

ENDO PHARMACEUTICALS HOLDINGS INC

Form 10-Q

August 02, 2010

Table of Contents

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

Washington, DC 20549

**FORM 10-Q**

(Mark One)

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

**FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2010.**

**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**  
(Address of Principal Executive Offices)

**19317**  
(Zip Code)

**(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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Large accelerated filer  Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

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 July 22, 2010: 115,414,861

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**INDEX**

	<b>Page</b>
<u>Forward-Looking Statements</u>	i
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
Item 1. <u>Financial Statements</u>	1
<u>Condensed Consolidated Balance Sheets (Unaudited) June 30, 2010 and December 31, 2009</u>	1
<u>Condensed Consolidated Statements of Operations (Unaudited) Three and Six Months Ended June 30, 2010 and 2009</u>	2
<u>Condensed Consolidated Statements of Cash Flows (Unaudited) Six Months Ended June 30, 2010 and 2009</u>	3
<u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>	4
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	42
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	59
Item 4. <u>Controls and Procedures</u>	59
<b><u>PART II. OTHER INFORMATION</u></b>	
Item 1. <u>Legal Proceedings</u>	60
Item 1A. <u>Risk Factors</u>	60
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	63
Item 3. <u>Defaults Upon Senior Securities</u>	63
Item 4. <u>Removed and Reserved</u>	63
Item 5. <u>Other Information</u>	63
Item 6. <u>Exhibits</u>	63
<b><u>SIGNATURES</u></b>	64

**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 revenues, 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, 2009, filed with the Securities and Exchange Commission on February 26, 2010, 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 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 our Annual Report on Form 10-K for the year ended December 31, 2009 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 our Annual Report on Form 10-K. Important factors that could cause our actual results to differ materially from the expectations reflected in the forward-looking statements in our Annual Report on Form 10-K include those factors described herein under the caption Risk Factors and in documents incorporated 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 most of our products;

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

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

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

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, and the performance of indemnitors with respect to claims for which we have the right to be indemnified;

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

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 or have engaged 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 ability to successfully execute our strategy;

disruption of our operations if our information systems fail or if we are unsuccessful in implementing necessary upgrades or new software;

our ability to maintain or expand our business if we are unable to retain or attract key personnel and continue to attract additional professional staff;

our ability to successfully integrate HealthTronics, Inc. (HealthTronics) and realize all anticipated benefits of our acquisition;

HealthTronics ability to establish or maintain relationships with physicians and hospitals; and

HealthTronics ability to comply with special risks and requirements related to its medical products manufacturing business.

We do not undertake any obligation to update our forward-looking statements after the date of this Report for any reason, even if new information becomes available or other events occur in the future. You are advised, however, to consult any further disclosures we make on related subjects in our 10-Q, 10-K, and 8-K reports to the Securities and Exchange Commission (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)

	June 30, 2010	December 31, 2009
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 992,271	\$ 708,462
Restricted cash		1,515
Marketable securities		25,275
Accounts receivable, net	354,361	323,501
Inventories	85,280	84,893
Prepaid expenses and other current assets	88,702	17,081
Auction-rate securities rights, at fair value		15,659
Income taxes receivable	16,545	13,762
Deferred income taxes	91,233	90,433
Total current assets	1,628,392	1,280,581
MARKETABLE SECURITIES	22,010	211,792
PROPERTY AND EQUIPMENT, Net	44,962	47,529
GOODWILL	302,534	302,534
OTHER INTANGIBLES, Net	562,338	609,909
OTHER ASSETS	35,961	36,458
TOTAL ASSETS	\$ 2,596,197	\$ 2,488,803
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 178,751	\$ 176,076
Accrued expenses	313,976	286,606
Income taxes payable		9,498
Total current liabilities	492,727	472,180
DEFERRED INCOME TAXES	50,467	49,180
ACQUISITION-RELATED CONTINGENT CONSIDERATION	59,590	58,470
CONVERTIBLE SENIOR SUBORDINATED NOTES DUE 2015	269,402	260,279
NON-RECOURSE NOTES PAYABLE	62,068	62,255
OTHER LIABILITIES	90,476	89,028
COMMITMENTS AND CONTINGENCIES (NOTE 10)		
<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; 135,487,183 and 134,986,612 shares issued; 115,615,561 and 117,270,309 outstanding at June 30, 2010 and December 31, 2009, respectively	1,355	1,350

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

Additional paid-in capital	829,865	817,467
Retained earnings	1,217,106	1,105,291
Accumulated other comprehensive loss	(1,979)	(1,881)
Treasury stock, 19,871,622 and 17,716,303 shares at June 30, 2010 and December 31, 2009, respectively	(474,880)	(424,816)
Total stockholders' equity	1,571,467	1,497,411
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 2,596,197</b>	<b>\$ 2,488,803</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 June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
<b>REVENUES:</b>				
Net sales	\$ 394,121	\$ 370,625	\$ 754,470	\$ 704,628
Royalty and other revenue	2,403	2,483	6,466	3,780
<b>TOTAL REVENUES</b>	<b>396,524</b>	<b>373,108</b>	<b>760,936</b>	<b>708,408</b>
<b>COSTS AND EXPENSES:</b>				
Cost of revenues	107,216	95,069	201,289	178,078
Selling, general and administrative	133,251	129,592	266,586	249,598
Research and development	44,656	48,508	73,824	76,922
Impairment of other intangible assets	13,000		13,000	
Acquisition-related costs	4,796	35,023	6,325	61,428
<b>OPERATING INCOME</b>	<b>93,605</b>	<b>64,916</b>	<b>199,912</b>	<b>142,382</b>
INTEREST EXPENSE, NET	9,984	10,416	19,788	18,009
OTHER INCOME, NET	(201)	(1,515)	(420)	(410)
<b>INCOME BEFORE INCOME TAX</b>	<b>83,822</b>	<b>56,015</b>	<b>180,544</b>	<b>124,783</b>
<b>INCOME TAX</b>	<b>32,362</b>	<b>25,986</b>	<b>68,729</b>	<b>55,717</b>
<b>NET INCOME</b>	<b>\$ 51,460</b>	<b>\$ 30,029</b>	<b>\$ 111,815</b>	<b>\$ 69,066</b>
<b>NET INCOME PER SHARE:</b>				
Basic	\$ 0.44	\$ 0.26	\$ 0.96	\$ 0.59
Diluted	\$ 0.44	\$ 0.26	\$ 0.95	\$ 0.59
<b>WEIGHTED AVERAGE SHARES:</b>				
Basic	116,060	117,158	116,704	116,990
Diluted	116,660	117,350	117,346	117,279

See Notes to Condensed Consolidated Financial Statements.

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

	<b>Six Months Ended June 30,</b>	
	<b>2010</b>	<b>2009</b>
<b>OPERATING ACTIVITIES:</b>		
Net income	\$ 111,815	\$ 69,066
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	42,955	34,647
Stock-based compensation	10,391	7,844
Amortization of debt issuance costs and premium / discount	11,564	9,299
Selling, general and administrative expenses paid in shares of common stock	110	126
Deferred income taxes	988	(18,521)
Loss (gain) on disposal of property and equipment	18	(190)
Change in the fair value of acquisition-related contingent consideration	1,120	25,930
Loss on auction-rate securities rights	15,659	2,513
Gain on trading securities	(15,420)	(4,816)
Impairment of other indefinite-lived intangibles	13,000	
Changes in assets and liabilities which provided (used) cash:		
Accounts receivable	(30,860)	(49,110)
Inventories	(387)	(3,354)
Prepaid and other assets	(2,601)	11,856
Accounts payable	3,072	(10,655)
Accrued expenses	27,542	44,583
Other liabilities	(329)	1,213
Income taxes receivable/payable	(12,281)	20,141
 Net cash provided by operating activities	 176,356	 140,572
<b>INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	(6,166)	(6,012)
Proceeds from sales of trading securities	161,775	7,050
Acquisition, net of cash acquired		(249,546)
Funding of acquisition-related escrow		(175,000)
Other investments	(824)	(1,250)
 Net cash provided by (used in) investing activities	 154,785	 (424,758)
<b>FINANCING ACTIVITIES:</b>		
Capital lease obligations repayments	(172)	(119)
Tax benefits of stock awards	452	675
Exercise of Endo Pharmaceuticals Holdings Inc. Stock Options	2,452	6,536
Principal payments on 6.25% convertible notes due July 2009		(3,610)
Purchase of common stock	(50,064)	
 Net cash (used in) provided by financing activities	 (47,332)	 3,482
 <b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	 <b>283,809</b>	 <b>(280,704)</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>	<b>708,462</b>	<b>775,693</b>

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

CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 992,271	\$ 494,989
SUPPLEMENTAL INFORMATION:		
Interest paid	\$ 9,012	\$ 21,021
Income taxes paid	\$ 79,701	\$ 55,566
SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES		
Accrual for purchases of property and equipment	\$ 2,238	\$ 1,111

See Notes to Condensed Consolidated Financial Statements.

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

**NOTE 1. BASIS OF PRESENTATION**

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission for interim financial information. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, the accompanying Condensed Consolidated Financial Statements of Endo Pharmaceuticals Holdings Inc. (the Company or we, 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 June 30, 2010 and the results of our operations and our cash flows for the periods presented. Operating results for the three-month and six-month period ended June 30, 2010 is not necessarily indicative of the results that may be expected for the year ending December 31, 2010.

On February 23, 2009, the Company acquired Indevus Pharmaceuticals, Inc. (now, Endo Pharmaceuticals Solutions Inc.). Accordingly, as of February 23, 2009, all of the assets acquired and liabilities assumed were recorded at their respective fair values and our six month period ended June 30, 2009's condensed consolidated results of operations include Endo Pharmaceuticals Solutions Inc.'s operating results from February 23, 2009 through June 30, 2009.

On July 2, 2010 (referred to as the HealthTronics Acquisition Date), Endo completed its initial tender offer (the Offer) for all outstanding shares of common stock, par value \$0.01 per share (the Shares), of HealthTronics, at a price of \$4.85 per Share. On the HealthTronics Acquisition Date, Endo acquired a controlling financial interest in HealthTronics. On July 12, 2010, Endo completed its acquisition of HealthTronics for approximately \$212.9 million in aggregate cash consideration for 100% of the outstanding shares.

**NOTE 2. RECENT ACCOUNTING PRONOUNCEMENTS**

***Recently Adopted Accounting Pronouncements***

The Company adopted new authoritative guidance on variable interests effective January 1, 2010. The amendments change the process for how an enterprise determines which party consolidates a variable interest entity (a VIE) to a primarily qualitative analysis. The party that consolidates the VIE (the primary beneficiary) is defined as the party with (1) the power to direct activities of the VIE that most significantly affect the VIE's economic performance and (2) the obligation to absorb losses of the VIE or the right to receive benefits from the VIE. Upon adoption, reporting enterprises must reconsider their conclusions on whether an entity should be consolidated and should a change result; the effect on net assets will be recorded as a cumulative effect adjustment to retained earnings. This pronouncement did not have a material impact on the Company's consolidated financial statements.

The Company elected to adopt early the new authoritative guidance on revenue recognition effective January 1, 2010. The guidance provides greater ability to separate and allocate arrangement consideration in a multiple element revenue arrangement. In addition, it will require the use of estimated selling price to allocate arrangement considerations, therefore eliminating the use of the residual method of accounting. The Company has elected to prospectively adopt these provisions. Our adoption of this pronouncement did not have a material impact on the Company's consolidated financial statements.

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(UNAUDITED)**

**FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

The Company adopted the new authoritative guidance on convertible debt instruments that may be settled in cash or other assets on conversion as of January 1, 2009. The guidance 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 this new guidance. Therefore, we are 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. The provisions of the guidance are to be applied retrospectively to all periods presented upon adoption and became effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. The adoption will result in the recognition of approximately \$138.7 million of additional interest expense, on a pre-tax basis, over the life of our Convertible Notes. See Note 12 for further details.

The Company adopted the new authoritative guidance on interim disclosure about fair value of financial instruments beginning with the period ending June 30, 2009. The guidance amends previous authoritative guidance by requiring disclosures with respect to the fair value of financial instruments in interim and annual financial statements. The adoption did not have a material effect on the Company's consolidated results of operations or financial condition; however it did result in enhanced disclosures about fair value of financial instruments in our interim financial statements. See Note 3 for further details.

**NOTE 3. FAIR VALUE MEASUREMENTS**

The financial instruments recorded in our Condensed Consolidated Balance Sheets include cash and cash equivalents, accounts receivable, marketable securities, auction-rate securities rights, equity and cost method investments, accounts payable, acquisition related contingent consideration and our debt obligations. Included in cash and cash equivalents are money market funds representing 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. Due to their short-term maturity, the carrying amounts of cash and cash equivalents, accounts receivable and accounts payable approximate their fair values.

**Table of Contents****ENDO PHARMACEUTICALS HOLDINGS INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(UNAUDITED)****FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

The following table presents the carrying amounts and estimated fair values of our other financial instruments for the six-months ended June 30, 2010 and year ended December 31, 2009 (in thousands):

	June 30, 2010		December 31, 2009	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
<b>Current assets:</b>				
Auction-rate securities	\$	\$	\$ 25,275	\$ 25,275
Auction-rate securities rights			15,659	15,659
<b>Long-term assets:</b>				
Auction-rate securities	17,695	17,695	207,334	207,334
Equity securities	4,315	4,315	4,458	4,458
Equity and cost method investments	30,716	N/A	30,236	N/A
	\$ 52,726		\$ 282,962	
<b>Long-term liabilities:</b>				
Acquisition-related contingent consideration	\$ (59,590)	\$ (59,590)	\$ (58,470)	\$ (58,470)
1.75% Convertible Senior Subordinated Notes Due 2015	(269,402)	(271,043)	(260,279)	(277,651)
Non-recourse Notes Payable	(62,068)	(61,362)	(62,255)	(61,896)
Minimum Voltaren® Gel royalties due to Novartis	(51,772)	(51,772)	(49,996)	(49,996)
	\$ (442,832)	\$ (443,767)	\$ (431,000)	\$ (448,013)

Equity securities consist of publicly traded common stock the value which is based on a quoted market price. These securities are not held to support current operations and are therefore classified as non-current assets. The acquisition-related contingent consideration represents amounts payable to the former shareholders under contingent cash consideration agreements relating to the development of Avedd™ and octreotide (see Note 5 for further details). These amounts are required to be measured at fair value on a recurring basis. The fair value of our 1.75% Convertible Senior Subordinated Notes is based on an income approach known as the binomial lattice model which incorporated certain inputs and assumptions, including scheduled coupon and principal payments, the conversion feature inherent in the Convertible Notes, the put feature inherent in the Convertible Notes, and a stock price volatility of 36% that was based on historic volatility of the Company's common stock and other factors. The Non-recourse Notes were recorded at fair value as of February 23, 2009, the date we acquired Indevus. Fair value was determined using an income approach (present value technique). The Non-recourse Notes due in 2024 are being amortized down to their face value at maturity of \$57.0 million (see Note 12 for further details). The fair value of our Non-recourse Notes at June 30, 2010 was determined using an income approach (present value technique) consistent with the methodology used as of February 23, 2009.

The minimum Voltaren® Gel royalty due to Novartis AG was recorded at fair value at inception during 2008 using an income approach (present value technique) and is being accreted up to the maximum potential future payment of \$60.0 million. The Company is not aware of any events or circumstances that would have a significant effect on the fair value of this Novartis AG liability. We believe the carrying amount of this minimum royalty guarantee at June 30, 2010 and December 31, 2009 represents a reasonable approximation of the price that would be paid to transfer the liability in an orderly transaction between market participants at the measurement date. Accordingly, the carrying value approximates fair value as of June 30, 2010 and December 31, 2009. The fair value of equity method and cost method investments is not readily available nor have we estimated the fair value of these investments and disclosure is not required. The Company is not aware of any identified events or changes in circumstances that would have a significant adverse effect on the carrying value of our one \$20.8 million cost method investment.

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

As of June 30, 2010, the Company held certain assets and liabilities that are required to be measured at fair value on a recurring basis, including money market funds, available-for-sale securities and trading securities, auction-rate securities rights, and acquisition-related contingent consideration. Fair value guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include:

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.

**Table of Contents****ENDO PHARMACEUTICALS HOLDINGS INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(UNAUDITED)****FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

The Company's financial assets and liabilities measured at fair value on a recurring basis at June 30, 2010 and December 31, 2009, respectively, were as follows (in thousands):

	<b>Fair Value Measurements at Reporting Date Using</b>			
	<b>Quoted Prices in</b>			
	<b>Active</b>			
	<b>Markets</b>			
	<b>for</b>	<b>Significant Other</b>	<b>Significant</b>	
	<b>Identical</b>	<b>Observable</b>	<b>Unobservable</b>	
	<b>Assets</b>	<b>Inputs (Level</b>	<b>Inputs (Level 3)</b>	<b>Total</b>
	<b>(Level 1)</b>	<b>2)</b>		
<b>June 30, 2010</b>				
<b>Assets:</b>				
Money market funds	\$ 241,320	\$	\$	\$ 241,320
Auction-rate securities			17,695	17,695
Equity securities	4,315			4,315
<b>Total</b>	<b>\$ 245,635</b>	<b>\$</b>	<b>\$ 17,695</b>	<b>\$ 263,330</b>
<b>Liabilities:</b>				
Acquisition-related contingent consideration long-term			(59,590)	\$ (59,590)
<b>Total</b>	<b>\$</b>	<b>\$</b>	<b>\$ (59,590)</b>	<b>\$ (59,590)</b>
	<b>Fair Value Measurements at Reporting Date Using</b>			
	<b>Quoted Prices in</b>			
	<b>Active</b>			
	<b>Markets</b>			
	<b>for</b>	<b>Significant Other</b>	<b>Significant</b>	
	<b>Identical</b>	<b>Observable</b>	<b>Unobservable</b>	
	<b>Assets</b>	<b>Inputs (Level</b>	<b>Inputs (Level 3)</b>	<b>Total</b>
	<b>(Level 1)</b>	<b>2)</b>		
<b>December 31, 2009</b>				
<b>Assets:</b>				
Money market funds	\$ 279,772	\$	\$	\$ 279,772
Auction-rate securities	25,275		207,334	232,609
Auction-rate securities rights			15,659	15,659
Equity securities	4,458			4,458
<b>Total</b>	<b>\$ 309,505</b>	<b>\$</b>	<b>\$ 222,993</b>	<b>\$ 532,498</b>
<b>Liabilities:</b>				
Acquisition-related contingent consideration long-term			(58,470)	\$ (58,470)
<b>Total</b>	<b>\$</b>	<b>\$</b>	<b>\$ (58,470)</b>	<b>\$ (58,470)</b>



***Overview of Auction-Rate Securities***

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.

At June 30, 2010, the Company determined that the market for its auction-rate securities was still 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.

***Overview of Auction-Rate Securities Rights***

In October 2008, UBS AG (UBS) made an offer (the UBS Offer) to the Company and other clients of UBS Securities LLC and UBS Financial Services Inc. (collectively, the UBS Entities), pursuant to which the Company received auction-rate securities rights (the Rights) 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 permitted the Company to require UBS to purchase the Eligible Auction-Rate Securities for a price equal to par value plus any accrued but unpaid dividends or interest beginning on June 30, 2010 and ending on July 2, 2012. As of June 30, 2010, we exercised the Rights and on July 1, 2010 received cash for our remaining UBS portfolio at par. Accordingly, our UBS auction-rate securities were reclassified into a current receivable and \$68.6 million was included within Prepaid expenses and other current assets within the condensed consolidated balance sheet as of June 30, 2010. The remaining \$18.8 million of our auction-rate securities portfolio, at par-value, are not held in a UBS account and therefore were not subject to the UBS Offer.

Acceptance of the UBS Offer constituted a substantive change in facts and circumstances that altered the Company's view that it intended to hold the impaired securities until their anticipated recovery. Accordingly, we could no longer assert that we had the intent to hold the auction-rate securities until anticipated recovery. As a result, during the fourth quarter of 2008, we recognized an other-than-temporary impairment charge recorded in earnings. The charge was measured as the difference between the par value and fair value of the auction-rate securities on November 10, 2008. Previously recognized declines in fair value associated with the Eligible Auction-Rate Securities that were determined to be temporary were transferred out of other comprehensive income and charged to earnings as part of the impairment charge.

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(UNAUDITED)**

**FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

Acceptance of the UBS Offer created an enforceable legal right by and between the Company and UBS. The UBS Offer was a legally separate contractual agreement and was non-transferable. The Rights were not readily convertible to cash and did not provide for net settlement. Accordingly, the Rights did not meet the definition of a derivative instrument and were treated as a freestanding financial instrument. Accordingly, during the fourth quarter of 2008, the Company recognized an asset, measured at fair value, with the resultant gain recorded in earnings.

***Subsequent Accounting for Auction-Rate Securities and Auction-Rate Securities Rights***

As a result of the acceptance of the UBS Offer, we recognized an other than temporary impairment charge as of December 31, 2008 of approximately \$26.4 million that is included in Other (income) expense, net in the Consolidated Statements of Operations.

Concurrent with the acceptance of the UBS offer, the Company made a one-time election to re-classify the Eligible Auction-Rate Securities from an available-for-sale security to a trading security. The Company made the election to transfer the securities into trading after considering the unprecedented failure of the entire market for auction-rate securities and the broad-reaching legal settlements that have been agreed to by certain broker-dealers and securities regulators. Subsequent changes to the fair value of these trading securities resulted in \$13.7 million and \$15.4 million, respectively, of income during the three and six months ended June 30, 2010 and additional income of \$10.9 million and \$4.8 million, respectively, during the three and six months ended June 30, 2009, and were recorded in other expense and other income, net in the Condensed Consolidated Statements of Operations.

During 2008, we elected the fair value option for our auction-rate securities rights. As a result of our election, the fair value of the auction-rate securities rights are re-measured each reporting period with the corresponding changes in fair value reported in earnings. Since the auction-rate securities rights are freestanding financial instruments, they do not affect the separate determination of the fair value of the Eligible Auction-Rate Securities. However, in management's view, the auction-rate securities rights act as an economic hedge against further fair value changes in the Eligible Auction-Rate Securities. At June 30, 2010, the fair value of our auction-rate securities rights were written off to the income statement as a result of the execution of the Rights. Accordingly, the decrease in fair value for the three and six months ended June 30, 2010 of \$13.8 million and \$15.7 million, respectively, was recognized as a charge to earnings and included in Other income, net in the Condensed Consolidated Statements of Operations.

***Valuation of the Auction-Rate Securities***

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 to determine an indication of fair value.

To calculate a price for our auction-rate securities, the Company calculates duration 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 duration 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 five to eight years. The weighted average life measured across the entire auction-rate portfolio is approximately eight 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 rate on June 30, 2010 was 4.91% for the remaining securities. 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 June 30, 2010, the base rate for our securities applied to our securities was 167 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 do not believe it is 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 June 30, 2010, the fair value of our auction-rate securities, as determined by applying the above described discount rate adjustment technique, was approximately \$17.7 million, representing a six percent (6%), or \$1.1 million discount from their original purchase price or par value. This compares to approximately \$232.6 million, representing a 7%, or \$16.5 million discount from their original purchase price or par value at December 31, 2009. 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 at June 30, 2010 and December 31, 2009 were reduced by approximately \$1.1 million and \$16.5 million, respectively. These adjustments appropriately reflect the changes in fair value, which the Company attributes to liquidity issues rather than credit issues.

**Table of Contents****ENDO PHARMACEUTICALS HOLDINGS INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(UNAUDITED)****FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

The portion of this decline in fair value related to the Eligible Auction-Rate Securities was recorded in earnings as an other-than-temporary impairment charge or as changes in the fair value of trading securities. The Company has assessed the portion of the decline in fair value not associated with the Eligible Auction-Rate Securities 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 \$0.01 million loss and a \$0.6 million gain in shareholders' equity in accumulated other comprehensive loss as of June 30, 2010 and December 31, 2009, respectively. Securities not subject to the UBS Offer 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 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. However, there can be no assurance that our current belief that the securities not subject to the UBS Offer will recover their value will not change.

***Valuation of the Auction-Rate Securities Rights***

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 the auction-rate securities rights. Specifically, the Company used the discount rate adjustment technique to determine an indication of fair value.

The values of the Rights at December 31, 2009 were estimated as the value of a portfolio designed to approximate the cash flows of the UBS Agreement. The portfolio consists of a bond issued by UBS that will mature equal to the face value of the auction-rate securities, a series of payments that will replicate the coupons of the auction-rate securities, and a short position in the callable auction-rate security. If the UBS agreement is in the money on the exercise date, then both the UBS agreement and the replicating portfolio will be worth the difference between the par value of the ARS and the market value of the ARS. If the UBS agreement is out of the money on the exercise date, then both the replicating portfolio and the UBS agreement will have no value.

For purposes of valuing the UBS bond, management selected a required rate of return for a UBS obligation based on market factors including relevant credit default spreads. The rate of return for the auction-rate securities is determined as described above under "Valuation of the Auction-Rate Securities" and is used to determine the present value of the coupons of the auction-rate security.

At June 30, 2010, the fair value of our auction-rate securities rights were adjusted to \$0 due to the Rights being exercised and the associated UBS securities being sold as of June 30, 2010. For comparable 2009 periods, the Company chose to use a four-year term to adjust for the lack of liquidity on the auction-rate securities as we believe it is the point within the range that is most representative of fair value. Accordingly, the same term was used when valuing the Rights. We believe we have appropriately reflected our best estimate of the assumptions that market participants would use in pricing the asset in a current transaction to sell the asset at the measurement date.

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) for the three months ended June 30, 2010 and 2009 (in thousands):

	<b>Fair Value Measurements Using Significant Unobservable Inputs (Level 3)</b>		
	<b>Auction-rate Securities</b>	<b>Auction-rate Securities Rights</b>	<b>Total</b>
Balance at April 1, 2010	\$ 186,851	\$ 13,749	\$ 200,600
Securities sold or redeemed	(182,850)		(182,850)

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

Securities purchased or acquired			
Transfers in and/or (out) of Level 3			
Changes in fair value recorded in earnings	13,714	(13,749)	(35)
Unrealized gain included in other comprehensive loss	(20)		(20)
Balance at June 30, 2010	\$ 17,695	\$	\$ 17,695

Table of Contents

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(UNAUDITED)

## FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3) Acquisition-related Contingent Consideration	
<b>Liabilities:</b>		
Balance at April 1, 2010	\$	(59,360)
Amounts acquired or issued		
Transfers in and/or (out) of Level 3		
Changes in fair value recorded in earnings		(230)
Balance at June 30, 2010	\$	(59,590)

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)		
	Auction-rate Securities	Auction-rate Securities Rights	Total
Balance at April 1, 2009	\$ 227,670	\$ 33,587	\$ 261,257
Securities sold or redeemed	(400)		(400)
Securities purchased or acquired			
Transfers in and/or (out) of Level 3	(850)		(850)
Changes in fair value recorded in earnings	10,910	(8,779)	2,131
Unrealized gain included in other comprehensive loss	440		440
Balance at June 30, 2009	\$ 237,770	\$ 24,808	\$ 262,578

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3) Acquisition-related Contingent Consideration	
<b>Liabilities:</b>		
Balance at April 1, 2009	\$	(188,020)
Amounts acquired or issued		
Transfers in and/or (out) of Level 3		
Changes in fair value recorded in earnings		(25,930)
Balance at June 30, 2009	\$	(213,950)

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) for the six months ended June 30, 2010 and 2009 (in thousands):

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)		
	Auction-rate Securities	Auction-rate Securities Rights	Total
Balance at January 1, 2010	\$ 207,334	\$ 15,659	\$ 222,993
Securities sold or redeemed	(205,050)		(205,050)
Securities purchased or acquired			
Transfers in and/or (out) of Level 3			
Changes in fair value recorded in earnings	15,420	(15,659)	(239)
Unrealized gain included in other comprehensive loss	(9)		(9)
Balance at June 30, 2010	\$ 17,695	\$	\$ 17,695

Table of Contents

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(UNAUDITED)

## FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3) Acquisition-related Contingent Consideration	
<b>Liabilities:</b>		
Balance at January 1, 2010	\$	(58,470)
Amounts acquired or issued		
Transfers in and/or (out) of Level 3		
Changes in fair value recorded in earnings		(1,120)
Balance at June 30, 2010	\$	(59,590)

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)		
	Auction-rate Securities	Auction-rate Securities Rights	Total
Balance at January 1, 2009	\$ 234,005	\$ 27,321	\$ 261,326
Securities sold or redeemed	(550)		(550)
Securities purchased or acquired			
Transfers in and/or (out) of Level 3	(850)		(850)
Changes in fair value recorded in earnings	4,816	(2,513)	2,303
Unrealized gain included in other comprehensive loss	349		349
Balance at June 30, 2009	\$ 237,770	\$ 24,808	\$ 262,578

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3) Acquisition-related Contingent Consideration	
<b>Liabilities:</b>		
Balance at January 1, 2009	\$	
Amounts acquired or issued		(188,020)
Transfers in and/or (out) of Level 3		
Changes in fair value recorded in earnings		(25,930)
Balance at June 30, 2009	\$	(213,950)

At June 30, 2010, the fair value of the Company's trading securities was \$0. The following is a summary of available-for-sale securities held by the Company as of June 30, 2010 and December 31, 2009 (in thousands):



	Amortized Cost	Available-for-sale		Fair Value
		Gross Unrealized Gains	Gross Unrealized (Losses)	
<b>June 30, 2010:</b>				
Money market funds	\$ 241,320	\$	\$	\$ 241,320
<i>Total included in cash and cash equivalents</i>	241,320			241,320
Auction-rate securities	18,800		(1,105)	17,695
Equity securities	5,564		(1,248)	4,315
<i>Long-term available-for-sale securities</i>	24,364		(2,353)	22,010
<i>Total available-for-sale securities</i>	\$ 265,684	\$	\$ (2,353)	\$ 263,330

Table of Contents

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(UNAUDITED)

FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010

	Amortized Cost	Available-for-sale Gross Unrealized Gains	Gross Unrealized (Losses)	Fair Value
<b>December 31, 2009:</b>				
Money market funds	\$ 279,772	\$	\$	\$ 279,772
<i>Total included in cash and cash equivalents</i>	279,772			279,772
Auction-rate securities	18,800		(1,096)	17,704
Equity securities	5,564		(1,106)	4,458
<i>Long-term available-for-sale securities</i>	24,364		(2,202)	22,162
<i>Total available-for-sale securities</i>	\$ 304,136	\$	\$ (2,202)	\$ 301,934

**Table of Contents****ENDO PHARMACEUTICALS HOLDINGS INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(UNAUDITED)****FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

During the six-month period ended June 30, 2010, we sold \$230.3 million of auction-rate securities at par value. During the three-month period ended June 30, 2010, we sold \$197.9 million of auction-rate securities at par value. There were no realized holding gains and losses resulting from the sales of our auction rate securities and variable rate demand obligations during the period ended June 30, 2010 and 2009. The cost of securities sold is based on the specific identification method.

The underlying assets of our auction-rate securities are student loans. Student loans are insured by the Federal Family Education Loan Program, or FFELP.

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 June 30, 2010 and December 31, 2009 (in thousands):

	Underlying Credit Rating(1)					Total
	AAA	A	B2	Ba2	Baa3	
<b>As of June 30, 2010:</b>						
<i>Underlying security:</i>						
Student loans	\$ 17,695	\$	\$	\$	\$	\$ 17,695
<i>Total auction-rate securities included in long-term marketable securities</i>	\$ 17,695	\$	\$	\$	\$	\$ 17,695

	Underlying Credit Rating(1)					Total
	AAA	A	B2	Ba2	Baa3	
<b>As of December 31, 2009:</b>						
<i>Underlying security:</i>						
Student loans	\$ 130,861	\$ 51,781	\$ 9,934	\$ 7,201	\$ 7,557	\$ 207,334
<i>Total auction-rate securities included in long-term marketable securities</i>	\$ 130,861	\$ 51,781	\$ 9,934	\$ 7,201	\$ 7,557	\$ 207,334

(1) Our auction-rate securities maintain split ratings. For purposes of this table, securities are categorized according to their lowest rating. As of June 30, 2010, the yields on our long-term auction-rate securities ranged from 0.62% to 0.633%. 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 June 30, 2010, the weighted average yield for our long-term auction-rate securities was 0.626%. Total interest recognized on our auction-rate securities during the six-months ended June 30, 2010, and 2009 was \$0.6 million and \$1.5 million, respectively. The issuers have been making interest payments promptly.

The amortized cost and estimated fair value of available-for-sale 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.

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

	June 30, 2010		December 31, 2009	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Available-for-sale debt securities:				
Due in less than 1 year	\$	\$	\$	\$
Due in 1 to 5 years				
Due in 5 to 10 years				
Due after 10 years	18,800	17,695	18,800	17,704
Equity securities	5,564	4,315	5,564	4,458
<b>Total</b>	<b>\$ 24,364</b>	<b>\$ 22,010</b>	<b>\$ 24,364</b>	<b>\$ 22,162</b>

**Table of Contents****ENDO PHARMACEUTICALS HOLDINGS INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(UNAUDITED)****FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010*****Nonrecurring Fair Value Measurements***

The Company's financial assets measured at fair value on a nonrecurring basis at June 30, 2010 were as follows (in thousands):

	Fair Value Measurements at June 30, 2010 Using			Total Loss
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
<b>Assets:</b>				
Pagoclone indefinite-lived intangible asset	\$	\$	\$ 8,000	\$ (13,000)
<b>Total</b>	<b>\$</b>	<b>\$</b>	<b>\$ 8,000</b>	<b>\$ (13,000)</b>

In September 2008, Indevus Pharmaceuticals, Inc. (Indevus), which the Company acquired in 2009, entered into a Development, License and Commercialization Agreement (the Teva agreement), with Teva Pharmaceutical Industries Ltd. (Teva) for the exclusive, worldwide rights to pagoclone. Under the terms of the Teva Agreement, the Company conducted, and Teva reimbursed expenses for a Phase IIb study for stuttering. Teva would have then been responsible for the conduct of all remaining development and commercialization, including the Phase III program. Additionally, the Company would have received royalties on net sales, in addition to milestone payments. In May 2010, following the completion of the phase IIb study, Teva terminated the Teva agreement. As a result of the termination, all rights to pagoclone were returned to the Company.

Due to the termination of the Teva agreement, as well as our preliminary analysis of the completed phase IIb study, the Company concluded that an impairment assessment was required to evaluate the recoverability of the indefinite-lived intangible asset as of June 30, 2010. To estimate fair value, we assessed the product's indication and targeted population of eligible recipients, the future probability of regulatory approval, relative timing of commercialization, and estimates of the amount and timing of future cash flows. To calculate the fair value of the pagoclone intangible asset, the Company used an income approach using a discounted cash flow model considering management's current evaluation of the above mentioned factors. The Company utilized a probability-weighted cash flow model using a present value discount factor of 17% which we believe to be commensurate with the overall risk associated with this particular product. The cash-flow models included our best estimates of future FDA approval associated with the indication and population of eligible recipients. The Company presently believes that the level and timing of cash flows assumed, discount rate, and probabilities of success appropriately reflect market participant assumptions.

The fair value of the pagoclone intangible asset was determined to be \$8.0 million. Accordingly, the Company recorded a pre-tax non-cash impairment charge of \$13.0 million for the three months ended June 30, 2010, representing the difference between the carrying value of the intangible asset and its estimated fair value. The impairment charge was recognized in earnings and included the Impairment of other intangible assets line item in the Condensed Consolidated Statements of Operations. Changes in any of our assumptions may result in a further reduction to the estimated fair value of the pagoclone intangible asset and could result in additional and potentially full future impairment charges of up to \$8.0 million.

**NOTE 4. INVENTORIES**

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

Inventories are comprised of the following at June 30, 2010 and December 31, 2009, respectively (in thousands):

	<b>June 30, 2010</b>	<b>December 31, 2009</b>
Raw materials	\$ 12,419	\$ 8,510
Work-in-process	23,910	25,799
Finished goods	48,951	50,584
Total	\$ 85,280	\$ 84,893

**Table of Contents****ENDO PHARMACEUTICALS HOLDINGS INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(UNAUDITED)****FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010****NOTE 5. ACQUISITIONS***Indevus Pharmaceuticals, Inc.*

On February 23, 2009 (the Acquisition Date), the Company completed its initial tender offer (the Offer) for all outstanding shares of common stock of Indevus. Through purchases in tender offer periods, the exercise of a top-up option and a subsequent merger (the Merger), the Company completed its acquisition of Indevus on March 23, 2009, at which time Indevus became a wholly-owned subsidiary of the Company.

The Indevus Shares were purchased at a price of \$4.50 per Indevus Share, net to the seller in cash, plus contractual rights to receive up to an additional \$3.00 per Indevus Share in contingent cash consideration payments, pursuant to the terms of the Agreement and Plan of Merger, dated as of January 5, 2009. Accordingly, the Company paid approximately \$368 million in aggregate initial cash consideration for the Indevus Shares and entered into the Aveed<sup>TM</sup> Contingent Cash Consideration Agreement and the Octreotide Contingent Cash Consideration Agreement (each as defined in the Merger Agreement), providing for the payment of up to an additional \$3.00 per Indevus Share in contingent cash consideration payments, in accordance with the terms of the Offer. The total cost to acquire all outstanding Indevus Shares pursuant to the Offer and the Merger could be up to an additional approximately \$267 million, if Endo is obligated to pay the maximum amounts under the Aveed<sup>TM</sup> Contingent Cash Consideration Agreement and the Octreotide Contingent Cash Consideration Agreement.

Management believes the Company's acquisition of Indevus is particularly significant because it reflects our commitment to expand our business beyond pain management into complementary medical areas where we believe we can be innovative and competitive. The combined company markets products through four field sales forces and has the capability to develop innovative new therapies using a novel drug delivery technology.

The operating results of Indevus from February 23, 2009 are included in the accompanying condensed consolidated statements of operations. The consolidated balance sheet as of December 31, 2009 reflects the acquisition of Indevus, effective February 23, 2009, the date the Company obtained control of Indevus. The acquisition date fair value of the total consideration transferred was \$540.9 million, which consisted of the following (in thousands):

	<b>Fair Value of Consideration Transferred</b>
Cash	\$ 368,034
Contingent consideration	172,860
<b>Total</b>	<b>\$ 540,894</b>

As of June 30, 2010 and December 31, 2009, the fair value of the contingent consideration is \$59.6 million and \$58.5 million, respectively.

In the event that the Company receives an approval letter from the FDA with respect to the Aveed<sup>TM</sup> NDA on or before the third anniversary of the time at which we purchased the Indevus Shares in the Offer, then the Company will, subject to the terms described below, (i) pay an additional \$2.00 per Indevus Share to the former stockholders of Indevus, if such approval letter grants the right to market and sell Aveed<sup>TM</sup> immediately and provides labeling for Aveed<sup>TM</sup> that does not contain a boxed warning (Aveed<sup>TM</sup> With Label) or alternatively, (ii) pay an additional \$1.00 per Indevus Share, if such approval letter grants the right to market and sell Aveed<sup>TM</sup> immediately and provides labeling for Aveed<sup>TM</sup> that contains a boxed warning (Aveed<sup>TM</sup> Without Label). In the event that either an Aveed<sup>TM</sup> With Label approval or an Aveed<sup>TM</sup>

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

Without Label approval has not been obtained prior to the third anniversary of the closing of the Offer, then the Company will not pay, and the former Indevus stockholders will not receive, any payments under the Aveed™ Contingent Cash Consideration Agreement.

Further, in the event that the Aveed™ Without Label approval is received and subsequently, Endo and its subsidiaries publicly report audited financial statements which reflect net sales of Aveed™ of at least \$125.0 million in the aggregate for any four consecutive calendar quarters on or prior to the fifth anniversary of the date of the first commercial sale of Aveed™ (Aveed™ Net Sales Event), then the Company will, subject to the terms described below, pay an additional \$1.00 per Indevus Share to the former stockholders of Indevus. In the event that the Aveed™ Net Sales Event does not occur prior to the fifth anniversary of the date of the first commercial sale of Aveed™ then the Company will not pay, and former Indevus stockholders will not receive, any additional amounts under the Aveed™ Contingent Cash Consideration Agreement.



**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(UNAUDITED)**

**FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

The range of the undiscounted amounts the Company could pay under the Aveed™ Contingent Cash Consideration Agreement is between \$0 and approximately \$175 million. The fair value of the contractual obligation to pay the Aveed™ contingent consideration recognized on the Acquisition Date was \$133.1 million. We determined the fair value of the obligation to pay the Aveed™ contingent consideration based on a probability-weighted income approach. This fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy. Under the Aveed™ Contingent Cash Consideration Agreement, there are three scenarios that could potentially lead to amounts being paid to the former stockholders of Indevus. These scenarios are (1) obtaining an Aveed™ With Label approval, (2) obtaining an Aveed™ Without Label approval and (3) achieving the \$125.0 million sales milestone on or prior to the fifth anniversary of the date of the first commercial sale of Aveed™ should the Aveed™ Without Label approval be obtained. The fourth scenario is Aveed™ not receiving approval within three years of the closing of the Offer, which would result in no payment to the former stockholders of Indevus. Each scenario was assigned a probability based on the current regulatory status of Aveed™. The resultant probability-weighted cash flows were then discounted using a discount rate of U.S. Prime plus 300 basis points, which the Company believes is appropriate and is representative of a market participant assumption. In May 2010, the Company met with the FDA to discuss our path-forward as well as the understanding of the existing clinical data provided to the FDA. The Company expects to have further correspondence with the FDA in the second half of 2010, the results of which could materially impact the fair value of the Aveed™ contingent consideration liability due to the potential to pay in the range of \$0 to the maximum amount of \$175 million under the Aveed™ Contingent Cash Consideration Agreement. The fair value of the contractual obligation to pay the Aveed™ contingent consideration was \$7.0 million and \$7.5 million at June 30, 2010 and December 31, 2009, respectively. Future changes in any of our assumptions could result in further volatility to the estimated fair value of the acquisition-related contingent consideration. Such additional changes to fair value could materially impact our results of operations in future periods.

Similarly, in the event that an approval letter from the FDA is received with respect to an octreotide NDA (such approval letter, the Octreotide Approval) on or before the fourth anniversary of the closing of the Offer, then the Company will, subject to the terms described below, pay an additional \$1.00 per Indevus Share to the former stockholders of Indevus (such payment, the Octreotide Contingent Cash Consideration Payment). In the event that an Octreotide Approval has not been obtained prior to the fourth anniversary of the closing of the Offer, then the Company will not pay, and the former Indevus stockholders shall not receive, the Octreotide Contingent Cash Consideration Payment.

The range of the undiscounted amounts the Company could pay under the Octreotide Contingent Cash Consideration Agreement is between \$0 and approximately \$91 million. The fair value of the octreotide contractual obligation to pay the contingent consideration recognized on the Acquisition Date was \$39.8 million. We determined the fair value of the contractual obligation to pay the Octreotide Contingent Consideration Payment based on a probability-weighted income approach. This fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy. Under the Octreotide Contingent Cash Consideration Agreement, the two scenarios that require consideration are (1) Octreotide Approval on or before the fourth anniversary of the closing of the Offer or (2) no Octreotide Approval on or before the fourth anniversary of the closing of the Offer. Each scenario was assigned a probability based on the current development stage of octreotide. The resultant probability-weighted cash flows were then discounted using a discount rate of U.S. Prime plus 300 basis points, which the Company believes is appropriate and is representative of a market participant assumption. The fair value of the contractual obligation to pay the octreotide contingent consideration was approximately \$44 million and \$43 million at June 30, 2010 and December 31, 2009, respectively. Future changes in any of our assumptions could result in further volatility to the estimated fair value of the acquisition-related contingent consideration. Such additional changes to fair value could materially impact our results of operations in future periods.

In addition to the potential contingent payments under the Aveed™ Contingent Cash Consideration Agreement and the Octreotide Contingent Cash Consideration Agreement, the Company has assumed a pre-existing contingent consideration obligation relating to Indevus's acquisition of Valera Pharmaceuticals, Inc. (the Valera Contingent Consideration), which was consummated on April 18, 2007. The Valera Contingent Consideration entitles former Valera shareholders to receive additional Indevus Shares based on an agreed upon conversion factor if FDA approval of the octreotide implant for the treatment for acromegaly is achieved on or before April 18, 2012. Upon Endo's acquisition of Indevus, each Valera shareholder's right to receive additional Indevus Shares was converted into the right to receive \$4.50 per Indevus Share that such

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

former Valera shareholder would have received plus contractual rights to receive up to an additional \$3.00 per Indevus Share that such former Valera shareholder would have received in contingent cash consideration payments under the Aveed™ Contingent Cash Consideration Agreement and the Octreotide Contingent Cash Consideration Agreement. These amounts would only be payable to former Valera shareholders if there were Octreotide Approval. The range of the undiscounted amounts the Company could pay with respect to the Valera Contingent Consideration is between \$0 and approximately \$33 million.

The Company is accounting for the Valera Contingent Consideration in the same manner as if it had entered into that arrangement with respect to its acquisition of Indevus. Accordingly, the fair value of the Valera Contingent Consideration recognized on the Acquisition Date was \$13.7 million. Fair value was estimated based on a probability-weighted discounted cash flow model, or income approach. This fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy. The fair value of the Valera Contingent Consideration is estimated using the same assumptions used for the Aveed™ Contingent Cash Consideration Agreement and Octreotide Contingent Cash Consideration Agreement, except that the probabilities associated with the Valera Contingent Consideration take into account the probability of obtaining the Octreotide Approval on or before the fourth anniversary of the closing of the Offer. This is due to the fact that the Valera Contingent Consideration will not be paid unless Octreotide for the treatment of acromegaly is approved prior to April 18, 2012. The fair value of the contractual obligation to pay the Valera contingent consideration was \$9 million and \$8 million at June 30, 2010 and December 31, 2009, respectively. Future changes in any of our assumptions could result in further volatility to the estimated fair value of the acquisition-related contingent consideration. Such additional changes to fair value could materially impact our results of operations in future periods.

**Table of Contents****ENDO PHARMACEUTICALS HOLDINGS INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(UNAUDITED)****FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

As of June 30, 2010, the aggregate fair values of the three acquisition-related contingent consideration liabilities increased by approximately \$1.1 million from December 31, 2009 primarily reflecting changes of our present value assumptions associated with our valuation model. The increase in the liability was recorded as a loss and is included in the Acquisition-related items line item in the accompanying Condensed Consolidated Statements of Operations.

The following table summarizes the fair values of the assets acquired and liabilities assumed at the Acquisition Date (in thousands):

	<b>February 23, 2009</b>
Cash and cash equivalents	\$ 117,675
Accounts receivable	14,591
Inventories	17,157
Prepaid and other current assets	8,322
Property, plant and equipment	8,856
Other intangible assets	532,900
Deferred tax assets	167,749
Other non-current assets	1,331
<b>Total identifiable assets</b>	<b>\$ 868,581</b>
Accounts payable	\$ (5,116)
Accrued expenses	(26,725)
Convertible notes	(72,512)
Non-recourse notes	(115,235)
Deferred tax liabilities	(210,647)
Other non-current liabilities	(18,907)
<b>Total liabilities assumed</b>	<b>(449,142)</b>
<b>Net identifiable assets acquired</b>	<b>\$ 419,439</b>
Goodwill	\$ 121,455
<b>Net assets acquired</b>	<b>\$ 540,894</b>

The above fair values of assets acquired and liabilities assumed are based on the information that was available as of the Acquisition Date to estimate the fair value of assets acquired and liabilities assumed.

The valuation of the intangible assets acquired and related amortization periods are as follows:

**Valuation  
(in millions)**

		<b>Amortization Period (in years)</b>
<b>In Process Research &amp; Development:</b>		
Valstar <sup>®</sup> (1)	\$ 88.0	n/a
Aveed <sup>™</sup> (2)	100.0	n/a
Octreotide	31.0	n/a
Pagoclone(3)	21.0	n/a
Pro2000(4)	4.0	n/a
Other	11.9	n/a
 Total	 \$ 255.9	 n/a
<b>License Rights:</b>		
Hydron <sup>®</sup> Polymer	\$ 22.0	10
Vantas <sup>®</sup>	36.0	10
Sanctura <sup>®</sup> Franchise	94.0	12
Supprelin <sup>®</sup> LA	124.0	10
Other	1.0	4
 Total	 \$ 277.0	 11
 Total other intangible assets	 \$ 532.9	

- (1) The FDA approved the sNDA for Valstar<sup>®</sup> subsequent to the Acquisition Date. Therefore, Valstar<sup>®</sup> was initially classified as in-process research and development and subsequently transferred to License Rights upon obtaining FDA approval and is being amortized over a 15 year useful life.

**Table of Contents****ENDO PHARMACEUTICALS HOLDINGS INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(UNAUDITED)****FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

- (2) As a result of the FDA's complete response letter related to our filed NDA, we performed an impairment analysis during the fourth quarter ended December 31, 2009. The Company concluded there was a decline in the fair value of the indefinite-lived intangible. Accordingly, we recorded a \$65.0 million impairment charge. Changes in any of our assumptions may result in a further reduction to the estimated fair value of the Aveed™ intangible asset resulting in additional and potentially full future impairment charges. Such additional impairment charges could materially impact our results of operations in future periods.
- (3) In May 2010, Teva terminated the development and licensing arrangement with the Company upon the completion of the Phase IIb study. The Company concluded there was a decline in the fair value of the indefinite-lived intangible asset. Accordingly, we recorded a \$13.0 million impairment charge.
- (4) In December 2009, the Company's Phase III clinical trials for Pro2000 provided conclusive results that the drug was not effective. The Company concluded there was no further value or alternative future uses associated with this indefinite-lived asset. Accordingly, we recorded a \$4.0 million impairment charge to write-off the Pro2000 intangible asset in its entirety.

The fair value of the in-process research and development assets and License Rights assets, with the exception of the Hydron® Polymer Technology, were estimated using an income approach. Under this method, an intangible asset's fair value is equal to the present value of the incremental after-tax cash flows (excess earnings) attributable solely to the intangible asset over its remaining useful life. To calculate fair value, the Company used probability-weighted cash flows discounted at rates considered appropriate given the inherent risks associated with each type of asset. The Company believes that the level and timing of cash flows appropriately reflect market participant assumptions. Cash flows were generally assumed to extend either through or beyond the patent life of each product, depending on the circumstances particular to each product. The fair value of the Hydron® Polymer Technology was estimated using an income approach, specifically known as the relief from royalty method. The relief from royalty method is based on a hypothetical royalty stream that would be received if the Company were to out-license the technology. The Hydron® Polymer Technology is currently used in the following products: Vantas®, Supprelin® LA and octreotide. Thus, we derived the hypothetical royalty income from the projected revenues of those drugs. The fair value of the Hydron® Polymer Technology also includes an existing royalty payable by the Company to certain third party partners based on the net sales derived from drugs that use the Hydron® Polymer Technology. Discount rates applied to the estimated cash flows for all intangible assets acquired ranged from 13% to 20%, depending on the current stage of development, the overall risk associated with the particular project or product and other market factors. We believe the discount rates used are consistent with those that a market participant would use.

The \$121.5 million of goodwill was assigned to our pharmaceutical products segment, which was our only reportable segment as of December 31, 2009. The goodwill recognized is attributable primarily to the potential additional applications for the Hydron® Polymer Technology, expected corporate synergies, the assembled workforce of Indevus and other factors. None of the goodwill is expected to be deductible for income tax purposes.

The deferred tax assets of \$167.7 million are related primarily to federal net operating loss and credit carryforwards of Indevus and its subsidiaries. The deferred tax liabilities of \$210.6 million are related primarily to the difference between the book basis and tax basis of identifiable intangible assets.

The Company recognized \$0.2 million and \$35.0 million of acquisition-related costs that were expensed for the three-month period ended June 30, 2010 and 2009, respectively and \$1.6 million and \$61.4 million for the six-month periods ended June 30, 2010 and 2009, respectively. These costs are included in line item entitled "Acquisition-related items" in the accompanying Condensed Consolidated Statements of Operations and are comprised of the following items (in thousands):

<b>Acquisition-related Costs</b>	
<b>Three Months Ended</b>	<b>Three Months Ended</b>
<b>June</b>	<b>June 30, 2009</b>
<b>30, 2010</b>	<b>June 30, 2009</b>

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

Investment bank fees, includes Endo and Indevus	\$	\$	
Accounting and legal			1,073
Separation and other costs			8,020
Changes in fair value of acquisition-related contingent consideration	230		25,930
Total	\$ 230	\$	35,023

**Table of Contents****ENDO PHARMACEUTICALS HOLDINGS INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(UNAUDITED)****FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

	Acquisition-related Costs	
	Six Months Ended June 30, 2010	Six Months Ended June 30, 2009
Investment bank fees, includes Endo and Indevus	\$	\$ 13,030
Accounting and legal		6,962
Separation and other costs	452	15,506
Changes in fair value of acquisition-related contingent consideration	1,120	25,930
<b>Total</b>	<b>\$ 1,572</b>	<b>\$ 61,428</b>

The amounts of revenue and net loss of Indevus included in the Company's Condensed Consolidated Statements of Operations for the three months ended June 30, 2009 and from the Acquisition date to the period ending June 30, 2009 are as follows (in thousands, except per share data):

	Revenue and Losses included in the Condensed Consolidated Statements of Operations for the three-months ended June 30, 2009	Revenue and Losses included in the Condensed Consolidated Statements of Operations from February 23, 2009 to June 30, 2009
Revenue	\$ 16,518	\$ 24,434
Net loss	\$ (24,140)	\$ (35,392)
Basic and diluted loss per share	\$ (0.21)	\$ (0.30)

The following supplemental pro forma information presents the financial results as if the acquisition of Indevus had occurred January 1, 2009 for the six months ended June 30, 2009. This supplemental pro forma information has been prepared for comparative purposes and does not purport to be indicative of what would have occurred had the acquisition been made on January 1, 2009, nor are they indicative of any future results.

	Six Months ended June 30, 2009
<b>Pro forma consolidated results (in thousands, except per share data):</b>	
Revenue	\$ 718,708
Net income	\$ 46,066
Basic earnings per share	\$ 0.39
Diluted earnings per share	\$ 0.39

These amounts have been calculated after applying the Company's accounting policies and adjusting the results of Indevus to reflect a different revenue recognition model, the additional depreciation and amortization that would have been charged assuming the fair value adjustments to

property, plant and equipment, intangible assets, unfavorable leases and current and long-term debt, had been applied on January 1, 2009, together with the consequential tax effects.

**NOTE 6. LICENSE AND COLLABORATION AGREEMENTS**

***Commercial Products***

*Novartis AG and Novartis Consumer Health, Inc.*

On March 4, 2008, we entered into a License and Supply Agreement (the Voltaren® Gel Agreement) with and among Novartis AG and Novartis Consumer Health, Inc (Novartis) to obtain the exclusive U.S. marketing rights for the prescription medicine Voltaren® Gel (Voltaren® Gel or Licensed Product). Voltaren® Gel received regulatory approval in October 2007 from the U.S. Food and Drug Administration (the 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.



**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(UNAUDITED)**

**FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

Under the terms of the five-year Voltaren® Gel Agreement, Endo made an upfront cash payment of \$85 million. Endo has agreed to pay royalties to Novartis on annual Net Sales of the Licensed Product, subject to certain thresholds as defined in the Voltaren® Gel 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 Voltaren® Gel Agreement, subject to certain limitations. These guaranteed minimum royalties will be creditable against royalty payments on an annual basis such that Endo's obligation with respect to each 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 Voltaren® Gel Agreement year. No royalty payments were payable to Novartis during the six months ended June 30, 2010 or 2009. 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 million, representing the fair value of the exclusive license to market Voltaren® Gel. We are amortizing this intangible asset into cost of revenues over its estimated five-year useful life.

Endo shall be solely responsible to commercialize the Licensed Product during the term of the Voltaren® Gel Agreement. With respect to each year during the term of the Voltaren® Gel Agreement, Endo is required to incur a minimum amount of annual advertising and promotional expenses on the commercialization of the Licensed Product, subject to certain limitations. In addition, Endo will be required to perform a minimum number of face-to-face one-on-one discussions with physicians and other healthcare practitioners (details) for the purpose of promoting the Licensed Product within its approved indication during each year of the Voltaren® Gel Agreement. Further, during the term of the Voltaren® Gel 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 Voltaren® Gel Agreement, Endo has agreed to purchase all of its requirements for the Licensed Product from Novartis. The price is fixed for the first year and subject to annual changes based upon changes in the producer price index and raw materials.

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 (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 Voltaren® Gel 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 Voltaren® Gel 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 prior to the launch of the OTC equivalent product by Novartis or its affiliates.

The initial term of the Voltaren® Gel Agreement will expire on June 30, 2013. Endo has the option to extend the Voltaren® Gel Agreement for two successive one year terms. The Voltaren® Gel 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 months prior to the expiration of any renewal term after the first renewal term or the Voltaren® Gel Agreement is otherwise terminated in accordance with its terms. Among other standard and customary termination rights granted under the Voltaren® Gel Agreement, the Voltaren® Gel 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 Voltaren® Gel 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 Voltaren® Gel Agreement upon reasonable written notice (1) if Endo fails to deliver a set percentage of the minimum details in any given six-month period under the Voltaren® Gel 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 Voltaren® Gel Agreement are less than a certain defined dollar amount.

*Hind Healthcare Inc.*

In November 1998, Endo entered into a license agreement (the Hind License Agreement) with Hind Healthcare Inc., (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 six-month periods ended June 30, 2010 and 2009 we recorded \$42.0 million and \$40.7 million for these royalties to Hind, respectively. At June 30, 2010 and 2009, \$42.0 million and \$40.7 million, respectively, is recorded as a royalty payable and included in accounts payable in the accompanying balance sheet. In March 2002, we extended this license with Hind to cover Lidoderm® in Canada and Mexico.

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(UNAUDITED)**

**FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

*Penwest Pharmaceuticals Co.*

In September 1997, we entered into a collaboration agreement with Penwest Pharmaceuticals Co. (Penwest) to exclusively co-develop opioid analgesic products for pain management, using Penwest's patent-protected proprietary technology, for commercial sale worldwide. On April 2, 2002, we amended and restated this agreement between the parties (the 2002 Agreement) to provide, among other things, that this collaboration would cover only the opioid analgesic product, 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 Opana® ER. Accordingly, we were responsible for funding 100% of these remaining costs until June 22, 2006, the date on which Opana® 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 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. As of June 30, 2010, Endo has recouped the full \$28 million of these unfunded development costs.

Royalties were reduced by fifty percent (50%) until we recouped our previously recognized unfunded development costs, after which time royalties became payable on annual net sales based on the royalty rates described above. In September 2008, the \$41 million royalty threshold was met. During the first quarter of 2010, the previously recognized unfunded development costs were recouped. During the three and six months ended June 30, 2010, we recorded in cost of revenues, royalties on the net sales of Opana® ER of approximately \$12.3 million and \$19.5 million, respectively. During the three and six month ended June 30, 2009, we recorded in cost of revenues, royalties on the net sales of Opana® ER of approximately \$4.4 million and \$8.8 million, respectively.

On June 8, 2010, the Company and Penwest entered into an amendment (the 2010 Amendment) to the 2002 Agreement as amended by the 2007 Amendment. Under the terms of the 2010 Amendment, the royalty rate on net sales of Opana ER will now be capped at 22% during the period from April 1, 2010 through December 31, 2012, subject to adjustment in the fourth quarter of 2012, and 20% during 2013, subject to adjustment in the fourth quarter of 2013.

*Valeant Canada Ltd*

In June 2009, the Company entered into a License Agreement with Valeant Canada Ltd (Valeant) granting Valeant a license to market Opana<sup>®</sup> and Opana<sup>®</sup> ER in Canada, Australia and New Zealand. Opana<sup>®</sup> ER, the extended release formulation of oxymorphone, was jointly developed by Penwest and Endo. Under the terms of the collaboration agreement between Penwest and Endo, the two companies have agreed to share equally in the proceeds received from Valeant for Opana<sup>®</sup> ER. The license agreement with Valeant also includes rights to Opana<sup>®</sup>, the immediate release formulation of oxymorphone developed by Endo. Under the terms of the License Agreement, Valeant made an upfront payment to Endo and may make future payments if certain sales milestones are reached. In addition, Valeant has agreed to pay royalties ranging from 10%-20% on net sales of Opana<sup>®</sup> ER and Opana<sup>®</sup> in each of the three countries, subject to royalty reductions upon patent expiry or generic entry.

*Vernalis Development Limited*

In July 2004, we entered into a License Agreement and a Loan Agreement with Vernalis Development Limited (Vernalis) under which Vernalis agreed to license, exclusively to us, rights to market frovatriptan succinate (Frova<sup>®</sup>) in North America (the Vernalis License Agreement). Frova<sup>®</sup> was launched June 2002 in the U.S, and indicated for the acute treatment of migraine headaches in adults. Under the terms of the Vernalis License Agreement, we paid Vernalis an upfront fee of \$30 million and annual \$15 million payments each in 2005 and 2006. Under the loan agreement, we provided Vernalis with a loan of \$50 million in August 2004. We 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 as an intangible asset representing the fair value of the exclusive license to market Frova<sup>®</sup>. We are amortizing this intangible asset into cost of revenues on a straight-line basis over its estimated life of twelve and one-half years.

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(UNAUDITED)**

**FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

Under the terms of the License Agreement 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> 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 years written notice. In July 2007, Vernalis and Endo entered into Amendment (Amendment No. 3) to the License Agreement dated July 14, 2004. Under Amendment No. 3, Vernalis granted an exclusive license to Endo to make, have made, use, commercialize and have commercialized the product Frova<sup>®</sup> 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. 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 was 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 was 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 cost of revenues on a straight-line basis over its estimated useful life of nine years.

*Allergan/Esprit*

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

In September 2007, Indevus entered into an Amended and Restated License, Commercialization and Supply Agreement with Esprit Pharma, Inc (Esprit), which modified the obligations of each party and superseded all previous agreements (the Allergan Agreement). In October 2007, Allergan, Inc. (Allergan) acquired Esprit resulting in Esprit being a wholly-owned subsidiary of Allergan. Under the Allergan Agreement, we received the right to receive a fixed percentage of net sales for the term of the Allergan Agreement, subject to increasing annual minimum royalties. Aggregate minimum royalties for the remainder of the Allergan Agreement amount to approximately \$100 million through December 31, 2014, provided there is no product adverse event, as defined in the Allergan Agreement. Commencing January 1, 2010, Allergan has the right to reduce, subject to quarterly and annual restrictions, royalty payments by \$20 million in the aggregate. The Company may also receive a payment of \$20 million related to a long-term commercialization milestone related to generic competition on December 31, 2013. Lastly, all third-party royalties paid by the Company as a result of existing licensing, manufacturing and supply agreements associated with sales of Sanctura<sup>®</sup> and Sanctura XR<sup>®</sup> will be reimbursed to the Company by Allergan up to six percent (6%) of net sales. The Allergan Agreement expires on the later of the twelfth annual anniversary of the launch of Sanctura XR<sup>®</sup> or February 1, 2025, the date of the last to expire patent covering Sanctura XR<sup>®</sup> in the United States. Either party may also terminate the Allergan Agreement in the event of a material breach by the other party. In August 2008, Indevus assigned its rights to receive a fixed percentage of net sales and \$20 million related to a long-term commercialization milestone related to generic competition to the holders of the Non-recourse Notes (see Note 12).

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(UNAUDITED)**

**FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

In May 2008, together with Madaus AG, Indevus licensed to Allergan the exclusive right to develop, manufacture, and commercialize Sanctura XR<sup>®</sup> in Canada. As a result, the Company could receive milestones upon the achievement of certain sales thresholds of up to \$2 million. In addition, any third-party royalties owed by the Company on net sales in Canada will be reimbursed by Allergan. This agreement will expire after the later of the expiration of the last applicable patent or our third party royalty obligation which is currently expected to be November 4, 2024, after which Allergan will have a fully-paid license.

*Madaus*

In November 1999, Indevus entered into an agreement with Madaus to license the exclusive rights to develop and market certain products, including Sanctura<sup>®</sup> in the United States. In November 2006, Indevus entered into (i) a License and Supply Agreement and (ii) an amendment to its original 1999 license agreement with Madaus (collectively, the Madaus Agreements). In March 2010, Endo amended the Madaus Agreements. Under the amended Madaus Agreements, (a) Madaus has licensed the rights to sell Sanctura XR<sup>®</sup> in all countries outside of the U.S. (the Madaus Territory) except Canada, Japan, Korea and China (the Joint Territory), (b) Madaus has agreed to pay a fee based on the number of capsules of Sanctura XR sold in the Madaus Territory through December 9, 2015 and (c) Endo has agreed to pay a fee based on the number of capsules of Sanctura XR<sup>®</sup> sold in the U.S. through the earlier of August 23, 2014 or upon generic formulations achieving a predetermined market share. In exchange, Madaus (a) agreed to make certain immaterial payments upon the achievement of certain commercial milestones and pay royalties of 5% of net sales based on future sales of Sanctura XR<sup>®</sup> in the Madaus Territory and (b) agreed to reimburse Endo for any amounts due to Supernus (see Supernus below) related to the development or commercialization in the Madaus territory. The Company and Madaus will share the development and commercialization costs in the countries in the Joint Territory. If either party decides not to pursue development and commercialization of Sanctura XR<sup>®</sup> in any country in the Joint Territory, the other party has the right to independently develop and commercialize Sanctura XR<sup>®</sup> in that country. The term of the Madaus Agreement for Sanctura XR<sup>®</sup> extends until the expiration, on a country-by-country basis, of all royalty obligations owed to the Company from Madaus which ceases upon the last to expire applicable patent in the Madaus Territory. Either party may terminate the amended Madaus Agreements in the event of a material breach by the other party.

*Supernus*

In March 2003, Indevus entered into a Development and License Agreement (the Supernus Agreement) with Supernus Pharmaceuticals, Inc. (Supernus) pursuant to which Supernus agreed to develop Sanctura XR<sup>®</sup> and granted exclusive, worldwide rights under certain Supernus patents and know-how to Indevus. The Supernus agreement includes potential future development and commercialization milestone payments from the Company to Supernus, including royalties based on sales of Sanctura XR<sup>®</sup>, and potential future development and commercialization milestone payments for up to an aggregate of \$2.4 million upon the launch of Sanctura XR<sup>®</sup> in certain geographic areas. In addition, the Supernus agreement includes potential future development and commercialization milestone payments for up to an aggregate of \$4.5 million upon the launch of new formulations and over-the-counter products. The Company is responsible for all development costs and the commercialization of Sanctura XR<sup>®</sup> under the Supernus agreement. The Supernus agreement continues until the earlier of, in any particular country, (i) the last date on which the manufacture, use or sale of licensed product in such country would infringe a valid claim of a licensed patent in such country but for the license granted by the agreement; or (ii) twelve years from the date of first commercial sale of licensed product in such country. Either party may also terminate this agreement in the event of a material breach by the other party or by mutual consent.

*The Population Council*

The Company markets its products utilizing the Hydron<sup>®</sup> Polymer Technology pursuant to an agreement between Indevus and the Population Council. Unless earlier terminated by either party in the event of a material breach by the other party, the term of the agreement is the shorter of twenty-five years from October 1997 or until the date on which The Population Council receives approximately \$40 million in payments from the Company. The Company is required to pay to The Population Council 3% of its net sales of Vantas<sup>®</sup> and any polymer implant containing an LHRH analog. We are also obligated to pay royalties to the Population Council ranging from 0.5% of net sales to 4% of net sales under certain conditions. We are also obligated to pay the Population Council 30% of certain profits and payments received in certain territories by the

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

Company from the licensing of Vantas<sup>®</sup> or any other polymer implant containing an LHRH analog and 5% for other implants.

### *Orion Corporation*

In April 2008, Indevus entered into a License, Supply and Distribution Agreement (the Orion Agreement) with Orion Corporation (Orion) granting Orion the rights to market Vantas<sup>®</sup> in Europe and in certain other countries outside of Europe. Vantas<sup>®</sup> is currently approved for the treatment of advanced prostate cancer in Denmark, the United Kingdom and other European countries, and the Company is seeking additional European approvals through the mutual recognition procedure. The Company could receive certain contingent payments from Orion based on the receipt of additional marketing authorizations and the achievement of sales thresholds, in an aggregate amount of up to approximately \$2.2 million and \$11.2 million, respectively. Additionally, the Company will supply Vantas<sup>®</sup> to Orion at a pre-determined transfer price subject to annual minimum purchase requirements. The Orion Agreement expires in April 2023, unless earlier terminated by either party in the event of a material breach by the other party. The Orion Agreement will automatically renew for one-year periods, subject to the right of either party to terminate the agreement at any time effective at the end of the initial fifteen-year term or any subsequent one-year renewal period thereafter with at least six months prior written notice to the other party.



**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(UNAUDITED)**

**FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

***Products in Development***

*Grünenthal GMBH*

In February 2009, we entered into a Development, License and Supply Agreement (the Grünenthal Agreement) with Grünenthal GMBH (Grünenthal), granting us the exclusive right in North America to develop and market Grünenthal's investigational drug, axomadol. Currently in Phase II trials, axomadol is a patented new chemical entity being developed for the treatment of moderate to moderately-severe chronic pain and diabetic peripheral neuropathic pain. Under the terms of the Grünenthal Agreement, Endo paid Grünenthal approximately \$9.4 million upfront and an additional \$25.2 million in 2009 upon the achievement of certain milestones. We could be obligated to pay additional clinical, regulatory and approval milestone payments of up to approximately 19 million euros (approximately \$23 million at June 30, 2010) and possibly development and commerce milestone payments of up to an additional \$68 million. In addition, Grünenthal will receive payments from Endo based on a percentage of Endo's annual net sales of the product in the United States and Canada. The Grünenthal Agreement will expire in its entirety on the date of (i) the 15th anniversary of the first commercial sale of the product; or (ii) the expiration of the last issued patent claiming or covering the product, or (iii) the expiration of exclusivity granted by the FDA for the product, whichever occurs later. Among other standard and customary termination rights granted under the Grünenthal Agreement, we may terminate the Grünenthal Agreement at our sole discretion at any time upon ninety (90) days' written prior notice to Grünenthal and payment of certain penalties.

*Impax Laboratories, Inc.*

In June 2010, the Company entered into a Development and Co-Promotion Agreement (the Impax Agreement) with Impax Laboratories, Inc. (Impax), whereby the Company was granted a royalty-free license for the co-exclusive rights to co-promote a next generation Parkinson's disease product. Under the terms of the Impax Agreement, Endo paid Impax an upfront payment of \$10 million, which was recorded as research and development expense as of June 30, 2010. In addition, under the terms of the Impax agreement, Impax could potentially receive up to approximately \$30 million in additional payments linked to the achievement of future clinical, regulatory, and commercial milestones related to the development product. Prior to the completion of Phase III trials, Endo may only terminate the Impax Agreement upon a material breach.

*Bioniche Life Sciences Inc.*

In July 2009, the Company entered into a License, Development and Supply Agreement (the Bioniche Agreement) with Bioniche Life Sciences Inc. and Bioniche Urology Inc. (collectively Bioniche), whereby the Company licensed from Bioniche the exclusive rights to develop and market Bioniche's proprietary formulation of Mycobacterial Cell Wall-DNA Complex (MCC), known as Urocidin, in the U.S. with an option for global rights. We exercised our option for global rights in the first quarter of 2010. Urocidin is a patented formulation of MCC developed by Bioniche for the treatment of non-muscle-invasive bladder cancer that is currently undergoing Phase III clinical testing. Under the terms of the Bioniche Agreement, Endo paid Bioniche an up-front cash payment of \$20.0 million in July 2009, which was recorded as research and development expense. In addition, Bioniche could potentially receive up to approximately \$69.5 million and \$26.0 million in additional payments linked to the achievement of future clinical, regulatory, and commercial milestones related to two separate indications for Urocidin. Bioniche will manufacture Urocidin and receive a transfer price for supply based on a percentage of Endo's annual net sales of Urocidin. Endo may terminate the Bioniche Agreement upon 180 days' prior written notice.

*Strakan International Limited*

In August 2009, we entered into a License and Supply Agreement with Strakan International Limited, a subsidiary of ProStrakan Group plc (ProStrakan), for the exclusive right to commercialize Fortesta in the U.S. (the ProStrakan Agreement). Fortesta, a patented two percent (2%) testosterone transdermal gel for testosterone replacement therapy in male hypogonadism, utilizes a metered dose delivery system designed to permit accurate dose adjustment to individual patient requirements. Under the terms of the ProStrakan Agreement, Endo paid ProStrakan an up-front cash payment of \$10 million, which was recorded as research and development expense. In addition, ProStrakan could potentially

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

receive up to approximately \$200 million in additional payments linked to the achievement of future regulatory and commercial milestones related to Fortesta . ProStrakan will exclusively supply Fortesta to Endo at a supply price based on a percentage of annual net sales subject to a minimum floor price as defined in the ProStrakan Agreement. Endo may terminate the ProStrakan Agreement upon six months prior written notice at no cost to the Company.

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(UNAUDITED)**

**FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

In October 2009, we received a Complete Response letter from the FDA regarding the NDA for Fortesta . The FDA issues Complete Response letters to communicate that their initial review of an NDA or abbreviated new drug application (ANDA) is complete and that the application cannot be approved in its present form. A Complete Response also informs applicants of changes that must be made before an application can be approved, with no implication regarding the ultimate approvability of the application. On July 1, 2010, Endo submitted a complete response to the FDA following the Company's re-analysis of the existing clinical samples. The milestone payment to ProStrakan related to FDA approval of Fortesta is fixed at \$12.5 million which reflects a \$7.5 million reduction due to the previous delays in approval.

*BayerSchering*

In July 2005, Indevus licensed exclusive U.S. rights from Schering AG, Germany, now BayerSchering Pharma AG (BayerSchering) to market a long-acting injectable testosterone preparation for the treatment of male hypogonadism that we refer to as Aveed™ (the BayerSchering Agreement). The Company is responsible for the development and commercialization of Aveed™ in the United States. BayerSchering is responsible for manufacturing and supplying the Company with finished product. As part of the BayerSchering Agreement, Indevus agreed to pay to BayerSchering up to \$30 million in up-front, regulatory milestone, and commercialization milestone payments, including a \$5.0 million payment due upon approval by the FDA to market Aveed™. Indevus also agreed to pay to BayerSchering 25% of net sales of Aveed™ to cover both the cost of finished product and royalties. The BayerSchering Agreement expires ten years from the first commercial sale of Aveed™ . Either party may also terminate the BayerSchering Agreement in the event of a material breach by the other party.

In October 2006, Indevus entered into a supply agreement with BayerSchering pursuant to which BayerSchering agreed to manufacture and supply Indevus with all of its requirements for Aveed™ for a supply price based on net sales of Aveed™ . The supply price is applied against the 25% of net sales owed to BayerSchering pursuant to the BayerSchering Agreement. The BayerSchering Agreement expires ten years after the first commercial sale of Aveed™.

*Sanofi-Aventis*

In February 1994, Indevus licensed from Rhone-Poulenc Rorer, S.A., now Aventis Pharma S.A. (Sanofi-Aventis), exclusive, worldwide rights for the manufacture, use and sale of pegoclone under patent rights and know-how related to the drug, except that Indevus granted Sanofi-Aventis an option to sublicense, under certain conditions, rights to market pegoclone in France. Indevus paid Sanofi-Aventis a license fee and agreed to make milestone payments based on clinical and regulatory developments, and to pay royalties based on net sales through the expiration of the composition of matter patent. If sublicensed, the Company would pay to Sanofi-Aventis a portion of receipts from the sublicensee in lieu of payments. Under the terms of the agreement with Sanofi-Aventis, the Company is responsible for all costs of developing, manufacturing, and marketing pegoclone. This agreement expires with respect to each country upon the last to expire applicable patent. Additionally either party may also terminate this agreement in the event of a material breach by the other party. The Company could owe an additional \$5.5 million if certain clinical and regulatory development milestones are achieved, as well as royalties on net sales or a percentage of royalties it receives if the product is sublicensed.

*Hydron Technologies, Inc.*

In November 1989, GP Strategies Corporation (GP Strategies), then known as National Patent Development Corporation, entered into an agreement (the Hydron Agreement) with Dento-Med Industries, Inc., now known as Hydron Technologies, Inc. In June 2000, Valera Pharmaceuticals, Inc. (Valera, now a wholly-owned subsidiary of the Company known as Endo Pharmaceuticals Valera Inc.) entered into a contribution agreement with GP Strategies, pursuant to which Valera acquired the assets of GP Strategies' drug delivery business, including all intellectual property, and all of GP strategies' rights under the Hydron Agreement, and certain other agreements with The Population Council and Shire US, Inc.

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

Pursuant to the Hydron Agreement, the Company has the exclusive right to manufacture, sell and distribute any prescription drug or medical device and certain other products made with the Hydron® Polymer Technology. Hydron Technologies retained an exclusive, worldwide license to manufacture, market or use products composed of, or produced with the use of, the Hydron® Polymer Technology in certain consumer and oral health fields. Neither party is prohibited from manufacturing, exploiting, using or transferring the rights to any new non-prescription drug product containing the Hydron® Polymer Technology, subject to certain exceptions, for limited exclusivity periods. Subject to certain conditions and exceptions, the Company is obligated to supply certain types of Hydron® Polymer Technology and Hydron Technologies is obligated to purchase them from the Company. In the event the Company withdraws from the business of manufacturing the Hydron® Polymer Technology, the Company will assign all of its right and interest in the Hydron trademark to Hydron Technologies. This agreement continues indefinitely, unless terminated earlier by the parties. Each party may owe royalties up to 5% to the other party on certain products under certain conditions.

### *EpiCept Corp.*

In December 2003, we entered into a license granting us exclusive, worldwide rights to certain patents of EpiCept Corp. (EpiCept) as well as exclusive, worldwide commercialization rights to EpiCept's LidoPAIN® BP product (EpiCept Agreement). The EpiCept Agreement provides for Endo to pay EpiCept milestones as well as royalties on the net sales of EpiCept's LidoPAIN® BP product. Under this Agreement, we made an upfront payment to EpiCept of \$7.5 million which we capitalized as an intangible asset representing the fair value of the exclusive right and the patents. We are amortizing this intangible asset over its useful life of thirteen (13) years. EpiCept has also retained an option to co-promote the LidoPAIN® BP product. Milestone payments made by Endo under this 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. In January 2009, EpiCept announced that it was discontinuing all drug discovery activities including the development of LidoPAIN® BP. However, the Company intends to maintain its patent rights conveyed by the EpiCept Agreement.

**Table of Contents****ENDO PHARMACEUTICALS HOLDINGS INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(UNAUDITED)****FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010***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. Under the terms of the agreement, we paid approximately \$4.9 million for the successful completion of a clinical milestone, which was recorded as research and development expense at June 30, 2010. Additional payments of approximately 65.0 million Euros (approximately \$80 million at June 30, 2010) 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 and discovery agreements with third parties for the development of pain management and other products. 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 similar firms 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 and other equity holders have provided a line of credit totaling \$25 million, of which Endo committed to fund \$3 million. During the second quarter of 2010, \$0.8 million has been funded by Endo under the line-of credit which would be converted into equity of the privately-held company upon certain events. During July of 2010, an additional payment of \$0.8 million was subsequently funded under the same commitment. Based on the equity ownership structure, Endo does not have the ability to exert significant influence over the privately-held company. Pursuant to authoritative accounting guidance, our investment constitutes a variable interest in this privately-held company. We have determined that Endo is not the primary beneficiary and therefore have not consolidated the assets, liabilities, and results of operations of the privately-held company into our Condensed Consolidated Financial Statements. Accordingly, Endo is accounting for this investment under the cost method. As of June 30, 2010, our investment in the privately-held company was \$20.8 million, representing our maximum exposure to loss.

**NOTE 7. GOODWILL AND OTHER INTANGIBLES**

Goodwill and other intangible assets consist of the following at June 30, 2010 and December 31, 2009, respectively (in thousands):

	<b>June 30, 2010</b>	<b>December 31, 2009</b>
Goodwill	\$ 302,534	\$ 302,534
Indefinite-lived intangibles:		

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

In process research and development	\$ 87,900	\$ 100,900
Definite-lived intangibles:		
Licenses	\$ 625,242	\$ 625,242
Less accumulated amortization	(150,804)	(116,233)
	474,438	509,009
Other intangibles, net	\$ 562,338	\$ 609,909

Changes in the gross carrying amount of our indefinite-lived other intangible assets for the six months ended June 30, 2010, are as follows:

(in thousands)	Gross carrying amount	
Balance at December 31, 2009:	\$	100,900
Pagoclone impairment		(13,000)
Balance at June 30, 2010	\$	87,900

Amortization expense for the six month periods ended June 30, 2010 and 2009 was \$34.6 million and \$27.3 million, respectively. As of June 30, 2010, the weighted average amortization period for our definite lived intangible assets in total was approximately 10 years.

**Table of Contents****ENDO PHARMACEUTICALS HOLDINGS INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(UNAUDITED)****FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

There were no changes in the gross carrying amount of our definite-lived intangible assets for the six-month period ended June 30, 2010. Estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2009 is as follows (in thousands):

2010	\$ 69,141
2011	\$ 69,141
2012	\$ 69,141
2013	\$ 56,836
2014	\$ 43,944

**NOTE 8. COMPREHENSIVE INCOME**

Comprehensive income includes the following components for the three and six months ended June 30, 2010 and 2009 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Net income	\$ 51,460	\$ 30,029	\$ 111,815	\$ 69,066
Other comprehensive income:				
Unrealized (loss) gain on securities, net of tax	(566)	583	(98)	(608)
Total comprehensive income	\$ 50,894	\$ 30,612	\$ 111,717	\$ 68,458

**NOTE 9. 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 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). During 2009, 43,500 restricted stock units and 66,503 non-qualified stock options were granted to an executive officer of the Company as an inducement to commence employment with the Company. The restricted stock units and non-qualified stock options were granted outside of the 2007 Stock Incentive Plan but are subject to the terms and conditions of the 2007 Stock Incentive Plan

and the applicable award agreements. Approximately 11.9 million shares were reserved for future issuance upon exercise of options granted or to be granted under the 2000, 2004 and 2007 Stock Incentive Plans. As of June 30, 2010, stock options, restricted stock awards, performance stock units and restricted stock units have been granted under the Stock Incentive Plans.

***Stock-Based Compensation***

The Company accounts for its stock-based compensation plans in accordance with the guidance for Share-Based Payments. Accordingly, 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 \$6.6 million and \$10.4 million, during the three and six months ended June 30, 2010 and \$5.9 million and \$7.8 million during the three and six months ended June 30, 2009, respectively. As of June 30, 2010, the total remaining unrecognized compensation cost related to all non-vested stock-based compensation awards amounted to \$73.0 million. This expected cost does not include the impact of any future stock-based compensation awards.



**Table of Contents****ENDO PHARMACEUTICALS HOLDINGS INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(UNAUDITED)****FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010***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 six months ended June 30, 2010 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding, January 1, 2010	5,158,541	\$ 22.84		
Granted	1,784,091	\$ 20.98		
Exercised	(145,220)	\$ 16.85		
Forfeited	(232,053)	\$ 21.43		
Expired	(45,874)	\$ 28.58		
Outstanding, June 30, 2010	6,519,485	\$ 22.47	7.32	\$ 11,073,395
Vested and expected to vest, June 30, 2010	6,059,784	\$ 22.61	7.17	\$ 10,300,541
Exercisable, June 30, 2010	2,830,980	\$ 24.20	5.23	\$ 5,016,113

The total intrinsic value of options exercised during the six months ended June 30, 2010 and 2009 was \$0.8 million and \$3.1 million, respectively. The weighted-average grant date fair value of the stock options granted in the six months ended June 30, 2010 and 2009 was \$7.36 per option and \$7.46 per option, respectively, determined using the following assumptions:

	2010	2009
Average expected term (years)	5.3	5.25
Risk-free interest rate	2.6%	2.04%
Dividend yield	0.00	0.00
Expected volatility	34%	40%

The weighted average remaining requisite service period of the non-vested stock options was 2.8 years.

*Restricted Stock Units*

A summary of our restricted stock units as of June 30, 2010 is presented below:

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

	Number of Shares	Aggregate Intrinsic Value
Outstanding, January 1, 2010	1,477,241	
Granted	1,302,091	
Forfeited	(102,582)	
Vested	(355,832)	
Outstanding, June 30, 2010	2,320,918	\$ 51,279,290
Vested and expected to vest, June 30, 2010	1,980,463	\$ 43,501,143

The weighted average remaining requisite service period of the non-vested restricted stock units was 2.9 years. The weighted-average grant date fair value of the restricted stock units granted during the six months ended June 30, 2010 was \$20.71 per unit.

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(UNAUDITED)**

**FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

*Performance shares*

Beginning in the first quarter ended March 31, 2010, the Company began to award performance stock units (PSU) to certain key employees. These PSUs are tied to both Endo's overall financial performance and Endo's financial performance relative to the financial performance of a selected industry group. Awards are granted annually, with each award covering a three-year performance cycle. Each PSU is convertible to one share of Endo common stock. Performance measures used to determine the actual number of performance shares issuable upon vesting include an equal weighting of Endo's total shareholder return (TSR) performance compared to the performance group over the three-year performance cycle and Endo's three-year cumulative revenue performance as compared to a three-year revenue target. TSR relative to peers is considered a market condition while cumulative revenue performance is considered a performance condition under applicable authoritative guidance. PSUs granted for the six months ended June 30, 2010 totaled 163,000. As of June 30, 2010, there was approximately \$2.8 million of total unrecognized compensation costs related to PSUs. That cost is expected to be recognized over a weighted-average period of 3.0 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, and accelerated stock repurchase transactions or otherwise, as determined by Endo.

This program does not obligate Endo to acquire any particular amount of common stock. Additional purchases, if any, 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. As a result of a two-year extension approved by the Board of Directors in February 2010, the share repurchase plan is set to expire in April 2012.

During 2010, pursuant to the existing share repurchase program, we purchased approximately 2.2 million shares of our common stock during the period ended June 30, 2010 totaling \$50.1 million. We did not purchase any shares of our common stock during the year ended December 31, 2009.

**NOTE 10. COMMITMENTS and CONTINGENCIES**

*Manufacturing, Supply and Other Service Agreements*

We contract with various third party manufacturers and suppliers to provide us with raw materials used in our products and finished goods. Our most significant agreements are with Novartis Consumer Health, Inc. and Novartis AG (collectively Novartis), Teikoku Seiyaku Co., Ltd., Mallinckrodt Inc., Sharp Corporation, and Ventiv Commercial Services, LLC. 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, it could have a material adverse effect on our business, financial condition, results of operations and cash flows.

*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 Consumer Health, Inc. 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 Consumer Health, Inc. 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 per year in 2010 and approximately \$21 million in 2011. Either party may terminate this agreement on three-years' notice, effective at any time after

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

the initial five-year term. Either party may also terminate this agreement on account of a material breach by the other.

Pursuant to the March 2008 Voltaren<sup>®</sup> Gel License and Supply Agreement (the Voltaren<sup>®</sup> Gel Agreement) with Novartis AG and Novartis Consumer Health, Inc. Endo has agreed to purchase from Novartis all of its requirements for Voltaren<sup>®</sup> Gel during the entire term of the Voltaren<sup>®</sup> Gel Agreement. The price of product purchased under the Voltaren<sup>®</sup> Gel Agreement is fixed for the first year and subject to annual changes based upon changes in the producer price index and raw materials.

As part of the Voltaren<sup>®</sup> Gel Agreement, we also agreed to undertake advertising and promotion of Voltaren<sup>®</sup> Gel (A&P Expenditures), subject to certain thresholds set forth in the Voltaren<sup>®</sup> Gel Agreement. We agreed to spend a minimum of \$15.0 million on A&P Expenditures during the first Voltaren<sup>®</sup> Gel Agreement Year which ended on June 30, 2009. During the second Voltaren<sup>®</sup> Gel Agreement Year beginning on July 1, 2009 and extended through June 30, 2010, we had agreed to spend a minimum of \$20 million on A&P Expenditures. During the third Voltaren<sup>®</sup> Gel Agreement Year beginning on July 1, 2010 and extending through June 30, 2011, we had agreed to spend 15% of prior year sales or approximately \$13 million on A&P Expenditures. In subsequent Agreement Years, the minimum A&P Expenditures set forth in the Voltaren<sup>®</sup> Gel Agreement are determined based on a percentage of net sales of Voltaren<sup>®</sup> Gel.

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(UNAUDITED)**

**FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

*Teikoku Seiyaku Co., Ltd.*

Under the terms of our agreement (the Teikoku Agreement) with Teikoku Seiyaku Co. Ltd. (Teikoku), a Japanese manufacturer, Teikoku manufactures Lidoderm<sup>®</sup> at its two Japanese facilities, located on adjacent properties, for commercial sale by us in the United States. We also have an option to extend the supply area to other territories. On April 24, 2007, we amended the Teikoku agreement (the Amended Agreement). The material components of the Amended Agreement are as follows:

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

Teikoku agreed to fix the supply price of Lidoderm<sup>®</sup> 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<sup>®</sup>.

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.

On January 6, 2010, the parties amended the Teikoku Agreement, effective December 16, 2009. Pursuant to the amendment, Teikoku has agreed to supply the product at a fixed price for a period of time after which the price will be adjusted at future dates certain based on a price index defined in the amendment.

*Mallinckrodt Inc.*

Under the terms of our agreement (the Mallinckrodt Agreement) with Mallinckrodt Inc. (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 the Mallinckrodt 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 the Mallinckrodt agreement in the event of a material breach by the other party.

*Sharp Corporation*

Under the terms of our agreement (the Sharp 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 (the Ventiv Agreement) with Ventiv Commercial Services, LLC (Ventiv). Under the terms of the Ventiv Agreement, Ventiv provides to Endo certain sales and marketing services through a contracted field force and other sales management positions, collectively referred to as the Ventiv Field Force. The Ventiv Field Force promotes primarily Voltaren® Gel and is required to perform a minimum number of face-to-face one-on-one discussions with physicians and other healthcare 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.

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(UNAUDITED)**

**FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

Under the terms of the Ventiv Agreement, we are required to pay Ventiv a monthly fixed fee based on a pre-approved budget. Included in the fixed monthly fee are certain costs such as the Ventiv sales representative and district manager salaries, Ventiv field force travel, and office and other expenses captured on routine expense reports, as well as a fixed management fee. Ventiv is also 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 satisfaction of certain conditions, including the sale of a minimum number of Voltaren<sup>®</sup> Gel tubes and a minimum number of Details achieved. In May 2009, we amended the Ventiv Agreement to change certain provisions including a reduction in the Ventiv Field Force from 275 to 80 sales representatives effective June 1, 2009. The expenses incurred with respect to Ventiv under the Ventiv Agreement were \$3.0 million and \$5.6 million for the three and six months ended June 30, 2010, respectively. The expenses incurred with respect to Ventiv under the Ventiv Agreement were \$7.4 million and \$16.7 million for the three and six months ended June 30, 2009.

The Ventiv Agreement expired on June 30, 2010. However, effective as of May 10, 2010, we entered into a second amendment to the Ventiv Agreement which extended its term to August 10, 2010, while we continue to negotiate a longer term service contract with Ventiv.

*UPS Supply Chain Solutions*

Under the terms of this agreement, we utilize UPS Supply Chain Solutions to provide customer service support, chargeback processing, accounts receivables management and warehouse, freight and distribution services for certain of our products in the United States. The initial term of the agreement will extend to March 31, 2015. The agreement may be terminated by either party (1) without cause upon prior written notice to the other party; (2) with cause in the event of an uncured material breach by the other party and (3) if the other party become insolvent or bankrupt. In the event of termination of services provided under the Warehouse Distribution Services Schedule to the agreement (i) by Endo without cause or (ii) by UPS due to Endo's breach, failure by Endo to make payments when due, or Endo's insolvency, we would be required to pay UPS certain termination costs. Such termination costs would not exceed \$2 million.

*General*

In addition to the manufacturing and supply agreements described above, we have agreements with various companies for clinical development services. Although we have no reason to believe that the parties to these agreements will not meet their obligations, failure by any of these third parties to honor their contractual obligations may have a materially adverse effect on our business, financial condition, results of operations and cash flows.

*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 our ongoing 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, results of operations and cash flows.

*Withdrawal of Redux, Legal Proceedings, Insurance Claims, and Related Contingencies*

In September 1997, Indevus announced a market withdrawal of its first commercial prescription product, the anti-obesity medication Redux (dexfenfluramine hydrochloride capsules C-IV), which had been launched in June 1996 by its licensee, American Home Products Corporation, which became Wyeth, and was later acquired by Pfizer. The withdrawal of Redux was based on a preliminary analysis by the FDA of potential abnormal echocardiogram findings associated with certain patients taking Redux or the combination of fenfluramine with phentermine. Following the withdrawal of Redux, Indevus was named, together with other pharmaceutical companies, as a defendant in several thousand product liability legal actions in federal and state courts relating to the use of Redux and other weight loss drugs. Fewer than 60 lawsuits are still pending against Indevus and/or the Company. In May 2001, Indevus entered into the AHP Indemnity and Release Agreement with Wyeth pursuant to which Wyeth agreed to indemnify Indevus against certain classes of product liability cases filed against Indevus related to Redux and Indevus agreed to dismiss Redux related claims against Wyeth. Under the terms of the AHP Indemnity and Release Agreement, Wyeth has agreed to indemnify Indevus for claims brought by plaintiffs who initially opted out of Wyeth's national class action settlement of diet drug claims and claimants alleging primary pulmonary hypertension. In addition, Wyeth has agreed to fund all future legal costs of Indevus related to the defense of Redux-related product liability cases. Also, pursuant to the AHP Indemnity and Release Agreement, Wyeth agreed to fund additional insurance coverage to supplement Indevus's existing product liability insurance. The Company believes the total insurance coverage, including the additional insurance coverage funded by Wyeth, is sufficient to address the potential remaining Redux product liability exposure. However, there can be no assurance Redux claims will not exceed the amount of insurance coverage available to the Company and Wyeth's indemnification obligations under the AHP Indemnity and Release Agreement. If such insurance coverage and Wyeth indemnification is not sufficient to satisfy Redux-related claims, the payment of amounts to satisfy such claims may have a material adverse effect on the Company's business, results of operations or financial condition. Prior to the effectiveness of the AHP Indemnity and Release Agreement, Redux-related defense costs of Indevus were paid by, or subject to reimbursement from, Indevus's product liability insurers. To date, there have been no Redux-related product liability settlements or judgments paid by Indevus or their insurers.



**Table of Contents****ENDO PHARMACEUTICALS HOLDINGS INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(UNAUDITED)****FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

As of June 30, 2010, the Company had an outstanding insurance claim of approximately \$2.8 million, relating to payments made by the Company to the group of law firms defending the Company in the Redux-related product liability litigation, for services rendered by such law firms through May 30, 2001. The full amount of the Company's current outstanding insurance claim is made pursuant to the Company's product liability policy issued to Indevus by Reliance Insurance Company (Reliance). In October 2001, the Commonwealth Court of Pennsylvania granted an Order of Liquidation to the Insurance Commissioner of Pennsylvania to begin liquidation proceedings against Reliance. It is uncertain when, if ever, the Company will collect any of its remaining \$2.8 million of claims. If the Company incurs additional product liability defense and other costs subject to claims on the Reliance product liability policy up to the \$5.0 million limit of the policy, the Company will have to pay such costs without expectation of reimbursement and will incur charges to operations for all or a portion of such payments.

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

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

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.

On January 22, 2010, without admitting any liability or wrongdoing, EPI and the plaintiffs reached an agreement in principle to resolve the foregoing federal cases brought by New York City and the New York counties on terms that are not material to the company's financial condition.

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(UNAUDITED)**

**FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

There is a previously reported case pending in the MDL against EPI and numerous other pharmaceutical companies: *State of Iowa v. Abbott Laboratories, Inc., et al.*, Civ. Action No. 4:07-cv-00461. On June 25, 2010, without admitting any liability or wrongdoing, EPI and the plaintiffs reached an agreement in principle to resolve this case brought by the State of Iowa on terms that are not material to the company's financial condition.

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, have been coordinated by the New York Litigation Coordinating Panel in the Supreme Court of the State of New York, Erie County.

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.*

There is a previously reported case pending in the Third Judicial District Court of Salt Lake County, Utah against EPI and numerous other pharmaceutical companies: *State of Utah v. Actavis US, Inc., et al.*, Civ. Action No. 070913719.

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 the above cases vigorously and to explore other options as appropriate in the best interests of the Company. 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 Lidoderm®*

On January 15, 2010, the Company and the holders of the Lidoderm® NDA and relevant patent, Teikoku Seiyaku Co., Ltd., and Teikoku Pharma USA, Inc. (Teikoku) received a Paragraph IV Certification Notice under 21 U.S.C. 355(j) from Watson Laboratories, Inc. advising of the filing of an Abbreviated New Drug Application (ANDA) for a generic version Lidoderm® (lidocaine topical patch 5%). The Paragraph IV Certification Notice refers to U.S. Patent No. 5,827,529, which covers the formulation of Lidoderm®, a topical patch to relieve the pain of post herpetic neuralgia launched in 1999. This patent is listed in the FDA's Orange Book and expires in October 2015. As a result of this Notice, on February 19, 2010, the Company, Teikoku Seiyaku Co., Ltd. and Teikoku Pharma USA, Inc. filed a lawsuit against Watson Laboratories, Inc. in the United States District Court of the District of Delaware. Because the suit was filed within the 45-day period under the FDA Act for filing a patent infringement action, we believe that it triggered an automatic 30-month stay of approval under the Act. On March 4, 2010, Watson filed an Answer and Counterclaims, claiming U.S. Patent No. 5,827,529 is invalid or not infringed. Endo intends, and has been advised by Teikoku that they too intend, to vigorously defend Lidoderm's intellectual property rights and to pursue all available legal and regulatory avenues in defense of Lidoderm, including enforcement of the product's intellectual property rights and approved labeling. We cannot, however, predict or determine the timing or outcome of any of these litigations but will explore all options as appropriate in the best interests of the Company.

*Paragraph IV Certifications on Opana® ER*

On December 14, 2007, the Company received a notice from IMPAX Laboratories, Inc. (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 (oxymorphone hydrochloride extended-release tablets CII). IMPAX stated in its letter that the FDA requested IMPAX to provide notification to us and Penwest of any

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

Paragraph IV certifications submitted with its ANDA, as required under section 355(j) of the Federal Food, Drug and Cosmetics Act, or the FDC 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 2023, 2013 and 2013, respectively. The Company's Opana® ER product had new dosage form exclusivity that prevented final approval of any ANDA by the FDA until the exclusivity expired 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 FDC Act, we believe IMPAX's notice triggered the 45-day period under the FDC 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 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. In response, IMPAX 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. Additionally, the lawsuit previously filed by the Company and Penwest on November 15, 2007 against IMPAX remains pending.

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(UNAUDITED)**

**FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

On June 16, 2008, the Company received a notice from IMPAX that it had filed an amendment to its 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 Penwest filed a lawsuit against IMPAX in the United States District Court for the District of Delaware in connection with IMPAX's amended ANDA. The lawsuit alleges infringement of certain Orange Book-listed U.S. patents that cover the Opana® ER formulation. In response, IMPAX 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. Additionally, the lawsuits previously filed by the Company and Penwest against IMPAX remain pending. All three of these suits against IMPAX were transferred to the United States District Court for the District of New Jersey.

On June 8, 2010 Endo and Penwest settled the IMPAX litigation. Both sides dismissed their respective claims and counterclaim with prejudice. Under the terms of the settlement, IMPAX agreed not to challenge the validity or enforceability of Penwest's patents relating to Opana® ER. Endo and Penwest agreed to grant IMPAX a license permitting the production and sale of generic Opana® ER for 5, 10, 20, 30 and 40 mg tablets commencing on January 1, 2013.

In February 2008, we along with Penwest, received a notice from Actavis South Atlantic LLC (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 or expired 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. patent 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.

On or around June 2, 2008, the Company received a notice from Actavis that it had filed an amendment to its 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 amendment to its 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. On August 14, 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.

On February 20, 2009, Endo and Penwest settled all of the Actavis litigation. Both sides dismissed their respective claims and counterclaim with prejudice. Under the terms of the settlement, Actavis agreed not to challenge the validity or enforceability of Penwest's patents relating to Opana® ER. Endo and Penwest agreed to grant Actavis a license permitting the production and sale of generic Opana® ER 7.5 and 15 mg tablets by the earlier of July 15, 2011, the last day Actavis would forfeit its 180-day exclusivity, and the date on which any third party commences commercial sales of a generic oxymorphone hydrochloride extended-release tablets, but not before November 28, 2010. Endo and Penwest also granted Actavis a license to produce and market other strengths of Opana® ER generic commencing on the earlier of July 15, 2011 and the date on which any third party commences commercial sales of a generic form of the drug.

On July 14, 2008, the Company received a notice from Sandoz, Inc. (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

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

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 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 an Orange Book-listed U.S. patent that covers the Opana® ER formulation. In response, Sandoz 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.

On November 20, 2008, the Company received a notice from Sandoz that it had filed an amendment to its ANDA containing Paragraph IV certifications for the 7.5 mg, 15 mg and 30 mg dosage strengths of oxymorphone hydrochloride extended release tablets. The notice covers Penwest's U.S. Patent Nos. 5,128,143, 7,276,250, 5,958,456 and 5,662,933. On December 30, 2008, the Company and Penwest, filed suit against Sandoz 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. In response, Sandoz 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. Both of these suits against Sandoz were transferred to the United States District Court for the District of New Jersey.

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(UNAUDITED)**

**FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

On June 8, 2010 Endo and Penwest settled the Sandoz litigation. Both sides dismissed their respective claims and counterclaim with prejudice. Under the terms of the settlement, Sandoz agreed not to challenge the validity or enforceability of Penwest's patents relating to Opana® ER. Endo and Penwest agreed to grant Sandoz a license permitting the production and sale of all strengths of Opana® ER commencing on September 15, 2012, or earlier under certain circumstances.

On September 12, 2008, the Company received a notice from Barr Laboratories, Inc. (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 had a new dosage form exclusivity that prevented final approval of any ANDA by the FDA until the exclusivity expired on June 22, 2009. Subsequently, on October 20, 2008, the Company and 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. In response, Barr 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. This suit was transferred to the United States District Court for the District of New Jersey. On June 2, 2009, 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 7.5 mg, 15 mg, and 30 mg dosage strengths. This notice also 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. On July 2, 2009, the Company and Penwest filed a lawsuit against Barr in the United States District Court for the District of New Jersey in connection with Barr's ANDA.

On April 12, 2010, Endo and Penwest settled all of the Barr litigation. Under the terms of the settlement, Barr agreed not to challenge the validity or enforceability of Penwest's patents relating to the production and sale of generic formulations of Opana® ER (oxymorphone hydrochloride) Extended Release Tablets CII.

Under the terms of the settlement, Endo and Penwest have agreed to grant Barr a license to sell a generic of Opana® ER commencing on or after September 15, 2012, or earlier under certain circumstances.

On December 29, 2009, the Company received a notice from Roxane Laboratories, Inc. (Roxane) advising of the filing by Roxane 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. The 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. Subsequently, on January 29, 2010, the Company and Penwest filed a lawsuit against Roxane in the U.S. District Court for the District of New Jersey in connection with Roxane's ANDA. The lawsuit alleges infringement of an Orange Book-listed U.S. patent that covers the Opana® ER formulation.

On January 20, 2010, the Company received a notice from Watson Laboratories, Inc. (Watson) advising of the filing by Watson 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. The 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. Subsequently, on March 4, 2010, the Company and Penwest filed a lawsuit against Watson in the U.S. District Court for the District of New Jersey in connection with Watson's ANDA. The lawsuit alleges infringement of an Orange Book-listed U.S. patent that covers the Opana® ER formulation. On March 19, 2010, the Company received a notice from Watson Laboratories, Inc. (Watson) advising of the filing by Watson 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, 7.5, 10, 15, 20, and 30 mg dosage strengths. Subsequently, on April 23, 2010, the Company and Penwest filed a lawsuit against Watson in the U.S. District Court for the District of New Jersey in connection with Watson's ANDA. The lawsuit alleges infringement of an Orange Book-listed

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

U.S. patent that covers the Opana® ER formulation.

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. We cannot, however, predict or determine the timing or outcome of any of these litigations but will explore all options as appropriate in the best interests of the Company.



**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(UNAUDITED)**

**FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

*Paragraph IV Certifications on Sanctura XR®*

On June 2, 2009, the Company's subsidiary, Endo Pharmaceuticals Solutions, Inc. (Endo Solutions), received a notice from Watson Laboratories, Inc. (Watson) advising that Watson had filed a certification with the FDA under 21 C.F.R. § 314.95(c)(1) in conjunction with ANDA 91-289 for approval to commercially manufacture and sell generic versions of Sanctura XR® trospium chloride extended release capsules. The Paragraph IV letter alleged that U.S. Patent No. 7,410,978, listed in the Orange Book for Sanctura XR® is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Watson's generic product. This patent expires February 1, 2025 and is owned by Supernus Pharmaceuticals, Inc. and licensed to Endo Solutions. The Sanctura XR® product has new dosage form exclusivity that prevents final approval of any ANDA by the FDA until the exclusivity expires on August 3, 2010.

In response to Watson's notice letter, on July 13, 2009, Supernus Pharmaceuticals, Inc., Endo Solutions and Allergan filed a lawsuit against Watson in the United States District Court for the District of Delaware alleging infringement of U.S. Patent No. 7,410,978 by Watson's ANDA 91-289. Because the suit was filed within the 45-day period under the FDC Act for filing a patent infringement action, we believe that it triggered an automatic 30-month stay of approval under the Act. We intend, and have been advised by Supernus and Allergan that they too intend, to contest this case vigorously. We cannot, however, predict or determine the timing or outcome of this litigation but will explore all options as appropriate in the best interests of the Company.

On November 4, 2009, the Company received a Paragraph IV Certification Notice under 21 U.S.C. 355(j) from Sandoz, Inc. (Sandoz) advising the Company that Sandoz had filed an ANDA 91-635 for approval to commercially manufacture, use and sell generic versions of Sanctura XR® trospium chloride extended release capsules. The Paragraph IV letter alleges that U.S. Patent No. 7,410,978, listed in the Orange Book for Sanctura XR® is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Sandoz's generic product. This patent expires February 1, 2025 and is owned by Supernus Pharmaceuticals, Inc. and licensed to Endo Solutions. The Sanctura XR® product has new dosage form exclusivity that prevents final approval of any ANDA by the FDA until the exclusivity expires on August 3, 2010.

In response to Sandoz's notice letter, on November 19, 2009, Supernus Pharmaceuticals, Inc., Endo Solutions and Allergan filed a lawsuit against Sandoz in the United States District Court for the District of Delaware alleging infringement of U.S. Patent No. 7,410,978 by Sandoz's ANDA 91-635. Because the suit was filed within the 45-day period under the FDC Act for filing a patent infringement action, we believe that it triggered an automatic 30-month stay of approval under the Act. We intend, and have been advised by Supernus and Allergan that they too intend, to contest this case vigorously. We cannot, however, predict or determine the timing or outcome of this litigation but will explore all options as appropriate in the best interests of the Company.

On April 26, 2010, the Company received a Paragraph IV Certification Notice under 21 U.S.C. 355(j) from Paddock Laboratories, Inc. (Paddock) advising the Company that Paddock had filed an ANDA 201291 for approval to commercially manufacture, use and sell generic versions of Sanctura XR® trospium chloride extended release capsules. The Paragraph IV letter alleges that U.S. Patent No. 7,410,978, listed in the Orange Book for Sanctura XR® is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Paddock's generic product. This patent expires February 1, 2025 and is owned by Supernus Pharmaceuticals, Inc. and licensed to Endo Solutions. The Sanctura XR® product has new dosage form exclusivity that prevents final approval of any ANDA by the FDA until the exclusivity expires on August 3, 2010.

In response to Paddock's notice letter, on June 9, 2010, Supernus Pharmaceuticals, Inc., Endo Solutions and Allergan filed a lawsuit against Paddock in the United States District Court for the District of Delaware alleging infringement of U.S. Patent No. 7,410,978 by Paddock's ANDA 20-1291. Because the suit was filed within the 45-day period under the FDC Act for filing a patent infringement action, we believe that it triggered an automatic 30-month stay of approval under the Act. We intend, and have been advised by Supernus and Allergan that they too intend, to contest this case vigorously. We cannot, however, predict or determine the timing or outcome of this litigation but will explore all options as appropriate in the best interests of the Company.

*Other Legal Proceedings*

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

**NOTE 11. NET INCOME 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 June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
<b>Numerator:</b>				
Net income available to common stockholders	\$ 51,460	\$ 30,029	\$ 111,815	\$ 69,066
<b>Denominator:</b>				
For basic per share data weighted average shares	116,060	117,158	116,704	116,990
Effect of dilutive stock options	600	192	642	289
For diluted per share data weighted average shares	116,660	117,350	117,346	117,279
Basic net income per share	\$ 0.44	\$ 0.26	\$ 0.96	\$ 0.59
Diluted net income per share	\$ 0.44	\$ 0.26	\$ 0.95	\$ 0.59

Basic net income per share is computed based on the weighted average number of common shares outstanding during the period. Diluted income per common share is computed based on the weighted average number of common shares outstanding and, if there is net income during the period, the dilutive impact of common stock equivalents outstanding during the period. Common stock equivalents are measured under the treasury stock method.

The 1.75% Convertible Senior Subordinated Notes due April 15, 2015 would only be included in the dilutive earnings per share calculation using the treasury stock method when the average market price of our common stock is above the applicable conversion price of the Convertible Notes, or \$29.20 per share. Under the treasury stock method, we would calculate the number of shares issuable under the terms of these notes based on the average market price of the stock during the period, and include that number in the total diluted shares figure for the period.

**Table of Contents****ENDO PHARMACEUTICALS HOLDINGS INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(UNAUDITED)****FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

We have entered into convertible note hedge and warrant agreements that, in combination, have the economic effect of reducing the dilutive impact of the Convertible Notes. However, we separately analyze the impact of the convertible note hedge and warrant agreements on diluted EPS. As a result, the purchases of the convertible note hedges are excluded because their impact will always be anti-dilutive. The treasury stock method will be applied when the warrant is in-the-money with the proceeds from the exercise of the warrant used to repurchase shares based on the average stock price in the calculation of diluted weighted average shares. Until the warrants are in-the-money, they have no impact to the diluted weighted average share calculation. The total number of shares that could potentially be included under the warrants is 1.3 million.

The following reconciliation shows the shares excluded from the calculation of diluted earnings per share as the inclusion of such shares would be anti-dilutive for the six months ended June 30 (in thousands):

	2010	2009
Weighted average shares excluded:		
1.75% Convertible senior subordinated notes due 2015 and warrants(1)	14,294	14,294
Employee stock-based awards	5,150	4,585
	19,444	18,879

- (1) Amount represents the potential total dilution that could occur if our Convertible Notes and warrants were converted to shares of our common stock.

**NOTE 12. DEBT*****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 \$370.7 million from the issuance, net of the initial purchaser's discount and certain other costs of the offering. Interest is payable semi-annually in arrears on each April 15 and October 15 with the first interest payment being made on October 15, 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.

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

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

our common stock upon conversion of the Convertible Notes by effectively increasing the initial conversion price of the notes to \$40.00 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. 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. The warrant transaction could have a dilutive effect on our earnings per share to the extent that the price of our common stock exceeds the strike price of the warrants at exercise.

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.

As discussed in Note 2, on January 1, 2009 the Company retrospectively adopted the provisions of the authoritative guidance relating to the accounting for convertible debt instruments. The guidance 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.

**Table of Contents****ENDO PHARMACEUTICALS HOLDINGS INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(UNAUDITED)****FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

As a result of our adoption, we separated the debt portion of our Convertible Notes from the equity portion at their fair value retrospective to the date of issuance and are amortizing the resulting discount into interest expense over the life of the Convertible Notes.

The carrying values of the debt and equity components of our Convertible Notes at June 30, 2010 and December 31, 2009 are as follows (in thousands):

	<b>June 30, 2010</b>	<b>December 31, 2009</b>
Principal amount of Convertible Notes	\$ 379,500	\$ 379,500
Unamortized discount related to the debt component(1)	(110,098)	(119,221)
<b>Net carrying amount of the debt component</b>	<b>\$ 269,402</b>	<b>\$ 260,279</b>
Carrying amount of the equity component	\$ 142,199	\$ 142,199

- (1) Represents the unamortized portion of the original purchaser's discount and certain other costs of the offering as well as the unamortized portion of the discount created from the separation of the debt portion of our Convertible Notes from the equity portion. This discount will be amortized to interest expense over the term of the Convertible Notes.

We recognized \$12.4 million and \$11.7 million of interest expense for the six months ended June 30, 2010 and 2009, respectively. For the amounts recognized in 2010, \$3.3 million related to the contractual interest payments and \$9.1 million related to the amortization of the debt discount and certain other costs of the offering. This compared to \$3.3 million of contractual interest payments and \$8.4 million related to the amortization of the debt discount and certain other costs of the offering for the six months ended June 30, 2009.

***Convertible Notes Due July 2009***

As a result of our acquisition of Indevus, the Company assumed Indevus's 6.25% Convertible Senior Notes due July 2009 (the Notes). Pursuant to the Indenture governing the Notes, within 30 days of the effective date of the Merger, holders of the Notes had the right to tender their Notes for the principal amount of the Notes plus any accrued and unpaid interest. During this 30-day period, approximately \$3.6 million in aggregate principal amount of Notes were tendered and the Company paid this amount in April 2009.

The Notes matured on July 15, 2009. Accordingly, the Company paid the remaining \$68.3 million in outstanding principal to satisfy the Notes in their entirety.

***Non-recourse Notes***

On August 26, 2008, Indevus closed a private placement to institutional investors of \$105.0 million in aggregate principal amount of 16% non-convertible, non-recourse, secured promissory notes due 2024 (Non-recourse Notes). The Non-recourse Notes were issued by Ledgemont Royalty Sub LLC (Royalty Sub), which was a wholly-owned subsidiary of Indevus at the time of the Non-recourse Note issuance and subsequently became a wholly-owned subsidiary of the Company upon our acquisition of Indevus. As of the Acquisition Date, the Company recorded these notes at their fair value of approximately \$115.2 million and began amortizing these notes to their face value of \$105.0 million at maturity in 2024.

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

In connection with the issuance of the Non-recourse Notes, Indevus and Royalty Sub entered into a Purchase and Sale Agreement pursuant to which Indevus sold to Royalty Sub its rights to receive royalty payments from Allergan arising under the Allergan Agreement (as described in Note 6) for sales in the U.S. of Sanctura<sup>®</sup> and Sanctura XR<sup>®</sup>. To secure repayment of the Non-recourse Notes, Royalty Sub granted a continuing security interest to the trustee for the benefit of the noteholders in, among other things, the royalty payments made by Allergan under the Allergan Agreement discussed above, all of its rights under the Purchase and Sale Agreement and any accounts established in accordance with the Indenture (and all amounts from time to time credited to such accounts). The Non-recourse Notes have not been guaranteed by Indevus or the Company. Principal on the Non-recourse Notes is required to be paid in full by the final legal maturity date of November 5, 2024, unless repaid or redeemed earlier. In the event the Non-recourse Notes are repaid or redeemed prior to November 5, 2024, the noteholders will be entitled to a redemption premium (as described below). The interest rate applicable to the Non-recourse Notes is 16% per year and is payable quarterly in arrears and commenced on November 5, 2008.

Principal and interest on the Non-recourse Notes will be paid from the royalties from Allergan. Payments may also be made from the interest reserve account (described below) and certain other accounts established in accordance with the Indenture. In connection with the issuance of the Non-recourse Notes, a \$10 million interest reserve account was established to fund potential interest payment shortfalls. As of June 30, 2010, there was no remaining restricted cash on the Company's consolidated balance sheet. Royalty Sub will receive directly all royalties payable to the Company until the Non-recourse Notes have been repaid in full.

**Table of Contents****ENDO PHARMACEUTICALS HOLDINGS INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(UNAUDITED)****FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

In August 2009, the Company commenced a cash tender offer for any and all outstanding Non-recourse notes. The purpose of the tender offer was to acquire any and all Notes to reduce our consolidated interest expense. The tender offer included an early tender deadline, whereby holders of the Non-recourse notes could early tender and receive the total early consideration of \$1,000 per \$1,000 principal amount of the Non-recourse notes. Holders who tendered their Non-recourse notes after such time and at or prior to the expiration of the tender offer period were eligible to receive the tender offer consideration of \$950 per \$1,000 principal amount of Non-recourse notes, which was the total early consideration less the early tender payment. The tender offer expired on September 24, 2009, at 5:00 p.m., New York City time (the Expiration Time). As of the Expiration Time, \$48 million Non-recourse notes had been validly tendered and not withdrawn. The Company accepted for payment and purchased Non-recourse notes at a purchase price of \$1,000 per \$1,000 principal amount, for a total amount of approximately \$48 million (excluding accrued and unpaid interest up to, but not including, the payment date for the Notes, fees and other expenses in connection with the tender offer). The aggregate principal amount of Non-recourse notes purchased represents approximately 46% of the \$105 million aggregate principal amount of Non-recourse notes that were outstanding prior to the Expiration Time. Accordingly, the Company recorded a \$4.0 million gain on the extinguishment of debt, net of transaction costs. The gain was calculated as the difference between the aggregate amount paid to purchase the Non-recourse notes and their carrying amount.

If the royalty payments from Allergan and amounts in the interest reserve account are insufficient to pay all of the interest and principal, if any, due on a payment date, the shortfall will accrue interest at the interest rate applicable to the Non-recourse Notes (16%) compounded quarterly. If any interest payment shortfall is not paid in full by the succeeding payment date, an Event of Default under the Indenture will occur, unless the Company contributes cash to a capital account of Royalty Sub in an amount sufficient to satisfy any such shortfall. Pursuant to the Indenture, the Company has the right, but not the obligation, to contribute cash in an amount equal to the shortfall to the capital account for distribution by the trustee to the noteholders. The Company has the right to satisfy such an interest payment shortfall no more than six times over the life of the Non-recourse Notes and no more than three consecutive times. In the event that the Company is no longer permitted to fund the capital account to satisfy an interest payment shortfall, and the Company does not redeem the Non-recourse Notes (as described below), an Event of Default will occur and the noteholders may accelerate the obligations of Royalty Sub under the Non-recourse Notes and exercise their remedies thereunder, including assuming all rights to future royalty payments from Allergan. We funded a shortfall of \$0.04 million and \$1.2 million with our February 2010 and May 2010 quarterly interest payments, respectively. Based on current expectations, it is reasonably possible that we may exceed the maximum number of times we can fund the capital account to satisfy an interest payment shortfall as early as November 2010.

The Non-recourse Notes will be subject to redemption at the option of Royalty Sub. If the applicable redemption of the Non-recourse Notes occurs on or prior to August 5, 2010, the redemption price will be equal to the greater of (x) the outstanding principal balance of the Non-recourse Notes being redeemed or (y) the present value, discounted at the rate on U.S. Treasury obligations with a comparable maturity to the remaining weighted average life of the Non-recourse Notes plus 1.00%, of the principal payment amounts and interest at the rate applicable to the Non-recourse Notes on the outstanding principal balance of the Non-recourse Notes. If the applicable redemption of the Non-recourse Notes occurs after August 5, 2010, the redemption price will be equal to the percentage of the outstanding principal balance of the Non-recourse Notes being redeemed specified below for the period in which the redemption occurs:

<b>Payment Dates (between indicated dates)</b>	<b>Redemption Percentage</b>
From November 5, 2010 to and including August 5, 2011	108%
From November 5, 2011 to and including August 5, 2012	104%
From November 5, 2012 and thereafter	100%

*Credit Facility*

In October 2009, we established a \$300 million, three-year senior secured revolving credit facility (the Credit Facility) with JP Morgan Chase Bank, Barclays Capital and certain other lenders. The Credit Facility will be available for letters of credit, working capital and general corporate

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

purposes. The Credit Facility also permits up to \$100 million of additional revolving or term loan commitments from one or more of the existing lenders or other lenders.

The obligations of the Company under the Credit Facility are guaranteed by certain of the Company's domestic subsidiaries and are secured by substantially all of the assets of the Company. The Credit Facility contains certain usual and customary covenants, including, but not limited to covenants to maintain a maximum leverage ratio and minimum interest coverage ratio as well as limitations on capital expenditures, asset sales, mergers and acquisitions, indebtedness, liens, dividends, investments and transactions with the Company's affiliates. Borrowings under the Credit Facility will be pegged to either (1) the London Interbank Offered Rate (LIBOR) or (2) an alternate base rate, plus a specified margin depending on the Company's leverage ratio from time to time. The alternate base rate is the greater of the prime rate, the federal funds rate plus 0.5%, or an adjusted LIBOR rate plus 1%. The Company will also pay a commitment fee of between 62.5 to 100 basis points, depending on the Company's leverage ratio, payable quarterly, on the average daily unused amount of the Credit Facility. As of the date of this filing, the Company has not drawn any amounts under the Credit Facility. Financing costs of \$5.2 million paid to establish the credit facility have been deferred and are being amortized to interest expense over the life of the credit facility.



**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(UNAUDITED)**

**FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

**NOTE 13. Subsequent Events**

*Acquisition of HealthTronics, Inc.*

On July 2, 2010 (referred to as the HealthTronics Acquisition Date), Endo completed its initial tender offer (the Offer) for all outstanding shares of common stock, par value \$0.01 per share (the Shares), of HealthTronics, at a price of \$4.85 per Share. On the HealthTronics Acquisition Date, Endo acquired a controlling financial interest in HealthTronics. On July 12, 2010, Endo completed its acquisition of HealthTronics for approximately \$212.9 million in aggregate cash consideration for 100% of the outstanding shares. In addition, Endo paid \$9.9 million for the acceleration of the HealthTronics outstanding stock-based compensation. In July of 2010, Endo also paid \$40.2 million to retire HealthTronics debt that had been outstanding under its Senior Credit Facility. As a result of the acquisition, the HealthTronics Senior Credit Facility was terminated. HealthTronics is a leading provider of healthcare services and manufacturer of medical devices, primarily for the urology community. The HealthTronics business and applicable services include:

*Lithotripsy services.*

HealthTronics provides lithotripsy services, which is a medical procedure where a device called a lithotripter transmits high energy shockwaves through the body to break up kidney stones. Lithotripsy services are provided principally through limited partnerships and other entities that HealthTronics manages, which use lithotripters. In 2009, physicians who are affiliated with HealthTronics used its lithotripters to perform approximately 50,000 procedures in the U.S. While the physicians render medical services, HealthTronics does not. As the general partner of limited partnerships or the manager of other types of entities, HealthTronics also provide services relating to operating its lithotripters, including scheduling, staffing, training, quality assurance, regulatory compliance, and contracting with payors, hospitals, and surgery centers.

*Prostate treatment services.*

HealthTronics provides treatments for benign and cancerous conditions of the prostate. In treating benign prostate disease, HealthTronics deploys three technologies in a number of its partnerships above: (1) photo-selective vaporization of the prostate (PVP), (2) trans-urethral needle ablation (TUNA), and (3) trans-urethral microwave therapy (TUMT). All three technologies apply an energy source which reduces the size of the prostate gland. For treating prostate and other cancers, HealthTronics uses a procedure called cryosurgery, a process which uses lethal ice to destroy tissue such as tumors for therapeutic purposes. In April 2008, HealthTronics acquired Advanced Medical Partners, Inc., which significantly expanded its cryosurgery partnership base. In July 2009, HealthTronics acquired Endocare, Inc., which manufactures both the medical devices and related consumables utilized by its cryosurgery operations and also provides cryosurgery treatments. The prostate treatment services are provided principally by using equipment that HealthTronics leases from limited partnerships and other entities that HealthTronics manages. Benign prostate disease and cryosurgery cancer treatment services are billed in the same manner as its lithotripsy services under either retail or wholesale contracts. HealthTronics also provides services relating to operating the equipment, including scheduling, staffing, training, quality assurance, regulatory compliance, and contracting.

*Radiation therapy services.*

HealthTronics provides image guided radiation therapy (IGRT) technical services for cancer treatment centers. Its IGRT technical services may relate to providing the technical (non-physician) personnel to operate a physician practice group's IGRT equipment, leasing IGRT equipment to a physician practice group, providing services related to helping a physician practice group establish an IGRT treatment center, or managing an IGRT treatment center.

*Anatomical pathology services.*

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

HealthTronics provides anatomical pathology services primarily to the urology community. HealthTronics has one pathology lab located in Georgia, called Claripath Laboratories, which provides laboratory detection and diagnosis services to urologists throughout the United States. In addition, in July 2008, HealthTronics acquired Uropath LLC (Uropath), which managed pathology laboratories located at Uropath sites for physician practice groups located in Texas, Florida and Pennsylvania. Through Uropath, HealthTronics continues to provide administrative services to in-office pathology labs for practice groups and pathology services to physicians and practice groups with its lab equipment and personnel at the Uropath laboratory sites.

### *Medical products manufacturing, sales and maintenance.*

HealthTronics manufactures and sells medical devices focused on minimally invasive technologies for tissue and tumor ablation through cryoablation, which is the use of lethal ice to destroy tissue, such as tumors, for therapeutic purposes. HealthTronics develops and manufactures these devices for the treatment of prostate and renal cancers and our proprietary technologies also have applications across a number of additional markets, including the ablation of tumors in the lung, liver metastases and palliative intervention (treatment of pain associated with metastases). HealthTronics manufactures the related spare parts and consumables for these devices. HealthTronics also sells and maintains lithotripters and related spare parts and consumables.

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(UNAUDITED)**

**FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2010**

The acquisition of HealthTronics reflects Endo's desire to continue expanding our business beyond pain management into complementary medical areas where HealthTronics can be innovative and competitive. We believe this expansion will enable us to be a provider of multiple healthcare solutions and services that fill critical gaps in patient care.

We believe there are several ways Endo may enhance HealthTronics continued growth and success. For example, we believe there are cross-selling opportunities to grow the business organically by bringing HealthTronics anatomical pathology and cryoablation equipment services to urologists with whom Endo details today. Further, we anticipate being able to enhance the healthcare solutions we currently offer to urologists.

We have an exceptional field force of urology representatives to support the HealthTronics team with expanded reach and presence. We believe the unique channel that HealthTronics has established with urologists, combined with our ability to invest in innovative therapeutics and devices, our internal and virtual R&D capabilities and our current pharmaceutical focus in urology, is an extremely valuable combination for the physicians we serve and our business overall.

In addition, HealthTronics core expertise in medical devices manufacturing and urology procedure complements extremely well our expertise in researching clinical development and managed care contracting.

The Company will account for the HealthTronics acquisition as a business combination. The Company will include HealthTronics' results of operations in our consolidated financial statements beginning on July 2, 2010, the acquisition date. Under the applicable guidance, we are required to recognize the assets acquired, liabilities assumed and noncontrolling interests at their fair value as of the acquisition date. Given the date on which we acquired a controlling financial interest in HealthTronics, we are unable to provide the acquisition date fair value of assets acquired, liabilities assumed, noncontrolling interests or supplemental pro forma financial information as it is impracticable to do so at this time. Accordingly, we are also unable to provide a qualitative description of the factors that make up goodwill to be recognized, if any.

Transaction costs are recorded in "Acquisition-related items" within the condensed consolidated statements of operations. As of June 30, 2010, the Company recorded \$4.6 million in acquisition-related expenses associated with the HealthTronics acquisition, which consisted primarily of legal and accounting fees. In July 2010, Endo incurred investment bank fees for both Endo and HealthTronics totaling \$5.3 million. These investment bank fees will be recognized in the quarter ended September 30, 2010.

## **Table of Contents**

### **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 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, 2009 (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 i of this Report.

## **EXECUTIVE SUMMARY**

### ***About the Company***

Endo Pharmaceuticals Holdings Inc., which we refer to as "Endo," "we," "us," or the "Company," is a specialty pharmaceutical company. The Company is engaged in the research, development, manufacturing, marketing and sale of branded and generic prescription pharmaceuticals used primarily to treat and manage pain, overactive bladder, prostate and bladder cancer and the early onset of puberty in children, or central precocious puberty.

We have a portfolio of branded products that includes established brand names such as Lidoderm<sup>®</sup>, Opana<sup>®</sup> ER and Opana<sup>®</sup>, Percocet<sup>®</sup>, Frova<sup>®</sup>, Voltaren<sup>®</sup> Gel, Sanctura XR<sup>®</sup>, Sanctura<sup>®</sup>, Vantas<sup>®</sup>, Valstar<sup>®</sup>, and Supprelin<sup>®</sup> LA. Branded products comprised approximately 92% of our revenues for the six months ended June 30, 2010, with 50% of our revenues coming from Lidoderm<sup>®</sup>. Our non-branded generic portfolio, which accounted for 7% of revenues for the six months ended June 30, 2010, 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.

In the first quarter of 2009, we acquired Indevus, a specialty pharmaceutical company engaged in the acquisition, development and commercialization of products to treat conditions in urology, endocrinology and oncology. Indevus's approved products include Sanctura<sup>®</sup> and Sanctura XR<sup>®</sup> for overactive bladder (OAB), which are promoted in the U.S. by Allergan, Vantas<sup>®</sup> for advanced prostate cancer, Supprelin<sup>®</sup> LA for central precocious puberty (CPP), Delatestryl<sup>®</sup> for the treatment of hypogonadism and Valstar<sup>®</sup> for bladder cancer. We also acquired from Indevus a core urology and endocrinology portfolio containing multiple compounds in development including Aveed<sup>™</sup> for hypogonadism, and the octreotide implant for acromegaly and carcinoid syndrome. Financial information presented herein reflects the operating results of Indevus from February 23, 2009.

Through a dedicated sales force in the United States, consisting of 329 specialty representatives, 378 pharmaceutical sales representatives focusing primarily on pain products, 83 sales representatives focusing primarily on urology and oncology, 40 sales representatives focusing primarily on managed markets, 30 medical center representatives and a contract sales force of approximately 80 sales representatives, we market our branded pharmaceutical products to high-prescribing physicians in pain management, orthopedics, neurology, rheumatology, surgery, anesthesiology, oncology, urology, endocrinology and primary care, including pediatricians. Our sales force also targets retail pharmacies and other healthcare professionals throughout the United States.

On July 2, 2010, we acquired HealthTronics, Inc. a leading provider of healthcare services and manufacturer of medical devices, primarily for the urology community.

### ***Healthcare Reform***

On March 23, 2010, President Obama signed into law H.R. 3590, the Patient Protection and Affordable Care Act (PPACA), which will make major changes to the U.S. healthcare system. On March 30, 2010, the President signed H.R. 4872, the Health Care and Education Reconciliation Act of 2010 (Reconciliation Act), which included a package of changes to the PPACA, as well as additional elements to reform health care in the United States.

While some provisions of the new healthcare reform law go into effect this year, most of the provisions will not begin to be implemented until 2014 and beyond. Since implementation will be incremental to the enactment date of the law, there are still many challenges and uncertainties ahead. Such a comprehensive reform measure may require expanded implementation efforts on the part of federal and state agencies embark on rule-making to develop the specific components of their new authority. The Company will monitor closely the implementation of the new law.

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

The passage of the PPACA and the Reconciliation Act will result in a transformation of the delivery and payment for health care services in the U.S. The combination of these measures will expand health insurance coverage to an estimated 32 million Americans. In addition, there are significant health insurance reforms that are expected to improve patients' ability to obtain and maintain health insurance. Such measures include: the elimination of lifetime caps, no rescission of policies, and no denial of coverage due to preexisting conditions. The expansion of healthcare insurance and these additional market reforms should result in greater access to the Company's products.

**Table of Contents**

The overall impact from healthcare reform reflects a number of uncertainties. Nevertheless, we believe that changes to the Medicaid fee for service program and Managed Medicaid will drive the bulk of our estimated impact in 2010. There are a number of other provisions in the legislation that collectively are expected to have a small impact, including originator AMP for new formulations, the expansion of 340B pricing and the revision of the AMP definition to remove physician class of trade. We expect that these various elements of healthcare reform will adversely impact our total revenues by approximately \$20 million for the year ending December 31, 2010. Other elements will not have an effect until 2011. In particular, reducing the size of the donut hole in Medicare Part D coverage by 50% and the payment of a Health Care Reform fee will both have an incremental effect next year. These impacts are still fluid and will continue to evolve.

*HealthTronics Acquisition*

On July 2, 2010 (referred to as the HealthTronics Acquisition Date), Endo completed its initial tender offer (the Offer) for all outstanding shares of common stock, par value \$0.01 per share (the Shares), of HealthTronics, at a price of \$4.85 per Share. On the HealthTronics Acquisition Date, Endo acquired a controlling financial interest in HealthTronics. On July 12, 2010, Endo completed its acquisition of HealthTronics for approximately \$212.9 million in aggregate cash consideration for 100% of the outstanding shares. In addition, Endo paid \$9.9 million for the acceleration of the HealthTronics outstanding stock-based compensation. In July of 2010, Endo also paid \$40.2 million to retire HealthTronics debt that had been outstanding under its Senior Credit Facility. As a result of the acquisition, the HealthTronics Senior Credit Facility was terminated.

*Pipeline Developments*

In August 2009, we entered into a License and Supply Agreement with Strakan International Limited, a subsidiary of ProStrakan Group plc (referred to as ProStrakan), for the exclusive right to commercialize Fortesta in the U.S. Fortesta, a patented 2 percent testosterone transdermal gel for testosterone replacement therapy in male hypogonadism, utilizes a metered dose delivery system designed to permit accurate dose adjustment to individual patient requirements. On July 1, 2010, Endo submitted a complete response to the FDA following the company's re-analysis of the existing clinical samples. The company's Class 2 resubmission is the next step in its intention to offer Fortesta as a treatment option in the United States for men diagnosed with low testosterone (Low T), also known as hypogonadism. The FDA has informed us they consider our response complete and has issued a PDUFA date of December 30, 2010.

In September 2008, Indevus entered into a Development, License and Commercialization Agreement with Teva Pharmaceutical Industries Ltd. (Teva) for the exclusive, worldwide rights to pagoclone (the Teva Agreement). Under the terms of the Teva Agreement, the Company would conduct, and Teva would reimburse expenses for, a Phase IIIb study for stuttering. Teva was responsible for the conduct of all remaining development and commercialization, including the Phase III program. On May 16, 2010, Teva terminated the Teva Agreement and all rights have been returned to the Company. The Company is currently evaluating future development of this licensed asset.

*Branded Business Activity*

In June 2010, the Company and Penwest Pharmaceuticals (Penwest) settled litigation with both Impax Laboratories (IMPAX) and Sandoz regarding the production and sale of generic formulations of Opana<sup>®</sup> ER (oxymorphone hydrochloride) Extended Release Tablets CII. Endo and Penwest have agreed to dismiss their suit with prejudice and IMPAX and Sandoz has agreed to dismiss its counterclaims with prejudice. Under the terms of the settlement, Endo and Penwest have agreed to grant IMPAX and Sandoz a license to the patents to sell a generic version of Opana<sup>®</sup> ER on or after January 1, 2013 and September 15, 2012, respectively, and earlier under certain circumstances and have agreed not to sue IMPAX or Sandoz under such patents.

*Changes in Directors & Officers and Other Related Matters*

On April 28, 2010, Clive A. Meanwell, M.D., Ph.D. notified the company of his intent to not stand for reelection as a director of the Company at the Company's 2010 Annual Meeting of Stockholders, so that he may better focus on his other professional responsibilities. Dr. Meanwell served as a director of the Company until the expiration of his term at the Company's 2010 Annual Meeting of Stockholders.

On March 12, 2010, the Company's Board of Directors appointed Julie McHugh as the Company's Executive Vice President and Chief Operating Officer. Most recently, Ms. McHugh was president and CEO for Nora Therapeutics, a venture capital backed biotech start-up developing novel therapies to prevent implantation failure in the setting of in-vitro fertilization and recurrent pregnancy loss. Before joining Nora, she held senior positions at Johnson & Johnson during a twelve year period. Her last role at J&J was Company Group Chairman for the Global Virology Business Unit. Before that she was President of Centocor, Inc., a J&J company. Previously, Ms. McHugh held marketing positions of increasing scope and accountability at Astra-Merck, Rhone-Poulenc Rorer (Sanofi Aventis) and SmithKline (GlaxoSmithKline). Ms. McHugh currently serves on the Board of Visitors for the Smeal College of Business of the Pennsylvania State University, the Board of Directors for the Nathaniel

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

Adamczyk Foundation and was 2009 Chairman of the Board of Directors for the Pennsylvania Biotechnology Association. She received her Bachelor of Science degree from Pennsylvania State University and her Masters of Business Administration degree from Saint Joseph's University.

**Table of Contents****RESULTS OF OPERATIONS**

Our quarterly results have fluctuated in the past, and may continue to fluctuate. These fluctuations are primarily due to (1) the timing of new product launches, (2) purchasing patterns of our customers, (3) market acceptance of our products, (4) the impact of competitive products and products we recently acquired and (5) pricing. These fluctuations are also attributable to charges incurred for compensation related to stock compensation, amortization of intangible assets, impairment of intangible assets, and certain upfront, milestone and certain other payments made or accrued pursuant to acquisition or licensing agreements.

**Revenues**

Revenues for the three and six months ended June 30, 2010 increased 6% to \$396.5 million and 7% to \$760.9 million, respectively, from the comparable 2009 periods. This increase in revenues is primarily driven by increased revenues of Lidoderm<sup>®</sup>, Opana<sup>®</sup> ER and Opana<sup>®</sup> and Voltaren<sup>®</sup> Gel. Also, included in the six months ended June 30, 2010 are the revenues of our recently acquired products, included in other brands, from our acquisition of Indevus Pharmaceuticals, Inc. This compares to a partial six months in 2009 as the acquired products were included from February 23, 2009 through June 30, 2009 in the comparable 2009 period. For the six months ended June 30, 2010, increased sales volume contributed 7% of the total revenue growth of 7%, while price contributed a negative (0.1%) of the total revenue growth.

The following table displays our revenues by product category and as a percentage of total revenues for the three and six months ended June 30, 2010 and 2009 (dollars in thousands):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2010		2009		2010		2009	
	\$	%	\$	%	\$	%	\$	%
Lidoderm <sup>®</sup>	\$ 196,090	49%	\$ 195,472	52	\$ 378,697	50	\$ 367,108	52
Opana <sup>®</sup> ER and Opana <sup>®</sup>	73,838	19	55,219	15	139,995	18	107,984	15
Percocet <sup>®</sup>	31,805	8	32,014	9	60,478	8	65,704	9
Voltaren <sup>®</sup> Gel	26,323	7	25,534	7	46,685	6	37,853	5
Frova <sup>®</sup>	14,680	4	15,187	4	29,762	4	27,479	4
Supprelin <sup>®</sup> LA	12,209	3	7,295	2	22,796	3	9,999	1
Other brands	11,492	3	9,620	3	22,497	3	15,824	2
Total brands*	366,437	92	340,341	91	700,910	92	631,951	89
Total generics	27,684	7	30,284	8	53,560	7	72,677	10
Total royalty and other revenues	2,403	1	2,483	1	6,466	1	3,780	1
<b>Total revenues*</b>	<b>\$ 396,524</b>	<b>100</b>	<b>\$ 373,108</b>	<b>100</b>	<b>\$ 760,936</b>	<b>100</b>	<b>\$ 708,408</b>	<b>100</b>

\* Total percentages may not sum due to rounding.

**Lidoderm<sup>®</sup>**. Net sales of Lidoderm<sup>®</sup> for the three months ended June 30, 2010 increased by \$0.6 million, or 0.3%, from the comparable 2009 period. Net sales of Lidoderm<sup>®</sup> for the six months ended June 30, 2010 increased by \$11.6 million, or 3%, from the comparable 2009 period. During the three and six months ended June 30, 2010, the increase in Lidoderm<sup>®</sup> is attributable to volumes compared to the same period in 2009.

**Opana<sup>®</sup> ER and Opana<sup>®</sup>**. Net sales of Opana<sup>®</sup> ER and Opana<sup>®</sup> for the three months ended June 30, 2010 increased by \$18.6 million, or 34% from the comparable 2009 period. Net sales of Opana<sup>®</sup> ER and Opana<sup>®</sup> for the six months ended June 30, 2010 increased by \$32.0 million, or 30% from the comparable 2009 period. The growth in net sales is primarily attributable to continued prescription and market share growth of the products, as we continue to drive our promotional efforts through physician targeting. In addition, our strategy to aggressively contract with managed care organizations has resulted in increases in volume as we have broadened our access for the brand.

**Percocet<sup>®</sup>**. Net sales of Percocet<sup>®</sup> for the three months ended June 30, 2010 decreased by \$0.2 million, or 0.6% from the comparable 2009 period. Net sales of Percocet<sup>®</sup> for the six months ended June 30, 2010 decreased by \$5.2 million, or 8% from the comparable 2009 period. The decreases are primarily attributable to decreased volumes during the first six-months of 2010 as compared to 2009.





**Table of Contents**

**Voltaren® Gel.** Net sales of Voltaren® Gel for the three months ended June 30, 2010 increased by \$0.8 million or 3% from the comparable 2009 period. Net sales of Voltaren® Gel for the six months ended June 30, 2010 increased by \$8.8 million or 23% compared to from the comparable 2009 period. The 2010 increases were driven by volume which were offset partially due to the absence of the recognition of \$11.3 million associated with the initial launch of our therapeutic doses of 3 and 5 tubes of Voltaren® Gel. The Company launched Voltaren® Gel in March 2008 and we believe the growth of Voltaren® Gel since its launch is driven by the product's proven clinical efficacy combined with our continued promotional activities aimed at increasing product awareness in the target audience.

**Supprelin® LA.** Net sales of Supprelin® LA for the three months ended June 30, 2010 increased by \$4.9 million or 67% from the comparable 2009 period. Net sales of Supprelin® LA for the six months ended June 30, 2010 increased by \$12.8 million or 128% compared to from the comparable 2009 period. These increases were driven primarily by volume growth for both periods in 2010. In addition, the increase for the six months ended 2010 was driven by our February 2009 acquisition of Indevus, which contributed a full six months of activity in 2010 compared to a partial period in 2009.

**Other brands.** Net sales of our other branded products for the three months ended June 30, 2010 increased by \$1.9 million from the comparable 2009 period. Net sales of our other branded products for the six months ended June 30, 2010 increased by \$6.7 million from the comparable 2009 period. This increase is primarily driven by our February 2009 acquisition of Indevus, which contributed approximately \$5.5 million and \$10.7 million of net sales during the three months ended June 30, 2009 and the period from February 23, 2009 through June 30, 2009, respectively. This compares to \$10.5 million and \$19.8 million for the full three and six months ended June 30, 2010, which also included revenues from our launch of Valstar™ in the third quarter of 2009.

**Generics.** Net sales of our generic products for the three months ended June 30, 2010 decreased by \$2.6 million, or 9% from the comparable 2009 period. Net sales of our generic products for the six months ended June 30, 2010 decreased by \$19.1 million, or 26% from the comparable 2009 period. The decrease was primarily due to a shortage of other competing generic opioids in the market during 2009 which was an anomaly and did not recur during 2010.

**Royalty and other revenues.** Royalty and other revenues for the three and six months ended June 30, 2010 were \$2.4 million and \$6.5 million. Royalty and other revenues for the three and six months ended June 30, 2009 were \$2.5 million and \$3.8 million. These amounts consist primarily of royalties earned on net sales of Sanctura® and Sanctura XR®.

**Gross Margin, Costs and Expenses**

The following table sets forth costs and expenses for the three and six months ended June 30, 2010 and 2009:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2010		2009		2010		2009	
	\$	% of Revenues	\$	% of Revenues	\$	% of Revenues	\$	% of Revenues
Cost of revenues	\$ 107,216	27%	\$ 95,069	25%	\$ 201,289	26%	\$ 178,078	25%
Selling, general and administrative	133,251	34	129,592	35	266,586	35	249,598	35
Research and development	44,656	11	48,508	13	73,824	10	76,922	11
Acquisition related costs	4,796	1	35,023	9	6,325	1	61,428	9
Impairment of long-lived assets	13,000	3			13,000	2		
Total costs and expenses	\$ 302,919	76%	\$ 308,192	83%	\$ 561,024	74%	\$ 566,026	80%

**Cost of Revenues and Gross Margin.** Cost of revenues for the three months ended June 30, 2010 increased by \$12.1 million or 13%, to \$107.2 million from \$95.1 million in the comparable 2009 period. Cost of revenues for the six months ended June 30, 2010 increased by \$23.2 million or 13%, to \$201.3 million from \$178.1 million in the comparable 2009 period. Cost of revenues increased during the six months ended June 30, 2010 primarily as a result of increased revenues as well as an increase in cost of revenues as a percent of revenue. Gross profit margins for the three months ended June 30, 2010 and 2009 were 73% and 75%, respectively. Gross profit margins for the six months ended June 30, 2010 and 2009 were 74% and 75%, respectively. The reduction in gross profit margins is primarily due to the increased amortization expense in 2010 compared to the 2009 period as a result of a full six months of amortization on the acquired Indevus intangible assets and an increase in royalty expense recorded on net sales of Opana® ER for the three and six months ended June 30, 2010, compared to the 2009 period as a result of the

expiration of the 50% royalty holiday during the three months ended March 31, 2010.

***Selling, General and Administrative Expenses.*** Selling, general and administrative expenses for the three months ended June 30, 2010 increased to \$133.3 million from \$129.6 million in the comparable 2009 period. Selling, general and administrative expenses for the six months ended June 30, 2010 increased to \$266.6 million from \$249.6 million in the comparable 2009 period. The increase is primarily attributable to our acquisition of Indevus during the first quarter of 2009 and the recognition of a full six months of Indevus expenses during the six months ended June 30, 2010 as well as approximately \$9.0 million of certain costs incurred in connection with continued efforts to enhance the cost structure of the Company.

***Research and Development Expenses.*** Research and development expenses for the three months ended June 30, 2010 decreased to \$44.7 million from \$48.5 million in the comparable 2009 period. Research and development expenses for the six months ended June 30, 2010 decreased to \$73.8 million from \$76.9 million in the comparable 2009 period. These decreases are primarily a result of less upfront and milestone payments in 2010 as compared to 2009. We expect research and development expenses to increase in the future as a result of the recent investments in our pipeline including the recent acquisition of Indevus as well as our collaborative agreements with various partners.

**Table of Contents**

**Acquisition Related Items.** Acquisition-related expenses for the three months ended June 30, 2010 and 2009 decreased to \$4.8 million from \$35.0 million in the comparable 2009 period. Acquisition-related expenses for the six months ended June 30, 2010 and 2009 decreased to \$6.3 million from \$61.4 million. As a result of our acquisition of Indevus Pharmaceuticals, Inc. in the first quarter of 2009, we incurred \$26.4 million of acquisition related costs, which were attributable to transaction fees, professional service fees, employee retention and separation arrangements and other costs related to the acquisition. This compares to \$7.0 million in 2010 primarily reflecting changes in the fair value of the acquisition-related contingent consideration of \$1.2 million and \$4.6 million in transaction-related expenses for the acquisition of HealthTronics incurred during the three months ended June 30, 2010.

**Interest Expense, net**

The components of interest expense, net for the three and six months ended June 30, 2010 and 2009 are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Interest expense	\$ 10,407	\$ 11,471	\$ 20,635	\$ 20,204
Interest income	(423)	(1,055)	(847)	(2,195)
Interest expense, net	\$ 9,984	\$ 10,416	\$ 19,788	\$ 18,009

Interest expense for the three months ended June 30, 2010 decreased to \$10.4 million from \$11.5 million in the comparable 2009 period. For the six months ended June 30, 2010, interest expense increased to \$20.6 million from \$20.2 million in the comparable 2009 period. The decrease for the three months ended June 30, 2010 related to the \$48 million of our Non-recourse notes which were tendered in September of 2009. This increase for the six months ended June 30, 2010 is primarily due to the amortization of our deferred financing fees associated with our Credit Facility. Interest income decreased to \$0.4 million and \$0.8 million for the three and six months ended June 30, 2010, respectively, compared to \$1.1 million and \$2.2 million in the comparable 2009 periods. This decrease is 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.

**Other Income, net**

The components of other income, net for the three and six months ended June 30, 2010 and 2009 are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Gain on trading securities	\$ (13,714)	\$ (10,910)	\$ (15,420)	\$ (4,816)
Loss on auction-rate securities rights	13,749	8,779	15,659	2,513
Other (income) expense	(236)	616	(659)	1,893
Other income, net	\$ (201)	\$ (1,515)	\$ (420)	\$ (410)

During the three and six months ended June 30, 2010, the value of our trading auction-rate securities increased by \$13.7 million and \$15.4 million, respectively. The increases in fair value were more than offset by losses recorded as a result of decreases in the fair value of our auction-rate securities rights totaling \$13.7 million and \$15.7 million, respectively, for the three and six-months ended June 30, 2010. During the three and six months ended June 30, 2009, the value of our trading auction-rate securities decreased by \$10.9 million and \$4.8 million. During the three and six months ended June 30, 2009, decreases in the fair value of our auction-rate securities rights were \$8.8 million and \$2.5 million, respectively. These changes were primarily a result of the Company exercising the auction rate securities rights in the second quarter of 2010 and liquidating our outstanding UBS auction rate security portfolio at par value.

**Income Tax**

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

Income tax for the three months ended June 30, 2010 increased to \$32.4 million from \$26.0 million in the comparable period in 2009. For the six months ended June 30, 2010, income tax increased to \$68.7 million from \$55.7 million. The increases for the three and six months ended June 30, 2010 is due to the increase in income before income tax as compared to the same periods in 2009, partially offset by the decrease in our effective income tax rate to 38.6% and 38.1% for the three and six months ended June 30, 2010, respectively, from 46.4% and 44.7% in the comparable 2009 periods. The decrease in the effective income tax rate is primarily attributable to the absence of non-deductible Indevus contingent consideration fair value adjustments and certain non-deductible Indevus transaction costs which unfavorably impacted the effective tax rate by \$8.8 million and \$3.6 million, respectively, during the three and six month periods ended June 30, 2009. These decreases were offset slightly due to the absence of the research and development tax credit benefit which is not effective as of June 30, 2010.

**Table of Contents***2010 Outlook*

As a result of the acquisition of HealthTronics, our revised estimated 2010 total revenues will be between \$1.63 billion and \$1.68 billion. Our estimate is based on the continued growth of our branded product portfolio, primarily driven by prescription demand for Lidoderm<sup>®</sup>, Opana<sup>®</sup> ER and Voltaren<sup>®</sup> Gel, the full year impact of the acquisition of Indevus and growth of the products acquired as well as six-months of consolidated results for HealthTronics, our new wholly-owned subsidiary. Cost of revenues as a percent of total revenues is expected to increase when compared to 2009. This cost of revenues increase is expected due to a full year of amortization expense associated with the intangible assets acquired with Indevus, the impact of a full year of royalties on the 2010 net sales of Opana<sup>®</sup> ER, and the supply price of inventory purchased from third party manufacturers which includes an anticipated impact from foreign exchange. Selling, general and administrative expenses, as a percentage of revenues, are expected to decline in 2010, relative to 2009, reflecting new approaches to customer segmentation and marketing as well as annualized effects of the prior year's cost reduction efforts. We will continue to provide promotional support behind our key on-market products, including those acquired as part of our acquisition of Indevus. R&D expenses are expected to increase as we invest in clinical development programs in support of our third party collaboration agreements as well as the further advancement of the development products being acquired from Indevus. Of course, there can be no assurance that the Company will achieve these results.

**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. The Company continues to maintain a sufficient level of working capital, which was approximately \$1,136 million at June 30, 2010, increasing from \$808.4 million at December 31, 2009. Cash, cash equivalents and current marketable securities were approximately \$992.3 million at June 30, 2010 compared to \$733.7 million at December 31, 2009.

In 2010, we expect cash generated from operations together with our cash, cash equivalents and current marketable securities to be sufficient to cover cash needs for working capital, certain acquisitions, including the payment during July 2010 of approximately \$262.9 million for HealthTronics including the acceleration of HealthTronics employee stock-based compensation and its outstanding debt, and general corporate purposes, the payment of contractual obligations, including scheduled interest payments on our Convertible Notes, principal and interest payments on the remaining \$57.0 million of Indevus debt assumed by the Company, and any regulatory and/or sales milestones that may become due. We may also elect to incur additional debt or issue equity or convertible securities to finance future acquisitions or to meet our other liquidity needs. Any issuances of equity securities or convertible securities could have a dilutive effect on the ownership interest of our current shareholders and may adversely impact earnings per share in future periods. An acquisition may be accretive or dilutive and by its nature, involve numerous risks and uncertainties.

We expect that sales of our currently marketed products to allow us to continue to generate positive cash flow from operations. In February 2009, concurrent with the completion of the Indevus transaction, we placed \$175 million in escrow until December 15, 2009 to fund the potential Aved<sup>™</sup> Contingent Cash Consideration Agreement. Since we did not obtain FDA Approval by December 15, 2009, the \$175 million was returned to us.

Beyond 2010, we expect cash generated from operations together with our cash, cash equivalents and marketable securities to continue to be sufficient to cover cash needs for working capital and general corporate purposes, certain acquisitions of other businesses, including the potential payments of up to \$300 million in contingent cash consideration payments related to our acquisition of Indevus, products, product rights, or technologies, the payment of contractual obligations, including scheduled interest payments on our convertible notes, principal and interest payments on the remaining \$57.0 million of Indevus debt assumed by the Company, certain minimum royalties due to Novartis and the regulatory or sales milestones that may become due, and/or the purchase, redemption or retirement of our convertible notes, including a principal payment of \$379.5 million at maturity in 2015. We expect that sales of our currently marketed products will allow us to continue to generate positive cash flow from operations. At this time, we cannot accurately predict the effect of certain developments on the rate of sales growth, such as the degree of market acceptance, patent protection and exclusivity of our products, the impact of competition, the effectiveness of our sales and marketing efforts and the outcome of our current efforts to develop, receive approval for and successfully launch our near-term product candidates. If any of the above adversely affects our future cash flows, we may need to obtain additional funding for future strategic transactions, to repay our outstanding indebtedness, or for our future operational needs, and we cannot be certain that funding will be available on terms acceptable to us, or at all.

**Table of Contents**

On October 16, 2009, we established a \$300 million, three-year senior secured revolving credit facility (the Credit Facility) with JP Morgan Chase Bank, Barclays Capital and certain other lenders. The Credit Facility will be available for letters of credit, working capital and general corporate purposes. The Credit Facility also permits up to \$100 million of additional revolving or term loan commitments from one or more of the existing lenders or other lenders.

The obligations of the Company under the Credit Facility are guaranteed by certain of the Company's domestic subsidiaries and are secured by substantially all of the assets of the Company. The Credit Facility contains certain usual and customary covenants, including, but not limited to covenants to maintain a maximum leverage ratio and minimum interest coverage ratio as well as limitations on capital expenditures, asset sales, mergers and acquisitions, indebtedness, liens, dividends, investments and transactions with the Company's affiliates. Borrowings under the Credit Facility will be pegged to either (1) the London Interbank Offered Rate (LIBOR) or (2) an alternate base rate, plus a specified margin depending on the Company's leverage ratio from time to time. The alternate base rate is the greater of the prime rate, the federal funds rate plus 0.5%, or an adjusted LIBOR rate plus 1%. The Company will also pay a commitment fee of between 62.5 to 100 basis points, depending on the Company's leverage ratio, payable quarterly, on the average daily unused amount of the Credit Facility. As of the date of this filing, the Company has not drawn any amounts under the Credit Facility.

Pursuant to our previously announced \$750 million share repurchase plan, we may, from time to time, seek to repurchase our equity in open market purchases privately-negotiated transactions, accelerated stock repurchase transactions or otherwise. This program does not obligate Endo to acquire any particular amount of common stock. Repurchase activity, if any, 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. As a result of a two-year extension approved by the Board of Directors in February 2010, the share repurchase plan is set to expire in April 2012. During the first half of 2010, pursuant to the existing share repurchase program, we purchased approximately 2.2 million shares of our common stock during the period ended June 30, 2010 totaling \$50.1 million. We did not purchase any shares of our common stock during the year ended December 31, 2009.

**Marketable Securities.** Beginning in 2008 and continuing through early 2010, the securities and credit markets have been experiencing severe volatility and disturbance, increasing risk with respect to certain of our financial assets. As a result of our auction-rate securities rights agreement with UBS (described in more detail below), we have been able to minimize our credit risk losses. On June 30, 2010, we were able to exercise our Rights with UBS and liquidated our remaining UBS auction rate security portfolio at par value. At June 30, 2010, \$17.7 million of our marketable securities portfolio was invested in auction-rate debt securities with ratings of AAA. During 2008, the Board of Directors approved an amended investment policy which seeks to preserve the value of capital, consistent with maximizing return on the Company's investment, while maintaining adequate liquidity and security. The amended investment policy specifically prohibits the investment in auction-rate securities as well as the investment in any security that is below investment grade. However, such restrictions were implemented on a prospective basis and did not impact the Company's ability to continue to hold the auction-rate securities it was invested in when the amended investment policy was adopted.

The underlying assets of our auction-rate securities are student loans. Student loans are insured by the Federal Family Education Loan Program, or FFELP.

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 June 30, 2010 and December 31, 2009 (in thousands):

	Underlying Credit Rating(1)					Total
	AAA	A	B2	Ba2	Baa3	
<b>As of June 30, 2010:</b>						
<i>Underlying security:</i>						
Student loans	\$ 17,695	\$	\$	\$	\$	\$ 17,695
<i>Total auction-rate securities included in long-term marketable securities</i>	\$ 17,695	\$	\$	\$	\$	\$ 17,695

	Underlying Credit Rating(1)					Total
	AAA	A	B2	Ba2	Baa3	
<b>As of December 31, 2009:</b>						
<i>Underlying security:</i>						

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

Student loans	\$ 130,861	\$ 51,781	\$ 9,934	\$ 7,201	\$ 7,557	\$ 207,334
<i>Total auction-rate securities included in long-term marketable securities</i>	\$ 130,861	\$ 51,781	\$ 9,934	\$ 7,201	\$ 7,557	\$ 207,334

(1) Our auction-rate securities maintain split ratings. For purposes of this table, securities are categorized according to their lowest rating.



**Table of Contents**

During the six months ended June 30, 2010, we sold \$230.3 million of auction-rate securities at par value. Given the uncertainty in the auction-rate securities market, the Company cannot predict when future auctions related to our existing auction-rate securities portfolio will be successful. However, 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. 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 UBS Offer) to the Company and other clients of UBS Securities LLC and UBS Financial Services Inc. (collectively, the UBS Entities), pursuant to which the Company received auction-rate securities rights (the Rights) 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 permitted the Company to require UBS to purchase the Eligible Auction-Rate Securities for a price equal to par value plus any accrued but unpaid dividends or interest beginning on June 30, 2010 and ending on July 2, 2012. As of June 30, 2010, we exercised the Rights and on July 1, 2010 received cash for our remaining UBS portfolio at par. Accordingly, as of June 30, 2010, our UBS auction-rate securities were reclassified into a current receivable. The remaining \$18.8 million of our auction-rate securities portfolio, at par-value, are not held in a UBS account and therefore were not subject to the UBS Offer

On November 10, 2008, the Company accepted the UBS Offer. As a result, the Company granted 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.

As of June 30, 2010, the yields on our long-term auction-rate securities ranged from 0.62% to 0.633%. 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 June 30, 2010, the weighted average yield for our long-term auction-rate securities was 0.626%. Total interest recognized on our auction-rate securities during the six-months ended June 30, 2010, and 2009 was \$0.6 million and \$1.5 million, respectively. The issuers have been making interest payments promptly.

At June 30, 2010, the fair value of our auction-rate securities, as determined by applying the above described discount rate adjustment technique, was approximately \$17.7 million, representing a six percent (6%), or \$1.1 million discount from their original purchase price or par value. This compares to approximately \$232.6 million, representing a 7%, or \$16.5 million discount from their original purchase price or par value at December 31, 2009. Had the Company chosen to apply a three or five year term with respect to the liquidity adjustment at June 30, 2010, the resultant discount to the original purchase price or par value would have been \$0.9 million and \$1.3 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.

**Working Capital.** Working capital increased to \$1,136 million as of June 30, 2010 from \$808.4 million as of December 31, 2009. The components of our working capital as of June 30, 2010 and December 31, 2009 are below:

	June 30, 2010	December 31, 2009
Total current assets	\$ 1,628,392	\$ 1,280,581
Less: Total current liabilities	(492,727)	(472,180)
<b>Working capital</b>	<b>\$ 1,135,665</b>	<b>\$ 808,401</b>

Working capital increased primarily due to our cash flows from operations as well as the sale of \$230.3 million in auction-rate securities, \$205.0 million which were non-current assets as of December 31, 2009. These amounts were offset slightly by \$50.1 million in share repurchases and \$6.2 million in capital expenditures during the six months ended June 30, 2010.

**Table of Contents**

The following table summarizes our statement of cash flows and liquidity as of June 30, 2010 and 2009 (dollars in thousands):

	2010	2009
Net cash flow provided by (used in):		
Operating activities	\$ 176,356	\$ 140,572
Investing activities	154,785	(424,758)
Financing activities	(47,332)	3,482
Net increase (decrease) in cash and cash equivalents	283,809	(280,704)
Cash and cash equivalents, beginning of period	708,462	775,693
Cash and cash equivalents, end of period	\$ 992,271	\$ 494,989
Current ratio	3.3:1	1.78:1
Days sales outstanding	47	48

**Net Cash Provided by Operating Activities.** Net cash provided by operating activities was \$176.4 million for the six months ended June 30, 2010 compared to \$140.6 million for the six months ended June 30, 2009. Significant components of our operating cash flows for the six months ended June 30, 2010 and 2009 are as follows:

	Six Months Ended June 30,	
	2010	2009
<b>Cash Flow Data-Operating Activities:</b>		
Net income	\$ 111,815	\$ 69,066
Depreciation and amortization	42,955	34,647
Stock-based compensation	10,391	7,844
Change in fair value of contingent consideration	1,120	25,930
Impairment of long-lived assets	13,000	
Loss on auction-rate securities rights	15,659	2,513
Unrealized loss on trading securities	(15,420)	(4,816)
Changes in assets and liabilities which (used) provided cash:	(15,844)	15,064
Other, net	12,680	(9,676)
Net cash provided by operating activities	\$ 176,356	\$ 140,572

The primary drivers of the increase in cash flow provided by operating activities when compared to the prior year were the increase in net income as a result increase in total revenues and the absence of the 2009 transaction fees and costs required to fund the Indevus acquisition.

**Net Cash Provided by/Used in Investing Activities.** Net cash provided by investing activities was \$154.8 million for the six months ended June 30, 2010 compared to net cash used in investing activities of \$424.8 million during the same period of 2009. The change is primarily related to the absence of the amounts utilized to fund the Indevus acquisition. During the six months ended June 30, 2010, the Company sold \$161.8 million in auction rate securities at par value, which was partially offset by \$6.2 million relating to the acquisition of property and equipment. During the six months ended June 30, 2009, the Company completed its acquisition of Indevus Pharmaceuticals, Inc. for initial upfront cash consideration, net of cash acquired of \$249.6 million. The Company also deposited \$175.0 million in cash with a paying agent pursuant to the terms of the Aveed™ Contingent Cash Consideration Agreement which was subsequently returned in full to the Company during the fourth quarter of 2009. In addition, the Company sold \$7.1 million of trading auction-rate securities at par value, which was offset by the purchases of property and equipment of \$6.0 million and an additional investment of \$1.3 million in Life Sciences Opportunities Fund (Institutional) II, L.P.

**Net Cash Used in/Provided by Financing Activities.** Net cash used in financing activities was \$47.3 million for the six months ended June 30, 2010 compared to net cash provided by financing activities of \$3.5 million during the six months ended June 30, 2009. The change to cash used in financing activities was primarily a result of the Company's share repurchase of \$50.1 million during the six months ended June 30, 2010. Additionally, during the first six months of 2010, the exercise of equity awards provided \$2.5 million of cash flows from financing activities

compared to \$6.5 million in the same period in the prior year.

**Research and Development.** Over the past few years, we have incurred significant expenditures related to conducting clinical studies to develop new pharmaceutical products and exploring the value of our existing products in treating disorders beyond those currently approved in their respective labels. We may seek to mitigate the risk in, and expense of, our research and development programs by entering into collaborative arrangements with third parties. However, we intend to retain a portion of the commercial rights to these programs and, as a result, we still expect to spend significant funds on our share of the cost of these programs, including the costs of research, preclinical development, clinical research and manufacturing.

---

## **Table of Contents**

We expect to continue to incur significant levels of research and development expenditures as we focus on the development and advancement of our product pipeline. There can be no assurance that results of any ongoing or future pre-clinical or clinical trials related to these projects will be successful, that additional trials will not be required, that any drug or product under development will receive FDA approval in a timely manner or at all, or that such drug or product could be successfully manufactured in accordance with U.S. current Good Manufacturing Practices, or successfully marketed in a timely manner, or at all, or that we will have sufficient funds to develop or commercialize any of our products.

**Manufacturing, Supply and Other Service Agreements.** We contract with various third party manufacturers and suppliers to provide us with raw materials used in our products and finished goods. Our most significant agreements are with Novartis Consumer Health, Inc., Novartis AG, Teikoku Seiyaku Co., Ltd., Mallinckrodt Inc., Sharp Corporation, and Ventiv Commercial Services, LLC. 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, it could have a material adverse effect on our business, financial condition, results of operations and cash flows. For a complete description of commitments under manufacturing, supply and other service agreements, see Note 10 of the Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

**License and Collaboration Agreements.** We have agreed to certain contingent payments in certain of our 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 Condensed Consolidated Balance Sheets. 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. For a complete description of our contingent payments involving our license and collaboration agreements, see Note 6, and Note 10 of the Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

**Acquisitions.** As part of our business strategy, we plan to consider and, as appropriate, make acquisitions of other businesses, products, product rights or technologies. Our cash reserves and other liquid assets may be inadequate to consummate such acquisitions and it may be necessary for us to issue stock or raise substantial additional funds in the future to complete future transactions. In addition, as a result of our acquisition efforts, we are likely to experience significant charges to earnings for merger and related expenses (whether or not our efforts are successful) that may include transaction costs, closure costs or costs of restructuring activities.

**Indevus Acquisition.** On February 23, 2009 (the Acquisition Date), the Company completed its initial tender offer (the Offer) for all outstanding shares of common stock of Indevus. Through purchases in subsequent offering periods, the exercise of a top-up option and a subsequent merger (the Merger), the Company completed its acquisition of Indevus on March 23, 2009, at which time Indevus became a wholly-owned subsidiary of the Company.

The Indevus Shares were purchased at a price of \$4.50 per Indevus Share, net to the seller in cash, plus contractual rights to receive up to an additional \$3.00 per Indevus Share in contingent cash consideration payments, pursuant to the terms of the Agreement and Plan of Merger, dated as of January 5, 2009. Accordingly, the Company paid approximately \$368 million in aggregate initial cash consideration for the Indevus Shares and entered into the Aveed™ Contingent Cash Consideration Agreement and the Octreotide Contingent Cash Consideration Agreement (each as defined in the Merger Agreement), providing for the payment of up to an additional \$3.00 per Indevus Share in contingent cash consideration payments, in accordance with the terms of the Offer.

The total cost to acquire all outstanding Indevus Shares pursuant to the Offer and the Merger could be up to an additional approximately \$267 million, if Endo is obligated to pay the maximum amounts under the Aveed™ Contingent Cash Consideration Agreement and the Octreotide Contingent Cash Consideration Agreement.

Indevus was a specialty pharmaceutical company engaged in the acquisition, development, and commercialization of products to treat conditions in urology, endocrinology and oncology. Following the completion of the Merger, Indevus was renamed Endo Pharmaceuticals Solutions Inc.

Approved products include the following:

Sanctura® (trospium chloride) was launched in August 2004. Sanctura® is indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency and urinary frequency. Sanctura® is currently promoted in the U.S. by Allergan Inc.

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

Sanctura XR<sup>®</sup> (trospium chloride extended release capsules) is a 60 mg, once-daily formulation of Sanctura<sup>®</sup>, the only approved quaternary amine compound clinically proven to effectively treat OAB symptoms in as early as one week, with a low incidence of side effects. Sanctura XR<sup>®</sup> is currently promoted in the U.S. by Allergan Inc. and by Madaus AG in Europe.

**Table of Contents**

Supprelin<sup>®</sup> LA (histrelin acetate) was launched in June 2007. Supprelin<sup>®</sup> LA is a 12-month hydrogel implant for treating central precocious puberty (CPP) or the early onset of puberty in children. Supprelin<sup>®</sup> LA utilizes our patented Hydron<sup>®</sup> Polymer Technology, designed to provide the continuous 12-month administration of a controlled dose of histrelin, a GnRH agonist.

Vantas<sup>®</sup> (histrelin) was launched in the U.S. in November 2004. Vantas<sup>®</sup> is a soft and flexible 12-month hydrogel implant currently marketed in the U.S. that provides histrelin, a luteinizing hormone releasing hormone (LHRH) agonist, for the palliative treatment of advanced prostate cancer. The product utilizes our patented Hydron<sup>®</sup> Polymer Technology that allows for a controlled delivery of medicine over a 12-month period. In November 2005, Vantas<sup>®</sup> was approved in Denmark, and in March 2006, received approval for marketing in Canada from Health Canada. Regulatory approval was granted in May 2007 in Germany, Ireland, Italy, Spain and the United Kingdom. As of August 2007, Vantas<sup>®</sup> was approved in Thailand, Singapore, and Malaysia and approval is pending in Taiwan, Korea, Hong Kong and China. Additionally, Vantas<sup>®</sup> received approval in Argentina in January 2007 and is currently being marketed in that country.

Delatestryl<sup>®</sup> (testosterone enanthate) is a marketed injectable testosterone preparation for the treatment of male hypogonadism. Delatestryl<sup>®</sup> provides testosterone enanthate, a derivative of the primary endogenous androgen testosterone, for intramuscular injection.

Hydron<sup>®</sup> Implant is a subcutaneous, retrievable, non-biodegradable, hydrogel reservoir drug delivery device. The Hydron<sup>®</sup> Implant is designed to provide sustained release of a broad spectrum of drugs continuously, at constant, predetermined rates. The Hydron<sup>®</sup> Implant is the only soft, flexible, reservoir-based drug delivery system available for parenteral administration. The hydrogel polymer compositions possess flexible, tissue-like characteristics providing excellent biocompatibility and patient comfort. This technology serves as the basis for two of our currently marketed products including Vantas<sup>®</sup> and Supprelin<sup>®</sup> LA.

Valstar<sup>®</sup> (valrubicin) is a sterile solution of valrubicin for intravesical instillation and is the only product approved by the FDA for therapy of bacillus Calmette-Guerin (BCG)-refractory carcinoma *in situ* (CIS) of the bladder. Valstar<sup>®</sup>, originally approved by the FDA in 1998, was withdrawn from the market due to a manufacturing problem involving impurity issues in the original formulation and was placed on the FDA Drug Shortages List. In April 2007, the Company submitted a supplemental New Drug Application (sNDA) to the FDA seeking approval to reintroduce Valstar<sup>®</sup> and in February 2009 obtained FDA approval of its sNDA for Valstar<sup>®</sup>. In September 2009, we launched Valstar<sup>®</sup> for the treatment of patients with BCG-refractory CIS of the bladder. We continue to work closely with the manufacturer to build quantities of the product to support our newly launched product.

As of June 30, 2010, primary development products included the following from the Indevus acquisition:

Aveed<sup>™</sup> (testosterone undecanoate) is expected to be the first long-acting injectable testosterone preparation available in the U.S. for the treatment of male hypogonadism in the growing market for testosterone replacement therapies. Aveed<sup>™</sup> had historically been referred to as Nebido<sup>®</sup>. On May 6, 2009, we received notice from the FDA that Nebido<sup>®</sup> was unacceptable as a proprietary name for testosterone undecanoate. In August 2009, we received approval from FDA to use the name Aveed<sup>™</sup>. On May 18, 2010, a new patent covering Aveed was issued by the U.S. Patent and Trademark Office. The patent's expiration date is March 14, 2027. The Company acquired U.S. rights to Aveed<sup>™</sup> from Schering AG, Germany, in July 2005. In June 2008, we received an approvable letter from the FDA indicating that the NDA may be approved if the Company is able to adequately respond to certain clinical deficiencies related to the product. In September 2008, agreement was reached with the FDA with regard to the additional data and risk management strategy. In March 2009, the FDA accepted for review the complete response submission to the new drug application for Aveed<sup>™</sup> intramuscular injection. On December 2, 2009, we received a complete response letter from the FDA regarding Aveed<sup>™</sup> in response to our March 2009 complete response submission. In the complete response letter, the FDA has requested information from Endo to address the agency's concerns regarding very rare but serious adverse events, including post-injection anaphylactic reaction and pulmonary oil microembolism. The letter also specified that the proposed Risk Evaluation and Mitigation Strategy (REMS) is not sufficient. In May 2010, the Company met with the FDA to discuss the existing clinical data provided to the FDA as well as the potential path-forward. The Company is currently evaluating how best to address the concerns of the FDA and intends to have future dialogue with the agency regarding our regulatory pathway. The outcome of future communications with the FDA could have a material impact on (1) management's assessment of the overall probability of approval, (2) the timing of such approval, (3) the targeted indication or patient population and (4) the likelihood of additional clinical trials.



**Table of Contents**

Octreotide implant, currently in Phase III clinical trials for the treatment of acromegaly, utilizes our patented Hydron® Polymer Technology to deliver six months of octreotide, a long-acting octapeptide that mimics the natural hormone somatostatin to block production of growth hormone (GH). The octreotide implant is also currently in Phase II trials for the treatment of carcinoid syndrome.

The table below provides estimates as to the timing associated with completion of development for the remaining primary development products.

Product	Indication	Development Phase	Anticipated Year of Completion
Aveed™	Hypogonadism (Testosterone Deficiency)	NDA filed	2011 2013
Octreotide implant	Acromegaly	Phase III	2012
Octreotide implant	Carcinoid Syndrome	Phase II	2013

The anticipated year of completion shown in the above table represents our current best estimate as to the year in which the Company anticipates product approval from the FDA. This estimate assumes successful and timely completion of all clinical trials in preparation of an NDA filing. However, these anticipated completion dates are subject to significant change, particularly for those products not yet in Phase III clinical development due to uncertainty of the number, size, and duration of the trials which may be required to complete development. Once an NDA is filed with the FDA, there can be no assurance that the FDA will approve the NDA to permit the Company to market and sell the relevant product.

Management believes the Company's acquisition of Indevus is particularly significant because it reflects our commitment to expand our business beyond pain management into complementary medical areas where we believe we can be innovative and competitive. The combined company markets products through four field sales forces and has the capability to develop innovative new therapies using a novel drug delivery technology.

The operating results of Indevus from February 23, 2009 are included in the accompanying condensed consolidated statements of operations. The consolidated balance sheet as of December 31, 2009 reflects the acquisition of Indevus, effective February 23, 2009, the date the Company obtained control of Indevus.

The acquisition date fair value of the total consideration transferred was \$540.9 million, which consisted of the following (in thousands):

	Fair Value of Consideration Transferred
Cash	\$ 368,034
Contingent consideration	172,860
<b>Total</b>	<b>\$ 540,894</b>



**Table of Contents**

The following table summarizes the fair values of the assets acquired and liabilities assumed at the Acquisition Date (in thousands):

	<b>February 23, 2009</b>
Cash and cash equivalents	\$ 117,675
Accounts receivable	14,591
Inventories	17,157
Prepaid and other current assets	8,322
Property, plant and equipment	8,856
Other intangible assets	532,900
Deferred tax assets	167,749
Other non-current assets	1,331
<b>Total identifiable assets</b>	<b>\$ 868,581</b>
Accounts payable	\$ (5,116)
Accrued expenses	(26,725)
Convertible notes	(72,512)
Non-recourse notes	(115,235)
Deferred tax liabilities	(210,647)
Other non-current liabilities	(18,907)
<b>Total liabilities assumed</b>	<b>(449,142)</b>
<b>Net identifiable assets acquired</b>	<b>\$ 419,439</b>
Goodwill	\$ 121,455
<b>Net assets acquired</b>	<b>\$ 540,894</b>

The above estimated fair values of assets acquired and liabilities assumed are based on the information that was available as of the Acquisition Date to estimate the fair value of assets acquired and liabilities assumed.

The valuation of the intangible assets acquired and related amortization periods are as follows:

	<b>Valuation (in millions)</b>	<b>Amortization Period (in years)</b>
<b>In Process Research &amp; Development:</b>		
Valstar <sup>®</sup> (1)	\$ 88.0	n/a
Aveed <sup>™</sup> (2)	100.0	n/a
Octreotide	31.0	n/a
Pagoclone(3)	21.0	n/a
Pro2000(4)	4.0	n/a
Other	11.9	n/a
<b>Total</b>	<b>\$ 255.9</b>	<b>n/a</b>
<b>License Rights:</b>		
Hydron <sup>®</sup> Polymer	\$ 22.0	10
Vantas <sup>®</sup>	36.0	10
Sanctura <sup>®</sup> Franchise	94.0	12

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

Supprelin® LA	124.0	10
Other	1.0	4
<b>Total</b>	<b>\$ 277.0</b>	<b>11</b>
Total other intangible assets	\$ 532.9	

- (1) The FDA approved the sNDA for Valstar® subsequent to the Acquisition Date. Therefore, Valstar® was initially classified as in-process research and development and subsequently transferred to License Rights upon obtaining FDA approval and is being amortized over a 15 year useful life.

**Table of Contents**

- (2) As a result of the FDA's complete response letter related to our filed NDA, we performed an impairment analysis during the fourth quarter ended December 31, 2009. The Company concluded there was a decline in the fair value of the indefinite-lived intangible. Accordingly, we recorded a \$65.0 million impairment charge.
- (3) In May 2010, Teva terminated the development and licensing arrangement with the Company upon the completion of the Phase IIb study. The Company concluded there was a decline in the fair value of the indefinite-lived intangible asset. Accordingly, we recorded a \$13.0 million impairment charge.
- (4) In December 2009, the Company's Phase III clinical trials for Pro2000 provided conclusive results that the drug was not effective. The Company concluded there was no further value or alternative future uses associated with this indefinite-lived asset. Accordingly, we recorded a \$4.0 million impairment charge to write-off the Pro2000 intangible asset in its entirety.

The fair value of the in-process research and development assets and License Rights assets, with the exception of the Hydron® Polymer Technology, were estimated using an income approach. Under this method, an intangible asset's fair value is equal to the present value of the incremental after-tax cash flows (excess earnings) attributable solely to the intangible asset over its remaining useful life. To calculate fair value, the Company used probability-weighted cash flows discounted at rates considered appropriate given the inherent risks associated with each type of asset. The Company believes that the level and timing of cash flows appropriately reflect market participant assumptions. Cash flows were generally assumed to extend either through or beyond the patent life of each product, depending on the circumstances particular to each product. The fair value of the Hydron® Polymer Technology was estimated using an income approach, specifically known as the relief from royalty method. The relief from royalty method is based on a hypothetical royalty stream that would be received if the Company were to out-license the technology. The Hydron® Polymer Technology is currently used in the following products: Vantas®, Supprelin® LA and octreotide. Thus, we derived the hypothetical royalty income from the projected revenues of those drugs. The fair value of the Hydron® Polymer Technology also includes an existing royalty payable by the Company to the certain third party partners based on the net sales derived from drugs that use the Hydron® Polymer Technology. Discount rates applied to the estimated cash flows for all intangible assets acquired ranged from 13% to 20%, depending on the current stage of development, the overall risk associated with the particular project or product and other market factors. We believe the discount rates used are consistent with those that a market participant would use.

The \$121.5 million of goodwill was assigned to our pharmaceutical products segment, which is our only reportable segment as of December 31, 2009. The goodwill recognized is attributable primarily to the potential additional applications for the Hydron® Polymer Technology, expected corporate synergies, the assembled workforce of Indevus and other factors. None of the goodwill is expected to be deductible for income tax purposes.

**Acquisition-Related Contingent Consideration**

As of June 30, 2010 and December 31, 2009, the fair value of the contingent consideration is \$59.6 million and \$58.5 million, respectively.

In the event that the Company receives an approval letter from the FDA with respect to the Aveed™ NDA on or before the third anniversary of the time at which we purchased the Indevus Shares in the Offer, then the Company will, subject to the terms described below, (i) pay an additional \$2.00 per Indevus Share to the former stockholders of Indevus, if such approval letter grants the right to market and sell Aveed™ immediately and provides labeling for Aveed™ that does not contain a boxed warning (Aveed™ With Label) or alternatively, (ii) pay an additional \$1.00 per Indevus Share, if such approval letter grants the right to market and sell Aveed™ immediately and provides labeling for Aveed™ that contains a boxed warning (Aveed™ Without Label). In the event that either an Aveed™ With Label approval or an Aveed™ Without Label approval has not been obtained prior to the third anniversary of the closing of the Offer, then the Company will not pay, and the former Indevus stockholders will not receive, any payments under the Aveed™ Contingent Cash Consideration Agreement.

Further, in the event that the Aveed™ Without Label approval is received and subsequently, Endo and its subsidiaries publicly report audited financial statements which reflect cumulative net sales of Aveed™ of at least \$125.0 million for four consecutive calendar quarters on or prior to the fifth anniversary of the date of the first commercial sale of Aveed™ (Aveed™ Net Sales Event), then the Company will, subject to the terms described below, pay an additional \$1.00 per Indevus Share to the former stockholders of Indevus. In the event that the Aveed™ Net Sales Event does not occur prior to the fifth anniversary of the date of the first commercial sale of Aveed™ then the Company will not pay, and former Indevus stockholders will not receive, any additional amounts under the Aveed™ Contingent Cash Consideration Agreement.

The range of the undiscounted amounts the Company could pay under the Aveed™ Contingent Cash Consideration Agreement is between \$0 and approximately \$175 million. The fair value of the contractual obligation to pay the Aveed™ contingent consideration recognized on the Acquisition Date was \$133.1 million. We determined the fair value of the obligation to pay the Aveed™ contingent consideration based on a probability-weighted income approach. This fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy. Under the Aveed™ Contingent Cash Consideration Agreement, there are three scenarios that could potentially lead to amounts being paid to the former stockholders of Indevus. These scenarios are (1) obtaining an Aveed™ With Label approval, (2) obtaining an Aveed™ Without Label approval and (3) achieving the \$125.0 million sales milestone on or prior to the fifth anniversary of the date of the first commercial sale of Aveed™ should the Aveed™ Without Label approval be obtained. The fourth

scenario is Aveed™ not receiving approval within three years of the closing of the Offer, which would result in no payment to the former stockholders of Indevus. Each scenario was assigned a probability based on the current regulatory status of Aveed™. The resultant probability-weighted cash flows were then discounted using a discount rate of U.S. Prime plus 300 basis points, which the Company believes is appropriate and is representative of a market participant assumption. In May 2010, the Company met with the FDA to discuss our path-forward as well as the understanding of the existing clinical data provided to the FDA. The Company expects to have further correspondence with the FDA in the second half of 2010, the results of which could materially impact the fair value of the Aveed™ contingent consideration liability due to the potential to pay in the range of \$0 to the maximum amount of \$175 million under the Aveed™ Contingent Cash Consideration Agreement. The fair value of the contractual obligation to pay the Aveed™ contingent consideration was \$7.0 million and \$7.5 million at June 30, 2010 and December 31, 2009, respectively. Future changes in any of our assumptions could result in further volatility to the estimated fair value of the acquisition-related contingent consideration. Such additional changes to fair value could materially impact our results of operations in future periods.

---

**Table of Contents**

Similarly, in the event that an approval letter from the FDA is received with respect to an octreotide NDA (such approval letter, the Octreotide Approval) on or before the fourth anniversary of the closing of the Offer, then the Company will, subject to the terms described below, pay an additional \$1.00 per Indevus Share to the former stockholders of Indevus (such payment, the Octreotide Contingent Cash Consideration Payment). In the event that an Octreotide Approval has not been obtained prior to the fourth anniversary of the closing of the Offer, then the Company will not pay, and the former Indevus stockholders shall not receive, the Octreotide Contingent Cash Consideration Payment.

The range of the undiscounted amounts the Company could pay under the Octreotide Contingent Cash Consideration Agreement is between \$0 and approximately \$91 million. The fair value of the octreotide contractual obligation to pay the contingent consideration recognized on the Acquisition Date was \$39.8 million. We determined the fair value of the contractual obligation to pay the Octreotide Contingent Consideration Payment based on a probability-weighted income approach. This fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy. Under the Octreotide Contingent Cash Consideration Agreement, the two scenarios that require consideration are (1) Octreotide Approval on or before the fourth anniversary of the closing of the Offer or (2) no Octreotide Approval on or before the fourth anniversary of the closing of the Offer. Each scenario was assigned a probability based on the current development stage of octreotide. The resultant probability-weighted cash flows were then discounted using a discount rate of U.S. Prime plus 300 basis points, which the Company believes is appropriate and is representative of a market participant assumption. The fair value of the contractual obligation to pay the octreotide contingent consideration was approximately \$44 million and \$43 million at June 30, 2010 and December 31, 2009, respectively. Future changes in any of our assumptions could result in further volatility to the estimated fair value of the acquisition-related contingent consideration. Such additional changes to fair value could materially impact our results of operations in future periods.

In addition to the potential contingent payments under the Aved<sup>TM</sup> Contingent Cash Consideration Agreement and the Octreotide Contingent Cash Consideration Agreement, the Company has assumed a pre-existing contingent consideration obligation relating to Indevus's acquisition of Valera Pharmaceuticals, Inc. (the Valera Contingent Consideration), which was consummated on April 18, 2007. The Valera Contingent Consideration entitles former Valera shareholders to receive additional Indevus Shares based on an agreed upon conversion factor if FDA approval of the octreotide implant for the treatment for acromegaly is achieved on or before April 18, 2012. Upon Endo's acquisition of Indevus, each Valera shareholder's right to receive additional Indevus Shares was converted into the right to receive \$4.50 per Indevus Share that such former Valera shareholder would have received plus contractual rights to receive up to an additional \$3.00 per Indevus Share that such former Valera shareholder would have received in contingent cash consideration payments under the Aved<sup>TM</sup> Contingent Cash Consideration Agreement and the Octreotide Contingent Cash Consideration Agreement. These amounts would only be payable to former Valera shareholders if there were Octreotide Approval. The range of the undiscounted amounts the Company could pay with respect to the Valera Contingent Consideration is between \$0 and approximately \$33 million.

The Company is accounting for the Valera Contingent Consideration in the same manner as if it had entered into that arrangement with respect to its acquisition of Indevus. Accordingly, the fair value of the Valera Contingent Consideration recognized on the Acquisition Date was \$13.7 million. Fair value was estimated based on a probability-weighted discounted cash flow model, or income approach. This fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy. The fair value of the Valera Contingent Consideration is estimated using the same assumptions used for the Aved<sup>TM</sup> Contingent Cash Consideration Agreement and Octreotide Contingent Cash Consideration Agreement, except that the probabilities associated with the Valera Contingent Consideration take into account the probability of obtaining the Octreotide Approval on or before the fourth anniversary of the closing of the Offer. This is due to the fact that the Valera Contingent Consideration will not be paid unless Octreotide for the treatment of acromegaly is approved prior to April 18, 2012. The fair value of the contractual obligation to pay the Valera contingent consideration was \$9 million and \$8 million at June 30, 2010 and December 31, 2009, respectively. Future changes in any of our assumptions could result in further volatility to the estimated fair value of the acquisition-related contingent consideration. Such additional changes to fair value could materially impact our results of operations in future periods.

As of June 30, 2010, the aggregate fair values of the three acquisition-related contingent consideration liabilities increased by approximately \$1.1 million from December 31, 2009 primarily reflecting changes of our present value assumptions associated with our valuation model. The increase in the liability was recorded as a loss and is included in the Acquisition-related items line item in the accompanying Condensed Consolidated Statements of Operations.

*Acquisition of HealthTronics, Inc.*

On July 2, 2010 (referred to as the HealthTronics Acquisition Date), Endo completed its initial tender offer (the Offer) for all outstanding shares of common stock, par value \$0.01 per share (the Shares), of HealthTronics, at a price of \$4.85 per Share. On the HealthTronics Acquisition Date, Endo acquired a controlling financial interest in HealthTronics. On July 12, 2010, Endo completed its acquisition of HealthTronics for approximately \$212.9 million in aggregate cash consideration for 100% of the outstanding shares. In addition, Endo paid \$9.9 million for the acceleration of the HealthTronics outstanding stock-based compensation. In July of 2010, Endo also paid \$40.2 million to retire HealthTronics debt that had been outstanding under its Senior Credit Facility. As a result of the acquisition, the HealthTronics Senior Credit Facility was terminated. HealthTronics is a leading provider of healthcare services and manufacturer of medical devices, primarily for the urology community. The HealthTronics business and applicable services include:

*Lithotripsy services.*

HealthTronics provides lithotripsy services, which is a medical procedure where a device called a lithotripter transmits high energy shockwaves through the body to break up kidney stones. Lithotripsy services are provided principally through limited partnerships and other entities that HealthTronics manages, which use lithotripters. In 2009, physicians who are affiliated with HealthTronics used its lithotripters to perform approximately 50,000 procedures in the U.S. While the physicians render medical services, HealthTronics does not. As the general partner of limited partnerships or the manager of other types of entities, HealthTronics also provide services relating to operating its lithotripters, including scheduling, staffing, training, quality assurance, regulatory compliance, and contracting with payors, hospitals, and surgery centers.

*Prostate treatment services.*

HealthTronics provides treatments for benign and cancerous conditions of the prostate. In treating benign prostate disease, HealthTronics deploys three technologies in a number of its partnerships above: (1) photo-selective vaporization of the prostate (PVP), (2) trans-urethral needle ablation (TUNA), and (3) trans-urethral microwave therapy (TUMT). All three technologies apply an energy source which reduces the size of the prostate gland. For treating prostate and other cancers, HealthTronics uses a procedure called cryosurgery, a process which uses lethal ice to destroy tissue such as tumors for therapeutic purposes. In April 2008, HealthTronics acquired Advanced Medical Partners, Inc., which significantly expanded its cryosurgery partnership base. In July 2009, HealthTronics acquired Endocare, Inc., which manufactures both the medical devices and related consumables utilized by its cryosurgery operations and also provides cryosurgery treatments. The prostate treatment services are provided principally by using equipment that HealthTronics leases from limited partnerships and other entities that HealthTronics manages. Benign prostate disease and cryosurgery cancer treatment services are billed in the same manner as its lithotripsy services under either retail or wholesale contracts. HealthTronics also provides services relating to operating the equipment, including scheduling, staffing, training, quality assurance, regulatory compliance, and contracting.

*Radiation therapy services.*

HealthTronics provides image guided radiation therapy (IGRT) technical services for cancer treatment centers. Its IGRT technical services may relate to providing the technical (non-physician) personnel to operate a physician practice group's IGRT equipment, leasing IGRT equipment to a physician practice group, providing services related to helping a physician practice group establish an IGRT treatment center, or managing an IGRT treatment center.

*Anatomical pathology services.*

HealthTronics provides anatomical pathology services primarily to the urology community. HealthTronics has one pathology lab located in Georgia, called Claripath Laboratories, which provides laboratory detection and diagnosis services to urologists throughout the United States. In addition, in July 2008, HealthTronics acquired Uropath LLC (Uropath), which managed pathology laboratories located at Uropath sites for physician practice groups located in Texas, Florida and Pennsylvania. Through Uropath, HealthTronics continues to provide administrative services to in-office pathology labs for practice groups and pathology services to physicians and practice groups with its lab equipment and personnel at the Uropath laboratory sites.

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

*Medical products manufacturing, sales and maintenance.*

HealthTronics manufactures and sells medical devices focused on minimally invasive technologies for tissue and tumor ablation through cryoablation, which is the use of lethal ice to destroy tissue, such as tumors, for therapeutic purposes. HealthTronics develops and manufactures these devices for the treatment of prostate and renal cancers and our proprietary technologies also have applications across a number of additional markets, including the ablation of tumors in the lung, liver metastases and palliative intervention (treatment of pain associated with metastases). HealthTronics manufactures the related spare parts and consumables for these devices. HealthTronics also sells and maintains lithotripters and related spare parts and consumables.

The acquisition of HealthTronics reflects Endo's desire to continue expanding our business beyond pain management into complementary medical areas where HealthTronics can be innovative and competitive. We believe this expansion will enable us to be a provider of multiple healthcare solutions and services that fill critical gaps in patient care.

We believe there are several ways Endo may enhance HealthTronics continued growth and success. For example, we believe there are cross-selling opportunities to grow the business organically by bringing HealthTronics anatomical pathology and cryoablation equipment services to urologists with whom Endo details today. Further, we anticipate being able to enhance the healthcare solutions we currently offer to urologists.

We have an exceptional field force of urology representatives to support the HealthTronics team with expanded reach and presence. We believe the unique channel that HealthTronics has established with urologists, combined with our ability to invest in innovative therapeutics and devices, our internal and virtual R&D capabilities and our current pharmaceutical focus in urology, is an extremely valuable combination for the physicians we serve and our business overall.

In addition, HealthTronics core expertise in medical devices manufacturing and urology procedure complements extremely well our expertise in researching clinical development and managed care contracting.

The Company will account for the HealthTronics acquisition as a business combination. The Company will include HealthTronics' results of operations in our consolidated financial statements beginning on July 2, 2010, the acquisition date. Under the applicable guidance, we are required to recognize the assets acquired, liabilities assumed and noncontrolling interests at their fair value as of the acquisition date. Given the date on which we acquired a controlling financial interest in HealthTronics, we are unable to provide the acquisition date fair value of assets acquired, liabilities assumed, noncontrolling interests or supplemental pro forma financial information as it is impracticable to do so at this time. Accordingly, we are also unable to provide a qualitative description of the factors that make up goodwill to be recognized, if any.

Transaction costs are recorded in Acquisition-related items within the condensed consolidated statements of operations. As of June 30, 2010, the Company recorded \$4.6 million in acquisition-related expenses associated with the HealthTronics acquisition, which consisted primarily of legal and accounting fees. In July 2010, Endo incurred investment bank fees for both Endo and HealthTronics totaling \$5.3 million. These investment bank fees will be recognized in the quarter ended September 30, 2010.

**Table of Contents**

**Convertible Notes due 2009.** As discussed in Note 12 to the Condensed Consolidated Financial Statements in Part I, Item 1 of this Report, as a result of our acquisition of Indevus Pharmaceuticals, Inc., the Company assumed Indevus' 6.25% Convertible Senior Notes due July 2009 (the Notes). Pursuant to the Indenture governing the Notes, within 30 days of the effective date of the Merger, holders of the Notes had the right to tender their Notes for the principal amount of the Notes plus any accrued and unpaid interest. During this 30-day period, approximately \$3.6 million in aggregate principal amount of Notes were tendered and the Company paid this amount in April 2009.

The Notes matured on July 15, 2009. Accordingly, in July 2009, the Company paid \$68.3 million in outstanding principal to satisfy the Notes in their entirety.

**Convertible Senior Subordinated Notes due 2015.** As discussed in Note 12 to the Condensed Consolidated Financial Statements in Part I, Item 1 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.

We received proceeds of approximately \$370.7 million from the issuance, net of the initial purchaser's discount and certain other costs of the offering. Interest is payable semi-annually in arrears on each April 15 and October 15 with the first interest payment being made on October 15, 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.

**Non-recourse Notes.** As discussed in Note 12 to the Condensed Consolidated Financial Statements in Part I, Item 1 of this Report, on August 26, 2008, on August 26, 2008, Indevus closed a private placement to institutional investors of \$105.0 million in aggregate principal amount of 16% non-convertible, non-recourse, secured promissory notes due 2024 (Non-recourse Notes). The Non-recourse Notes were issued by Ledgemont Royalty Sub LLC (Royalty Sub), which was a wholly-owned subsidiary of Indevus at the time of the note issuance and subsequently became a wholly-owned subsidiary of the Company upon our acquisition of Indevus. As of the Acquisition Date, the Company recorded these notes at their fair value of approximately \$115.2 million. The Company was amortizing these notes to their face value of \$105.0 million at maturity in 2024.

In connection with the issuance of the Non-recourse Notes, Indevus and Royalty Sub entered into a Purchase and Sale Agreement pursuant to which Indevus sold to Royalty Sub its rights to receive royalty payments from Allergan arising under the Allergan Agreement (as described in Note 6 of the Condensed Consolidated Financial Statements in Part I, Item 1 of this Report) for sales in the U.S. of Sanctura<sup>®</sup> and Sanctura XR<sup>®</sup>. To secure repayment of the Non-recourse Notes, Royalty Sub granted a continuing security interest to the trustee for the benefit of the noteholders in, among other things, the royalty payments made by Allergan under the Allergan Agreement discussed above, all of its rights under the Purchase and Sale Agreement and any accounts established in accordance with the Indenture (and all amounts from time to time credited to such accounts). The Non-recourse Notes have not been guaranteed by Indevus or the Company. Principal on the Non-recourse Notes is required to be paid in full by the final legal maturity date of November 5, 2024, unless repaid or redeemed earlier. In the event the Non-recourse Notes are repaid or redeemed prior to November 5, 2024, the noteholders will be entitled to a redemption premium (as described below). The interest rate applicable to the Non-recourse Notes is 16% per year and is payable quarterly in arrears and commenced on November 5, 2008.

Principal and interest on the Non-recourse Notes will be paid from the royalties from Allergan. Payments may also be made from the interest reserve account (described below) and certain other accounts established in accordance with the Indenture. In connection with the issuance of the Non-recourse Notes, a \$10.0 million interest reserve account was established to fund potential interest payment shortfalls. As of June 30, 2010, there was no remaining restricted cash on the Company's consolidated balance sheet. Royalty Sub will receive directly all royalties payable to the Company until the Non-recourse Notes have been repaid in full.

In August 2009, the Company commenced a cash tender offer for any and all outstanding Non-recourse notes. The purpose of the tender offer was to acquire any and all Notes to reduce our consolidated interest expense. The tender offer included an early tender deadline, whereby holders of the Non-recourse notes could early tender and receive the total early consideration of \$1,000 per \$1,000 principal amount of the Non-recourse notes. Holders who tendered their Non-recourse notes after such time and at or prior to the expiration of the tender offer period were eligible to receive the tender offer consideration of \$950 per \$1,000 principal amount of Non-recourse notes, which was the total early



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

consideration less the early tender payment. The tender offer expired on September 24, 2009, at 5:00 p.m., New York City time (the Expiration Time). As of the Expiration Time, \$48 million Non-recourse notes had been validly tendered and not withdrawn. The Company accepted for payment and purchased Non-recourse notes at a purchase price of \$1,000 per \$1,000 principal amount, for a total amount of approximately \$48 million (excluding accrued and unpaid interest up to, but not including, the payment date for the Notes, fees and other expenses in connection with the tender offer). The aggregate principal amount of Non-recourse notes purchased represents approximately 46% of the \$105 million aggregate principal amount of Non-recourse notes that were outstanding prior to the Expiration Time. Accordingly, the Company recorded a \$4 million gain on the extinguishment of debt, net of transaction costs. The gain was calculated as the difference between the aggregate amount paid to purchase the Non-recourse notes and their carrying amount.

**Table of Contents**

If the royalty payments from Allergan and amounts in the interest reserve account are insufficient to pay all of the interest and principal, if any, due on a payment date, the shortfall will accrue interest at the interest rate applicable to the Non-recourse Notes (16%) compounded quarterly. If any interest payment shortfall is not paid in full by the succeeding payment date, an Event of Default under the Indenture will occur, unless the Company contributes cash to a capital account of Royalty Sub in an amount sufficient to satisfy any such shortfall. Pursuant to the Indenture, the Company has the right, but not the obligation, to contribute cash in an amount equal to the shortfall to the capital account for distribution by the trustee to the noteholders. The Company has the right to satisfy such an interest payment shortfall no more than six times over the life of the Non-recourse Notes and no more than three consecutive times. In the event that the Company is no longer permitted to fund the capital account to satisfy an interest payment shortfall, and the Company does not redeem the Non-recourse Notes (as described below), an Event of Default will occur and the noteholders may accelerate the obligations of Royalty Sub under the Non-recourse Notes and exercise their remedies thereunder, including assuming all rights to future royalty payments from Allergan. Based on current expectations, it is reasonably possible that we may exceed the maximum number of times we can fund the capital account to satisfy an interest payment shortfall as early as November 2010.

The Non-recourse Notes will be subject to redemption at the option of Royalty Sub. If the applicable redemption of the Non-recourse Notes occurs on or prior to August 5, 2010, the redemption price will be equal to the greater of (x) the outstanding principal balance of the Non-recourse Notes being redeemed or (y) the present value, discounted at the rate on U.S. Treasury obligations with a comparable maturity to the remaining weighted average life of the Non-recourse Notes plus 1.00%, of the principal payment amounts and interest at the rate applicable to the Non-recourse Notes on the outstanding principal balance of the Non-recourse Notes. If the applicable redemption of the Non-recourse Notes occurs after August 5, 2010, the redemption price will be equal to the percentage of the outstanding principal balance of the Non-recourse Notes being redeemed specified below for the period in which the redemption occurs:

Payment Dates (between indicated dates)	Redemption Percentage
From November 5, 2010 to and including August 5, 2011	108%
From November 5, 2011 to and including August 5, 2012	104%
From November 5, 2012 and thereafter	100%

**Legal Proceedings.** 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. For a complete description of legal proceedings, see Note 10 of the Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

**Fluctuations.** Our quarterly results have fluctuated in the past, and may continue to fluctuate. These fluctuations may be to the timing of new product launches, purchasing patterns of our customers, market acceptance of our products, the impact of competitive products and pricing, impairment of intangible assets, separation benefits, business combination transaction costs, upfront, milestone and certain other payments made or accrued pursuant to licensing agreements and changes in the fair value of financial instruments and contingent assets and liabilities recorded as part of a business combination. 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 businesses, 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 stockholder value. Through execution of our business strategy we intend to focus on developing new products through both an internal and a virtual research and development organization with greater scientific and clinical capabilities; expanding the Company's product line by acquiring new products and technologies in existing therapeutic and complementary areas; increasing revenues and earnings through sales and marketing programs for our innovative product offerings and effectively using the Company's resources; and providing additional resources to support our generics business.

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

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



**Table of Contents**

*Off-Balance Sheet Arrangements.* We have no off-balance sheet arrangements as defined in Item 303(a) (4) of Regulation S-K.

***CRITICAL ACCOUNTING ESTIMATES***

For a complete discussion of the Company's critical accounting estimates, see *Critical Accounting Estimates* in Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2009, filed with the Securities and Exchange Commission on February 26, 2010.

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

For quantitative and qualitative disclosures about market risk, see Item 7A, *Quantitative and Qualitative Disclosures about Market Risk*, of our annual report on Form 10-K for the year ended December 31, 2009, filed with the Securities and Exchange Commission on February 26, 2010. Our exposures to market risk have not changed materially since December 31, 2009.

**Item 4. Controls and Procedures.**

***Evaluation of Disclosure Controls and Procedures***

The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as of June 30, 2010. Based on that evaluation, the Company's Chief Executive Officer and Principal Financial Officer concluded that the Company's disclosure controls and procedures were effective as of June 30, 2010.

***Changes in Internal Control over Financial Reporting***

There were no changes in the Company's internal control over financial reporting during the second quarter of 2010 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

---

**Table of Contents**

**PART II**

**OTHER INFORMATION**

**Item 1. Legal Proceedings.**

The disclosures under Note 10. Commitments and Contingencies-Legal Proceedings included in Part 1 Item I of this Report is incorporated in this Part II, Item 1 by reference.

**Item 1A. Risk Factors**

The risk factors listed below are included for the purpose of supplementing the risk factors disclosed in the section entitled "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2009 filed with the SEC on February 26, 2010. Other than these new risk factors, there have been no material changes to the risk factors disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2009.

*While healthcare reform may increase the number of patients who have insurance coverage for our products, its cost containment measures may adversely affect reimbursement for our products.*

On March 23, 2010, President Obama signed into law H.R. 3590, the Patient Protection and Affordable Care Act (PPACA). On March 30, 2010, the President signed H.R. 4872, the Healthcare and Education Reconciliation Act of 2010 (Reconciliation Act), which included a package of fixes to the PPACA as well as additional elements to reform healthcare in the United States.

The passage of the PPACA and the Reconciliation Act is expected to result in a transformation of the delivery and payment for healthcare services in the U.S. The combination of these measures will expand health insurance coverage to an estimated 32 million Americans. In addition, there are significant health insurance reforms that will improve patients' ability to obtain and maintain health insurance. Such measures include the elimination of lifetime caps, no rescission of policies, and no denial of coverage due to preexisting conditions. The expansion of healthcare insurance and these additional market reforms should result in greater access to our products.

However, a number of provisions contained in the healthcare reform package may adversely affect reimbursement for our products. In 2010, the new law will increase the minimum basic Medicaid rebate for brand name prescription drugs to 23.1%, increase the minimum basic Medicaid rebate for generic drugs to 13%, require pharmaceutical manufacturers to pay states rebates on prescription drugs dispensed to Medicaid managed care enrollees, increase the additional Medicaid rebates for "new formulations", and expand the entities eligible for 340B pricing and the revision of the AMP definition to remove physician class of trade. Further, the best price requirements with respect to Medicaid rebates have traditionally been a significant consideration with respect to the level of rebates in our Medicare and commercial contracting which could adversely impact our future results of operations.

*We may not be able to realize all of the anticipated benefits of our acquisition of HealthTronics.*

The success of our recent acquisition of HealthTronics will depend, in large part, on our ability to realize the anticipated benefits and expand our business from integrating the operations of Endo and HealthTronics. If we are not able to successfully integrate certain aspects of the two companies, the anticipated benefits of the acquisition may not be realized fully or at all or may take longer to realize than expected.

*Our consolidated financial statements may be impacted in future periods based on the accuracy of our valuation of the HealthTronics business.*

Accounting for our recent acquisition of HealthTronics will involve a complex and subjective valuation of the assets, liabilities and noncontrolling interests of HealthTronics, which will be recorded in the Company's consolidated financial statements pursuant to the general accounting rules applicable for business combinations. Differences between the inputs and assumptions used in the valuation and actual results could have a significant impact on our consolidated financial statements in future periods.

*If HealthTronics is not able to establish or maintain relationships with physicians and hospitals, its ability to successfully commercialize current or future service offerings will be materially harmed.*

HealthTronics is dependent on healthcare providers in two respects. First, if physicians and hospitals and other healthcare facilities, which HealthTronics refers to as Customers, determine that HealthTronics' services are not of sufficiently high quality or reliability, or if its Customers determine that its services are not cost effective, they will not utilize HealthTronics' services. In addition, any change in the rates of or conditions for reimbursement could substantially reduce (1) the number of procedures for which HealthTronics or its Customers can obtain reimbursement or (2) the amounts reimbursed to HealthTronics or its Customers for services provided by HealthTronics. If third-party payors reduce the amount of their payments to Customers, HealthTronics Customers may seek to reduce their payments to HealthTronics or seek an alternate supplier of services. Because unfavorable reimbursement policies have constricted and may continue to constrict the profit margins of the hospitals and other healthcare facilities which HealthTronics bills directly, HealthTronics may need to lower fees to retain existing customers and attract new ones. These reductions could have a significant adverse effect on revenues and financial results of HealthTronics by decreasing demand for its services or creating downward pricing pressure. Second, physicians generally own equity interests in the HealthTronics' partnerships. HealthTronics provides a variety of services to the partnerships and, in general, manages the partnerships' day-to-day affairs. HealthTronics operations could become disrupted, and financial results adversely affected, if these physician partners became dissatisfied with HealthTronics services, if these physician partners believe that its competitors or other persons provide higher quality services or a more cost-beneficial model or service, or if HealthTronics became involved in disputes with its partners.

## **Table of Contents**

***Third party payors could refuse to reimburse healthcare providers for use of HealthTronics current or future service offerings and products, which could negatively impact its results of operations.***

Third party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of medical procedures and treatments. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Lithotripsy treatments are reimbursed under various federal and state programs, including Medicare and Medicaid, as well as under private healthcare programs, primarily at fixed rates. Governmental programs are subject to statutory and regulatory changes, administrative rulings, interpretations of policy and governmental funding restrictions, and private programs are subject to policy changes and commercial considerations, all of which may have the effect of decreasing program payments, increasing costs or requiring HealthTronics to modify the way in which it operates the business. These changes could have a material adverse effect on its operations.

***New and proposed federal and state laws and regulatory initiatives relating to various initiatives in healthcare reform (such as improving privacy and the security of patient information and combating healthcare fraud) could require HealthTronics to expend substantial sums to appropriately respond to and comply with this broad variety of legislation (such as acquiring and implementing new information systems for privacy and security protection), which could negatively impact its financial results.***

Recent legislation and several regulatory initiatives at the state and federal levels address patient privacy concerns. New federal legislation extensively regulates the use and disclosure of individually identifiable health-related information and the security and standardization of electronically maintained or transmitted health-related information. We do not yet know the total financial or other impact of these regulations on the HealthTronics business. Continuing compliance with these regulations will likely require us to spend substantial sums, including, but not limited to, purchasing new computer systems, which could negatively impact financial results. Additionally, if HealthTronics fails to comply with the privacy regulations, it could suffer civil penalties of up to \$25,000 per calendar year per standard (with well over fifty standards with which to comply) and criminal penalties with fines of up to \$250,000 for willful and knowing violations. In addition, healthcare providers will continue to remain subject to any state laws that are more restrictive than the federal privacy regulations. These privacy laws vary by state and could impose additional penalties.

The provisions of HIPAA criminalize situations that previously were handled exclusively civilly through repayments of overpayments, offsets and fines by creating new federal healthcare fraud crimes. Further, as with the federal laws, general state criminal laws may be used to prosecute healthcare fraud and abuse. We believe that HealthTronics business arrangements and practices comply with existing healthcare fraud law. However, a violation could subject HealthTronics to penalties, fines and/or possible exclusion from Medicare or Medicaid. Such sanctions could significantly reduce its financial results.

Future healthcare legislation or other changes in the administration of or interpretation of existing legislation regarding governmental healthcare programs could have an adverse effect on the HealthTronics business and the results of its operations.

***HealthTronics may be required to modify its agreements, operations, marketing and expansion strategies in response to changes in the statutory and regulatory environment.***

HealthTronics regularly monitors developments in statutes and regulations relating to its business. However, HealthTronics may be required to modify its agreements, operations, marketing and expansion strategies from time to time in response to changes in the statutory and regulatory environment. HealthTronics plans to structure all of its agreements, operations, marketing and strategies in accordance with applicable law, although HealthTronics can provide no assurance that its arrangements will not be challenged successfully or that required changes may not have a material adverse effect on its business, financial condition, and results of operations.

**Table of Contents**

*HealthTronics acquisition strategy could fail or present unanticipated problems for its business in the future, which could adversely affect its ability to make acquisitions or realize anticipated benefits from those acquisitions.*

HealthTronics has followed an acquisition strategy that has resulted in rapid growth in its business. This acquisition strategy includes acquiring healthcare services businesses and is dependent on the continued availability of suitable acquisition candidates and its ability to finance and complete any particular acquisition successfully. Moreover, the U.S. Federal Trade Commission, or FTC, initiated an investigation in 1991 to determine whether the limited partnerships in which Lithotripsy, Inc., now one of the HealthTronics wholly-owned subsidiaries, was the general partner, posed an unreasonable threat to competition in the healthcare field. While the FTC closed its investigation and took no action, the FTC or another governmental authority charged with the enforcement of federal or state antitrust laws or a private litigant might, due to HealthTronics' size and market share, seek to (1) restrict HealthTronics' future growth by prohibiting or restricting the acquisition of additional lithotripsy operations or (2) require that HealthTronics divest certain of its lithotripsy operations. Furthermore, acquisitions such as the acquisition of Endocare in July 2009, involve a number of risks and challenges, including:

diversion of HealthTronics' management's attention;

the need to integrate acquired operations;

the risk that the expected cost savings and other synergies from the acquisition may not be fully realized, realized at all or take longer to realize than anticipated;

potential loss of key employees of the acquired companies; and

an increase in its expenses and working capital requirements.

Any of these factors could adversely affect HealthTronics' ability to achieve anticipated levels of cash flows from its acquired businesses or realize other anticipated benefits from those acquisitions.



**Table of Contents**

*HealthTronics could be adversely affected by special risks and requirements related to its medical products manufacturing business.*

HealthTronics is subject to various special risks and requirements associated with being a medical equipment manufacturer, which could have adverse effects. These include the following:

the need to comply with applicable federal Food and Drug Administration and foreign regulations relating to good manufacturing practices and medical device approval requirements, and with state licensing requirements;

the need for special non-governmental certifications and registrations regarding product safety, product quality and manufacturing procedures in order to market products in the European Union;

potential product liability claims for any defective goods that are distributed; and

the need for research and development expenditures to develop or enhance products and compete in the equipment markets.

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

None.

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

None.

**Item 4. Removed and Reserved.**

**Item 5. Other Information.**

- (a) On June 2, 2010, the Company amended its existing Sales Representative Agreement (the Second Amendment), with Ventiv Commercial Services, LLC, The Second Amendment is filed as Exhibit 10.32.4 to this Quarterly Report on Form 10-Q.
- (b) As previously disclosed in the Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 8, 2010, Endo entered into the Fifth Amendment to the Amended and Restated Strategic Alliance Agreement by and between Penwest Pharmaceuticals Co. and Endo Pharmaceuticals Inc., dated as of June 8, 2010. The Fifth Amendment is filed as Exhibit 10.18.4 to this Quarterly Report on Form 10-Q.

**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/* ALAN G. LEVIN  
Name: **Alan G. Levin**  
Title: **Executive Vice President, Chief Financial Officer**

**(Principal Financial Officer)**

*/s/* EDWARD J. SWEENEY  
Name: **Edward J. Sweeney**  
Title: **Vice President, Controller and Principal Accounting Officer (Principal Accounting Officer)**

Date: August 2, 2010

**Table of Contents**

**Exhibit Index**

**Exhibit**

<b>No.</b>	<b>Title</b>
10.18.4	Fifth Amendment to the Amended and Restated Strategic Alliance Agreement by and between Penwest Pharmaceuticals Co. and Endo Pharmaceuticals Inc., dated as of June 8, 2010.
10.19*	Master Services Agreement, dated as of May 18, 2010, by and between Endo Pharmaceuticals Inc. and UPS Supply Chain Solutions, Inc. (incorporated herein by reference to Exhibit 10.19 of the Current Report on Form 8-K dated May 20, 2010)
10.32.4*	Second Amendment to the Sales Representative Services Agreement, dated as of May 10, 2010 between Endo Pharmaceuticals, Inc. and Ventiv Commercial Services, LLC.
10.91	Agreement and Plan of Merger dated May 5, 2010, by and between Endo, HT Acquisition Corp., and HealthTronics, Inc. (incorporated herein by reference to Exhibit 2.1 of the Current Report on Form 8-K dated May 7, 2010)
10.92	Form of Stockholder Tender Agreement (incorporated herein by reference to Exhibit 99.1 of the Current Report on Form 8-K dated May 7, 2010)
21	Subsidiaries of the Registrant
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 Chief Financial Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of the President and Chief Executive Officer of Endo pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of the Chief Financial Officer of Endo pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following financial statements from the Endo Pharmaceuticals Holdings Inc. Quarterly Report on Form 10-Q for the quarter ended June 30, 2010, filed on August 2, 2010, formatted in Extensive Business Reporting Language (XBRL), tagged as blocks of text: (i) consolidated balance sheets, (ii) consolidated statements of operations, (iii) consolidated statements of cash flows, and (iv) the notes to the consolidated financial statements.

\* Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.