an amended ANDA containing Paragraph IV certifications for the 7.5 mg, 15 mg and 30 mg strengths of oxymorphone hydrochloride extended release tablets. The notice covers Penwest's U.S. Patent Nos. 7,276,250, 5,958,456 and 5,662,933. Subsequently, on July 25, 2008, the Company and our partner Penwest filed a lawsuit against IMPAX in the United States District Court for the District of Delaware in connection with IMPAX's ANDA. The lawsuit alleges infringement of certain Orange Book-listed U.S. patents that cover the Opana® ER formulation. Additionally, the lawsuits previously filed by the Company and Penwest on s against IMPAX remain pending. We cannot predict the outcome of this litigation.

In February 2008, we along with our partner Penwest, received a notice from Actavis South Atlantic LLC, or Actavis, advising of the filing by Actavis of an ANDA containing a Paragraph IV certification under 21 U.S.C. Section 355(j) for a generic version of Opana® ER (oxymorphone hydrochloride extended-release tablets CII). The Actavis Paragraph IV certification notice refers to Penwest's U.S. Patent Nos. 5,128,143, 5,662,933, 5,958,456 and 7,276,250, which cover the formulation of Opana® ER. These patents are listed in the FDA's Orange Book and expire in 2008, 2013, 2013 and 2023, respectively. In addition to 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. Subsequently, on March 28, 2008, we and Penwest filed a lawsuit against Actavis in the U.S. District Court for the District of New Jersey in connection with Actavis's ANDA. The lawsuit alleges

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

infringement of an Orange Book-listed U.S. patents that covers the Opana® ER formulation. On May 5, 2008, Actavis filed an answer and counterclaims, asserting claims for declaratory judgment that the patents listed in the Orange Book are invalid, not infringed and/or unenforceable, as well as a claim of unfair competition against Endo and Penwest. Endo has filed a motion to dismiss or stay the unfair competition claim, which is pending. We cannot predict the outcome of this litigation. We intend, and we have been advised by Penwest that they too intend, to pursue all available legal and regulatory avenues in defense of Opana® ER, including enforcement of our intellectual property rights and approved labeling.

**Table of Contents**

On or around June 2, 2008, the Company received a notice from Actavis that it had filed an amended ANDA containing Paragraph IV certifications for the 7.5 mg and 15 mg dosage strengths of oxymorphone hydrochloride extended release tablets. On or around July 2, 2008, the Company received a notice from Actavis that it had filed an amended ANDA containing Paragraph IV certifications for the 30 mg dosage strength. Both notices cover Penwest's U.S. Patent Nos. 5,128,143, 7,276,250, 5,958,456 and 5,662,933. On July 11, 2008, the Company and Penwest, filed suit against Actavis in the United States District Court for the District of New Jersey. The lawsuit alleges infringement of an Orange Book-listed U.S. patent that covers the Opana® ER formulation. We cannot predict the outcome of this litigation. We intend, and we have been advised by Penwest that they too intend, to pursue all available legal and regulatory avenues in defense of Opana®ER, including enforcement of our intellectual property rights and approved labeling.

On July 14, 2008, the Company received a notice from Sandoz, Inc. or Sandoz, advising of the filing by Sandoz of an ANDA containing a Paragraph IV certification under 21 U.S.C. Section 355(j) with respect to oxymorphone hydrochloride extended-release oral tablets in 5 mg, 10 mg, 20 mg and 40 mg dosage strengths. The Sandoz Paragraph IV certification notice refers to Penwest's U.S. Patent Nos. 5,662,933, 5,958,456 and 7,276,250, which cover the formulation of Opana® ER. These patents are listed in the FDA's Orange Book and expire in 2013, 2013 and 2023, respectively. In addition to 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. Subsequently, on August 22, 2008, the Company and our partner Penwest filed a lawsuit against Sandoz in the United States District Court for the District of Delaware in connection with Sandoz's ANDA. The lawsuit alleges infringement of certain Orange Book-listed U.S. patents that cover the Opana® ER formulation. We cannot predict the outcome of this litigation. We intend, and we have been advised by Penwest that they too intend, to pursue all available legal and regulatory avenues in defense of Opana® ER, including enforcement of our intellectual property rights and approved labeling.

On September 12, 2008, the Company received a notice from Barr Laboratories, Inc. or Barr, advising of the filing by Barr of an ANDA containing a Paragraph IV certification under 21 U.S.C. Section 355(j) with respect to oxymorphone hydrochloride extended-release oral tablets in a 40 mg dosage strength. On September 15, 2008, the Company received a notice from Barr that it had filed an ANDA containing a Paragraph IV certification under 21 U.S.C. Section 355(j) with respect to oxymorphone hydrochloride extended-release oral tablets in 5 mg, 10 mg, and 20 mg dosage strengths.

Both notices refer to Penwest's U.S. Patent Nos. 5,662,933, 5,958,456 and 7,276,250, which cover the formulation of Opana® ER. These patents are listed in the FDA's Orange Book and expire in 2013, 2013 and 2023, respectively. In addition to 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. Subsequently, on October 20, 2008, the Company and our partner Penwest filed a lawsuit against Barr in the United States District Court for the District of Delaware in connection with Barr's ANDA. The lawsuit alleges infringement of certain Orange Book-listed U.S. patents that cover the Opana® ER formulation. We cannot predict the outcome of this litigation. We intend, and we have been advised by Penwest that they too intend, to pursue all available legal and regulatory avenues in defense of Opana® ER, including enforcement of our intellectual property rights and approved labeling.

*LecTec Corporation v. Chattem, Inc., et al.*

On July 25, 2008, the LecTec Corporation filed a complaint in the Eastern District of Texas against the Company and several other pharmaceutical companies alleging that each of the defendants sells product that infringes one or more claims of patents owned by LecTec. The Company's product Lidoderf® is identified in the complaint. The complaint alleges that Lidoderf® infringes U.S. Patents 5,536,263 and 5,741,510. On September 30, 2008, the Company filed an answer denying infringement and alleging that the patents are invalid. The Company intends to contest this case vigorously. However, we cannot predict the timing or outcome of this litigation.

*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.

**Recent Accounting Pronouncements**

In September 2006, the FASB issued SFAS No.157, *Fair Value Measurements* ( SFAS 157 ), 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. In February 2008, the FASB issued FASB Staff Position No. 157-2, *Effective Date of FASB Statement No. 157* ( FSP 157-2 ). FSP 157-2 delays the effective date of SFAS 157 for

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

certain non-financial assets and non-financial liabilities to fiscal years beginning after November 15, 2008. SFAS 157 defines fair value, establishes a framework for measuring fair value under generally accepted



**Table of Contents**

accounting principles and enhances disclosures about fair value measurements. Fair value is defined under SFAS 157 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value under SFAS 157 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company has adopted SFAS 157 for financial assets and liabilities. The adoption of SFAS 157 did not have a material impact on the Company's consolidated results of operations and financial condition.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* ( SFAS 159 ), 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. Upon adoption, we chose not to elect the fair value option for our existing financial assets and liabilities. Therefore, adoption of SFAS 159 did not have any impact on our consolidated financial statements. We have not elected the fair value option for any financial asset or liability acquired or incurred subsequent to the adoption date.

In June 2007, the Emerging Issues Task Force ( EITF or Task Force ) of the FASB reached a consensus on Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ( EITF 07-3 ). 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 to be rendered, the capitalized advance payment should be charged to expense. EITF 07-3 is effective for new contracts entered into in fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. Earlier application is not permitted. We have adopted EITF 07-3 as of January 1, 2008. The adoption of EITF 07-3 did not have a material effect on the Company's consolidated results of operations or financial condition.

In November 2007, the EITF of the FASB issued a consensus on Issue No. 07-1, *Accounting for Collaborative Arrangements* ( EITF 07-1 ). 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

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

policy election. The provisions of EITF 07-1 are effective for fiscal years beginning on or after December 15, 2008, and companies will be required to apply the provisions through retrospective application to all collaborative arrangements existing at adoption as a change in accounting principle. If it is impracticable to apply the consensus to a specific arrangement, disclosure is required regarding the reason why retrospective application is not practicable and the effect of reclassification on the current period. The Company is currently evaluating the impact of the adoption of EITF 07-1 on its consolidated financial statements.

**Table of Contents**

In December 2007, the FASB issued SFAS 141(R) *Business Combinations* ( SFAS 141(R) ) and SFAS 160, *Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51* ( SFAS 160 ). SFAS 141(R) will change how business acquisitions are accounted for and will impact financial statements both on the acquisition date and in subsequent periods. SFAS 160 will change the accounting and reporting for minority interests, which will be recharacterized as noncontrolling interests and classified as a component of equity. SFAS 141(R) and SFAS 160 are required to be adopted concurrently and are effective for fiscal years, beginning on or after December 15, 2008. Earlier adoption is prohibited.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, ( SFAS 162 ). SFAS 162 sets forth the sources of accounting principles and the framework, or hierarchy, for selecting principles to be used in financial statement preparation. Prior to the issuance of SFAS 162, the GAAP hierarchy was defined in the American Institute of Certified Public Accountants Statement on Auditing Standards No. 69, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. SFAS 162 will be effective following SEC approval. The FASB does not expect the issuance of SFAS 162 to result in a change in current practice.

In May 2008, the FASB issued FASB Staff Position APB 14-1, *Accounting for Convertible Debt Instruments That May be Settled in Cash upon Conversion (Including Partial Cash Settlement)* ( FSP APB 14-1 ). FSP APB 14-1 requires that issuers of convertible debt instruments that may be settled in cash or other assets on conversion to separately account for the liability and equity components of the instrument in a manner that will reflect the entity's nonconvertible debt borrowing rate on the instrument's issuance date when interest cost is recognized in subsequent periods. Our Convertible Notes are within the scope of FSP APB 14-1. Therefore, we will be required to separate the debt portion of our Convertible Notes from the equity portion at their fair value retrospective to the date of issuance and amortize the resulting discount into interest expense over the life of the debt. However, there will be no effect on our cash interest payments. FSP APB 14-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and will be applied retrospectively to all periods presented. The Company is currently evaluating the impact of adopting this pronouncement, however we expect there to be a dilutive effect on our earnings per share.

In October 2008, the FASB issued FASB Staff Position SFAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active* ( FSP SFAS 157-3 ). FSP SFAS 157-3 clarifies the application of SFAS 157 when determining the fair value of a financial asset when the market for that asset is not currently active. FSP SFAS 157-3 emphasizes that approaches other than the market approach to determining fair value may be appropriate when it is determined that, as a result of market inactivity, other valuation approaches are more representative of fair value. Other valuation approaches can involve significant assumptions regarding future cash flows. FSP SFAS 157-3 clarifies that these assumptions must incorporate adjustments for nonperformance and liquidity risks that market participants would consider in valuing the asset in an inactive market. FSP SFAS 157-3 emphasizes the existing disclosure requirements under SFAS 157 regarding significant unobservable inputs (Level 3 inputs). FSP SFAS 157-3 became effective on October 10, 2008, including prior periods for which financial statements have not been issued. The Company has adopted FSP SFAS 157-3 for the quarterly period ended September 30, 2008. See Note 3 to Condensed Consolidated Financial Statements in Part I Item I of this Report for a further discussion of fair value.

**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. in our annual report on Form 10-K for the year ended December 31, 2007.

Since mid-February 2008, the market for auction-rate securities has seen a dramatic decrease in the volume of trades relative to historical levels. At September 30, 2008, the Company determined that the market for its auction-rate securities was inactive. That determination was made considering that there are very few observable transactions for the auction-rate securities or similar securities, the prices for transactions that have occurred are not current, and the observable prices for those transactions to the extent they exist vary substantially either over time or among market makers, thus reducing the potential usefulness of those observations.

During the nine months ended September 30, 2008, we purchased \$15.0 million of equity securities consisting of investments in open-end mutual funds that invest in U.S. government securities and \$118.7 million of original par value auction-rate securities and variable rate demand obligations. In January 2008, the Company chose to reduce its exposure to auction-rate securities and ceased all purchases of auction-rate securities effective February 1, 2008, prior to when we began to experience failed auctions. During the nine months ended September 30, 2008, we sold \$113.8 million of original par value variable-rate demand obligations. During the same period, we also sold \$301.4 million of original par value auction-rate securities and a \$5.0 million original par value municipal bond. There were no realized holding gains or losses resulting from the sales of our available for sale securities during the nine months ended September 30, 2008.

As of October 29, 2008, all of our auction-rate securities in which we invest remain with AA and AAA underlying ratings. Specifically, 70% of our auction-rate securities are AAA rated and 30% are AA rated. The underlying assets of our auction-rate securities are student loans. Student

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

loans are insured by either the Federal Family Education Loan Program, or FFELP, or a combination of FFELP and other monoline insurers such as Ambac Assurance Corp., or AMBAC, and MBIA Insurance Corp., or MBIA. As of October 28, 2008, MBIA was rated Baa2 by Moody's and A- by Standard and Poor's. AMBAC was rated Aa3 by Moody's and AA by Standard and Poor's. Although our auction-rate securities continue to pay interest according to their stated terms, based on valuation models, the carrying value of our auction-rate securities were reduced by approximately \$27.7 million at September 30, 2008, reflecting the change in fair value, which the Company attributes to liquidity issues rather than credit issues. The Company assessed this decline in value to be temporary due to, the financial condition and near-term prospects of the underlying issuers, our intent and ability to retain our investment in the issuers for a period of time sufficient to allow for any anticipated recovery in market value and based on the extent to which fair value is less than par. Accordingly, we recorded a pre-tax \$27.7 million reduction in shareholders' equity in accumulated other comprehensive loss.

Of course, there can be no assurance that our current belief that the securities will recover their value will not change, at which time an other-than-temporary impairment could occur. An other-than-temporary impairment would be recorded in the statement of operations. If uncertainties in the credit and capital markets continue, these markets deteriorate further or we experience any additional cover rating downgrades on any investments in our portfolio (including on our auction-rate securities), we may incur additional impairments in future periods, which could negatively affect our financial condition, cash flow or reported earnings. Any of these events could materially affect our results of operations and our financial condition. In the event we need to access these funds, we could be required to sell these securities at an amount below our original purchase value. However, based on our ability to access our cash and cash equivalents and our other liquid investments, and our expected operating cash flows, we do not expect to be required to sell these securities at a loss. However, there can be no assurance that we will not have to sell these securities at a loss.

#### **Item 4. Controls and Procedures.** **Disclosure Controls and Procedures**

Our management, including our Chief Executive Officer and Principal 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 Principal 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 2008 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Notwithstanding the foregoing, we recently reported the resignation of Charles A. Rowland, Jr., our former Chief Financial Officer. Our current Vice President, Controller, and Principal Accounting Officer, Edward J. Sweeney, is acting as our Principal Financial Officer in the absence of a Chief Financial Officer. Inherent with any change in management is a change in understanding of the control environment and the internal controls.

**Table of Contents****PART II****OTHER INFORMATION****Item 1. Legal Proceedings.**

The disclosures under Note 12. 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**

In April 2008, we issued \$379.9 million in aggregate principal amount of 1.75% Convertible Senior Subordinated Notes due April 15, 2015 (the Convertible Notes) in a private offering for resale to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The holders of our 1.75% Convertible Senior Subordinated Notes due April 15, 2015 (the Convertible Notes) could require us to repurchase the principal amount of the notes for cash before maturity of the notes upon the occurrence of a Fundamental Change, as defined in the indenture relating to the Convertible Notes. Such a repurchase could require significant amounts of cash and could adversely affect our financial condition.

Other than the above, there has been no material change in our risk factors as previously disclosed in our Annual Report on Form 10-K/A for the fiscal year ended December 31, 2007 in response to Item 1A. to Part 1 of such Form 10-K/A, filed with the Securities and Exchange Commission on April 29, 2008.

**Item 2. Unregistered Sale of Equity Securities and Use of Proceeds.**

(c) Purchase of equity securities by the issuer and affiliated purchasers.

The following table reflects purchases of Endo Pharmaceuticals Holdings Inc. common stock by the Company during the nine months ended September 30, 2008:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plan (1)	Approximate Dollar Value of Shares that May Yet be Purchased Under the Plan
January 1, 2008 to January 31, 2008				
February 1, 2008 to February 29, 2008				
March 1, 2008 to March 31, 2008				
April 1, 2008 to April 30, 2008	12,576,519	\$ 27.18	12,576,519	\$ 408,144,317
May 1, 2008 to May 31, 2008	1,355,700	\$ 24.45	1,355,700	\$ 375,002,580
June 1, 2008 to June 30, 2008				\$ 375,002,580
July 1, 2008 to July 31, 2008				\$ 375,002,580
August 1, 2008 to August 31, 2008	1,375,880	0.03	1,375,880	\$ 374,961,303
September 1, 2008 to September 30, 2008	1,859,704	\$ 20.82	1,859,704	\$ 336,289,991
Total	17,167,803	\$ 24.10	17,167,803	\$ 336,289,991

(1)

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

In April 2008, our Board of Directors approved a share repurchase program, authorizing the Company to repurchase in the aggregate up to \$750 million of shares of its outstanding common stock. Purchases under this program may be made from time to time in open market purchases, privately-negotiated transactions, accelerated stock repurchase transactions or otherwise, as determined by Endo. In April 2008 we entered into a privately-negotiated \$325.0 million accelerated repurchase agreement as part of the broader share repurchase program described above. Pursuant to the accelerated share repurchase agreement, we purchased approximately 11.9 million shares of our common stock on April 15, 2008. On August 14, 2008, Endo received approximately 1.4 million additional shares of our common stock based on the volume-weighted average price of our common stock during a specified averaging period set forth by the accelerated share repurchase agreement. In addition to the accelerated share repurchase, beginning in April 2008 we made open market purchases of our common stock as part of our broader share repurchase program. As of September 30, 2008, we purchased approximately 3.9 million shares of our common stock on the open market for a total purchase price of approximately \$88.7 million. This column discloses the number of shares purchased pursuant to the Board's authorization.

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

None.

**Table of Contents**

**Item 4.** *Submission of Matters to a Vote of Security Holders.*  
None.

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

**Item 6.** *Exhibits.*  
The information called for by this item is incorporated by reference to the Exhibit Index of this Report.

**Table of Contents**

**SIGNATURES**

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

ENDO PHARMACEUTICALS HOLDINGS INC.  
(Registrant)

/s/ DAVID P. HOLVECK  
Name: David P. Holveck  
Title: *President and Chief Executive Officer*

*(Principal Executive Officer)*

/s/ EDWARD J. SWEENEY  
Name: Edward J. Sweeney  
Title: *Vice President, Controller*

*(Principal Financial Officer)*

Date: October 30, 2008



**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 10.32 of the Form 10-Q for the Quarter ended June 30, 2008 filed with the Commission on August 1, 2008)
3.2	Amended and Restated By-laws of Endo Pharmaceuticals Holdings Inc. (incorporated herein by reference to Exhibit 3.2 of the Form 10-Q for the Quarter ended March 31, 2008 filed with the Commission on May 2, 2008)
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 September 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)
10.4	Agreement dated April 29, 2008 between Endo Pharmaceuticals Holdings Inc. and D. E. Shaw Valence Portfolios, L.L.C. (on behalf of itself and its affiliates that are members of the 13D Group with respect to the Endo common stock) (incorporated herein by reference to Exhibit 99.1 of the Current Report on From 8-K/A dated May 1, 2008)



**Table of Contents**

Exhibit No.	Title
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	Convertible Bond Hedge Transaction Confirmation entered into by and between the Company and Deutsche Bank AG, London Branch, dated April 9, 2008 (incorporated herein by reference to Exhibit 10.7 of the Form 10-Q for the Quarter ended March 31, 2008 filed with the Commission on May 2, 2008)
10.8	Issuer Warrant Transaction Confirmation entered into by and between the Company and Deutsche Bank AG, London Branch, dated April 9, 2008 (incorporated herein by reference to Exhibit 10.8 of the Form 10-Q for the Quarter ended March 31, 2008 filed with the Commission on May 2, 2008)
10.9	Issuer Share Repurchase Transaction Confirmation entered into by and between the Company and Deutsche Bank AG, London Branch, dated April 9, 2008 (incorporated herein by reference to Exhibit 10.9 of the Form 10-Q for the Quarter ended March 31, 2008 filed with the Commission on May 2, 2008)
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	Endo Pharmaceuticals Holdings Inc. Executive Deferred Compensation Plan (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K dated December 19, 2007)
10.12	Endo Pharmaceuticals Holdings Inc. 401(k) Restoration Plan (incorporated herein by reference to Exhibit 10.2 of the Current Report on Form 8-K dated December 19, 2007)
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 Co. (incorporated herein by reference to Exhibit 10.18.1 of the Current report on Form 8-K dated January 11, 2007)
10.18.2	Amendment, dated July 14, 2008, to the Amended and Restated Strategic Alliance Agreement, dated as of April 2, 2002, by and between Endo Pharmaceuticals Inc. and Penwest Pharmaceuticals Co. (incorporated herein by reference to Exhibit 10.32 of the

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

Form 10-Q for the Quarter ended June 30, 2008 filed with the Commission on August 1, 2008)

- 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)

**Table of Contents**

10.20	Medical Affairs Support Services Agreement, dated as of June 1, 1999, by and between Endo Pharmaceuticals and Kunitz and Associates, Inc. (incorporated herein by reference to Exhibit 10.20 of the Registration Statement filed with the Commission on June 9, 2000)
10.21	Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.21 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.22	Endo LLC Amended and Restated 1997 Employee Stock Option Plan (incorporated herein by reference to Exhibit 10.22 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.23	Endo LLC Amended and Restated 1997 Executive Stock Option Plan (incorporated herein by reference to Exhibit 10.23 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.24	Endo LLC 2000 Amended and Restated Supplemental Employee Stock Option Plan (incorporated herein by reference to Exhibit 10.24 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.25	Endo LLC 2000 Amended and Restated Supplemental Executive Stock Option Plan (incorporated herein by reference to Exhibit 10.25 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.26	Separation Agreement, dated as of September 8, 2008, between Endo Pharmaceuticals Holdings Inc. and Charles A. Rowland, Jr. (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K dated September 8, 2008)
10.27	Amended and Restated Employment Agreement, dated as of December 19, 2007, by and between the Company and Joyce N. LaViscount (incorporated herein by reference to Exhibit 10.29 of the Form 10-K for the year ended December 31, 2007 filed with the Commission on February 26, 2008)
10.28	Amended and Restated Employment Agreement, dated as of December 19, 2007, by and between the Company and Nancy J. Wysenski (incorporated herein by reference to Exhibit 10.29 of the Form 10-K for the year ended December 31, 2007 filed with the Commission on February 26, 2008)
10.29	Intentionally Omitted
10.30	Employment Agreement, dated as of April 1, 2008, by and between Endo Pharmaceuticals Holdings Inc. and David P. Holveck (incorporated herein by reference to Exhibit 10.30 of the Current Report on Form 8-K dated March 12, 2008).
10.31	License and Supply Agreement by and by and among Novartis, AG, Novartis Consumer Health, Inc. and Endo Pharmaceuticals Inc. dated as of March 4, 2008 (incorporated herein by reference to Exhibit 10.31 of the Form 10-Q for the Quarter ended March 31, 2008 filed with the Commission on May 2, 2008)
10.31.1	Amendment No. 1 to the License and Supply Agreement by and by and among Novartis, AG, Novartis Consumer Health, Inc. and Endo Pharmaceuticals Inc. dated as of March 28, 2008 (incorporated herein by reference to Exhibit 10.31.1 of the Form 10-Q for the Quarter ended March 31, 2008 filed with the Commission on May 2, 2008)
10.32	Sales and Marketing Services Agreement, dated as of May 15, 2008 between Endo Pharmaceuticals and Ventiv Commercial Services, LLC (incorporated herein by reference to Exhibit 10.32 of the Form 10-Q for the Quarter ended June 30, 2008 filed with the Commission on August 1, 2008)
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 19, 2007, by and between the Company and Caroline B. Manogue (incorporated herein by reference to Exhibit 10.29 of the Form 10-K for the year ended December 31, 2007 filed with the Commission on February 26, 2008)
10.36	Amended and Restated Employment Agreement, dated as of December 19, 2007, by and between the Company and Peter A. Lankau (incorporated herein by reference to Exhibit 10.29 of the Form 10-K for the year ended December 31, 2007 filed with the Commission on February 26, 2008)

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

- 10.36.1 Separation Agreement, dated as of January 28, 2008, Endo Pharmaceuticals Holdings Inc. and Peter A. Lankau (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K dated January 30, 2008)

**Table of Contents**

- 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 Endo Pharmaceuticals Holdings Inc. 2007 Stock Incentive Plan (incorporated herein by reference to Exhibit D of the Definitive Proxy Statement on Schedule 14A filed with the Commission on April 30, 2007)
- 10.39 Master Development and Toll Manufacturing Agreement, dated as of May 3, 2001, by and between Novartis Consumer Health, Inc. and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.39 of the Form 10-Q for the Quarter Ended June 30, 2001 filed with the Commission on August 14, 2001)
- 10.39.1 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)
- 10.40.1 First Amendment to Lease Agreement, dated as of March 3, 2008 by and between Partners Crossing Three Associates, L.P. and Endo Pharmaceuticals Inc. (incorporated herein by reference to Exhibit 10.40.1 of the Form 10-Q for the Quarter ended March 31, 2008 filed with the Commission on May 2, 2008)
- 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 [Intentionally Omitted]
- 10.42.2 [Intentionally Omitted]
- 10.42.3 [Intentionally Omitted]
- 10.42.4 [Intentionally Omitted]
- 10.42.5 [Intentionally Omitted]
- 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)
- 10.48.5 Fourth Amendment, dated as of February 19, 2008, to the License Agreement by and between Endo Pharmaceuticals Inc. and Vernalis Development Limited (incorporated herein by reference to Exhibit 10.48.5 of the Form 10-K for the year ended December 31, 2007 filed with the Commission on February 26, 2008)
- 10.48.6 Agreement to Terminate the Co-Promotion Agreement by and between Endo Pharmaceuticals Inc. and Vernalis Development Limited, effective February 19, 2008 (incorporated herein by reference to Exhibit 10.48.6 of the Form 10-K for the year ended December 31, 2007 filed with the Commission on February 26, 2008)
- 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)
- 10.49.1 Agreement to Terminate the Loan Agreement by and between Endo Pharmaceuticals and Vernalis Development Limited, effective February 19, 2008 (incorporated herein by reference to Exhibit 10.49.1 of the Form 10-K for the year ended December 31, 2007 filed with the Commission on February 26, 2008)
- 31.1 Certification of the President and Chief Executive Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification of the Principal 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