

ENDO PHARMACEUTICALS HOLDINGS INC  
Form 10-Q  
November 02, 2010

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

Washington, DC 20549

**FORM 10-Q**

(Mark One)

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

**FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 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 October 26, 2010: 115,590,411

ENDO PHARMACEUTICALS HOLDINGS INC.

INDEX

	Page
<u>Forward-Looking Statements</u>	i
<b>PART I. FINANCIAL INFORMATION</b>	
Item 1. <u>Financial Statements</u>	1
<u>Condensed Consolidated Balance Sheets (Unaudited) September 30, 2010 and December 31, 2009</u>	1
<u>Condensed Consolidated Statements of Operations (Unaudited) Three and Nine Months Ended September 30, 2010 and 2009</u>	2
<u>Condensed Consolidated Statements of Cash Flows (Unaudited) Nine Months Ended September 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>	51
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	76
Item 4. <u>Controls and Procedures</u>	77
<b>PART II. OTHER INFORMATION</b>	
Item 1. <u>Legal Proceedings</u>	78
Item 1A. <u>Risk Factors</u>	78
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	98
Item 3. <u>Defaults Upon Senior Securities</u>	98
Item 4. <u>Removed and Reserved</u>	98
Item 5. <u>Other Information</u>	98
Item 6. <u>Exhibits</u>	98
<b><u>SIGNATURES</u></b>	99

### 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 make these forward-looking statements on our current expectations and projections about the growth of our business, our financial performance and the development of our industry. Because these statements reflect our current views concerning future events, these forward-looking statements involve risks and uncertainties. Investors should note that many factors, as more fully described 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;

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 Penwest Pharmaceuticals Co. (Penwest) and realize all anticipated benefits of our acquisitions;

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.

## PART I. FINANCIAL INFORMATION

## Item 1. Financial Statements

## ENDO PHARMACEUTICALS HOLDINGS INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

(In thousands, except share and per share data)

	September 30, 2010	December 31, 2009
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 774,075	\$ 708,462
Restricted cash		1,515
Marketable securities	250	25,275
Accounts receivable, net	419,120	323,501
Inventories	94,792	84,893
Prepaid expenses and other current assets	19,044	17,081
Auction-rate securities rights, at fair value		15,659
Income taxes receivable		13,762
Deferred income taxes	103,416	90,433
Total current assets	1,410,697	1,280,581
MARKETABLE SECURITIES	22,182	211,792
PROPERTY AND EQUIPMENT, Net	74,985	47,529
GOODWILL	492,656	302,534
OTHER INTANGIBLES, Net	719,795	609,909
OTHER ASSETS	43,439	36,458
TOTAL ASSETS	\$ 2,763,754	\$ 2,488,803
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 157,781	\$ 176,076
Accrued expenses	375,409	286,606
Nonrecourse notes and other short-term debt	64,563	
Income taxes payable	4,017	9,498
Total current liabilities	601,770	472,180
DEFERRED INCOME TAXES	23,357	49,180
ACQUISITION-RELATED CONTINGENT CONSIDERATION	60,620	58,470
CONVERTIBLE SENIOR SUBORDINATED NOTES DUE 2015	274,078	260,279
OTHER LONG-TERM DEBT	3,641	62,255
OTHER LIABILITIES	111,093	89,028
COMMITMENTS AND CONTINGENCIES (NOTE 12)		
<b>STOCKHOLDERS EQUITY:</b>		
Preferred Stock, \$0.01 par value; 40,000,000 shares authorized; none issued		

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

Common Stock, \$0.01 par value; 350,000,000 shares authorized; 135,782,556 and 134,986,612 shares issued; 115,530,534 and 117,270,309 outstanding at September 30, 2010 and December 31, 2009, respectively

	1,358	1,350
Additional paid-in capital	841,568	817,467
Retained earnings	1,271,313	1,105,291
Accumulated other comprehensive loss	(1,943)	(1,881)
Treasury stock, 20,252,022 and 17,716,303 shares at September 30, 2010 and December 31, 2009, respectively	(483,790)	(424,816)
Total Endo Pharmaceuticals Holdings Inc. stockholders' equity	1,628,506	1,497,411
Noncontrolling interests	60,689	
Total stockholders' equity	1,689,195	1,497,411
 TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	 \$ 2,763,754	 \$ 2,488,803

See Notes to Condensed Consolidated Financial Statements.



## ENDO PHARMACEUTICALS HOLDINGS INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
<b>REVENUES:</b>				
Net sales	\$ 389,264	\$ 358,344	\$ 1,143,734	\$ 1,062,972
Device, service and other revenues	54,839	2,683	61,305	6,463
<b>TOTAL REVENUES</b>	<b>444,103</b>	<b>361,027</b>	<b>1,205,039</b>	<b>1,069,435</b>
<b>COSTS AND EXPENSES:</b>				
Cost of revenues	133,920	97,307	335,209	275,385
Selling, general and administrative	137,816	139,922	404,402	389,520
Research and development	31,445	59,690	105,269	136,612
Impairment of other intangible assets			13,000	
Acquisition-related items	24,990	(20,206)	31,315	41,222
<b>OPERATING INCOME</b>	<b>115,932</b>	<b>84,314</b>	<b>315,844</b>	<b>226,696</b>
INTEREST EXPENSE, NET	12,979	10,204	32,767	28,213
OTHER INCOME, NET	(59)	(1,194)	(479)	(1,604)
GAIN ON EXTINGUISHMENT OF DEBT, NET		(4,025)		(4,025)
<b>INCOME BEFORE INCOME TAX</b>	<b>103,012</b>	<b>79,329</b>	<b>283,556</b>	<b>204,112</b>
INCOME TAX	33,540	29,907	102,269	85,624
<b>CONSOLIDATED NET INCOME</b>	<b>\$ 69,472</b>	<b>\$ 49,422</b>	<b>\$ 181,287</b>	<b>\$ 118,488</b>
Less: Net income attributable to noncontrolling interests	(15,266)		(15,266)	
<b>NET INCOME ATTRIBUTABLE TO ENDO PHARMACEUTICALS HOLDINGS INC.</b>	<b>\$ 54,206</b>	<b>\$ 49,422</b>	<b>\$ 166,021</b>	<b>\$ 118,488</b>
<b>NET INCOME PER SHARE ATTRIBUTABLE TO ENDO PHARMACEUTICALS HOLDINGS INC.:</b>				
Basic	\$ 0.47	\$ 0.42	\$ 1.43	\$ 1.01
Diluted	\$ 0.46	\$ 0.42	\$ 1.42	\$ 1.01
<b>WEIGHTED AVERAGE SHARES ATTRIBUTABLE TO ENDO PHARMACEUTICALS HOLDINGS INC.:</b>				
Basic	115,469	117,207	116,292	117,062
Diluted	116,597	117,643	117,096	117,401

See Notes to Condensed Consolidated Financial Statements.

## ENDO PHARMACEUTICALS HOLDINGS INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

(In thousands)

	Nine Months Ended September 30,	
	2010	2009
<b>OPERATING ACTIVITIES:</b>		
Net income	\$ 181,287	\$ 118,488
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	69,859	56,482
Stock-based compensation	16,753	14,626
Amortization of debt issuance costs and premium / discount	17,484	14,282
Selling, general and administrative expenses paid in shares of common stock	166	189
Deferred income taxes	(13,543)	(30,836)
Loss (gain) on disposal of property and equipment	59	(156)
Change in the fair value of acquisition-related contingent consideration	2,150	3,240
Loss on auction-rate securities rights	15,659	7,641
Gain on trading securities	(15,420)	(9,646)
Gain on extinguishment of debt		(4,025)
Impairment of other indefinite-lived intangibles	13,000	
Changes in assets and liabilities which provided (used) cash:		
Accounts receivable	(51,623)	(45,731)
Inventories	2,895	1,030
Prepaid and other assets	7,314	16,047
Accounts payable	(21,058)	9,522
Accrued expenses	54,442	44,335
Other liabilities	(23)	8,533
Income taxes receivable/payable	3,583	14,994
<b>Net cash provided by operating activities</b>	<b>282,984</b>	<b>219,015</b>
<b>INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	(11,318)	(7,815)
Proceeds from sales of trading securities	230,867	8,975
Acquisitions, net of cash acquired	(333,349)	(250,359)
Funding of acquisition-related escrow		(175,000)
Other investments	(1,648)	(1,250)
<b>Net cash used in investing activities</b>	<b>(115,448)</b>	<b>(425,449)</b>
<b>FINANCING ACTIVITIES:</b>		
Capital lease obligations repayments	(285)	(182)
Tax benefits of stock awards	2,074	715
Exercise of Endo Pharmaceuticals Holdings Inc. Stock Options	8,728	7,431
Principal payment on HealthTronics senior credit facility	(40,000)	
Principal payments on 6.25% convertible notes due July 2009		(71,990)
Principal payments on non-recourse notes payable		(48,480)
Proceeds on other indebtedness, net	1,230	
Purchase of common stock	(58,974)	
Distributions to noncontrolling interests	(13,971)	
Buy-out of noncontrolling interests, net of contributions	(725)	

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

Net cash used in financing activities	(101,923)	(112,506)
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>65,613</b>	<b>(318,940)</b>
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	708,462	775,693
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$ 774,075</b>	<b>\$ 456,753</b>
<b>SUPPLEMENTAL INFORMATION:</b>		
Interest paid	\$ 14,313	\$ 15,087
Income taxes paid	\$ 109,675	\$ 92,279
<b>SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES</b>		
Accrual for purchases of property and equipment	\$ 2,085	\$ 1,419
	See Notes to Condensed Consolidated Financial Statements.	

**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 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 September 30, 2010 and the results of our operations and our cash flows for the periods presented. Operating results for the three-month and nine-month period ended September 30, 2010 are 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 nine-month period ended September 30, 2009's condensed consolidated results of operations include Endo Pharmaceuticals Solutions Inc.'s operating results from February 23, 2009 through September 30, 2009.

On July 2, 2010, the Company acquired HealthTronics Inc. (HealthTronics). Accordingly, as of July 2, 2010, all of the assets acquired and liabilities assumed were recorded at their respective fair values and our consolidated results of operations include HealthTronics' operating results from July 2, 2010 through September 30, 2010.

On September 20, 2010, Endo completed its tender offer for the outstanding shares of common stock of Penwest Pharmaceuticals Co. (Penwest), at which time Penwest became a majority-owned subsidiary of the Company. Currently, Endo owns approximately 90.56% of Penwest's common stock. Accordingly, as of September 20, 2010, all of the assets acquired and liabilities assumed were recorded at their respective fair values and our consolidated results of operations include Penwest's operating results from September 20, 2010 through September 30, 2010.

**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.

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

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

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 15 for further details.

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)

## FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

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.

The following table presents the carrying amounts and estimated fair values of our other financial instruments at September 30, 2010 and December 31, 2009 (in thousands):

	September 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
Corporate commercial paper	250	250		
<b>Long-term assets:</b>				
Auction-rate securities	17,505	17,505	207,334	207,334
Equity securities	4,677	4,677	4,458	4,458
Equity and cost method investments	31,759	N/A	30,236	N/A
	\$ 54,191		\$ 282,962	
<b>Current liabilities:</b>				
Non-recourse notes payable	\$ (61,974)	\$ (61,021)	\$	\$
Other short-term debt	(2,589)	(2,589)		
<b>Long-term liabilities:</b>				
Acquisition-related contingent consideration	(60,620)	(60,620)	(58,470)	(58,470)
1.75% Convertible Senior Subordinated Notes Due 2015	(274,078)	(312,191)	(260,279)	(277,651)
Minimum Voltaren® Gel royalties due to Novartis	(52,684)	(52,684)	(49,996)	(49,996)
Other long-term debt	(3,641)	(3,641)	(62,255)	(61,896)
	\$ (455,586)	\$ (492,746)	\$ (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

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

payable to the former shareholders under contingent cash consideration agreements relating to the development of Aveed™ 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 34% 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 15 for further details). The fair value of our Non-recourse Notes were determined using an income approach (present value technique) at September 30, 2010, consistent with the methodology used as of February 23, 2009.

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)

## FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

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 September 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 September 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 \$21.6 million cost method investment.

As of September 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, 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.

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

	Fair Value Measurements at Reporting Date Using			Total
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
<b>September 30, 2010</b>				
<b>Assets:</b>				
Money market funds	\$ 314,019	\$	\$	\$ 314,019
Auction-rate securities			17,505	17,505
Equity securities	4,677			4,677
Corporate commercial paper		250		250
Total	\$ 318,696	\$ 250	\$ 17,505	\$ 336,451



<b>Liabilities:</b>				
Acquisition-related contingent consideration long-term			(60,620)	(60,620)
<b>Total</b>	\$	\$	\$ (60,620)	\$ (60,620)

	Fair Value Measurements at Reporting Date Using				Total
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)		
<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>	\$ 309,505	\$	\$ 222,993		\$ 532,498
<b>Liabilities:</b>					
Acquisition-related contingent consideration long-term			(58,470)		\$ (58,470)
<b>Total</b>	\$	\$	\$ (58,470)		\$ (58,470)

#### *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.

**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010**

At September 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. On June 30, 2010, we exercised the Rights and on July 1, 2010 received cash totaling \$68.6 million for our remaining UBS portfolio at par. The remaining auction-rate securities portfolio, which have a par value of \$18.8 million, were 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.

---

**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 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***

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 \$15.4 million of income during the nine months ended September 30, 2010. As we had exercised our Rights as of June 30, 2010 and had no remaining Eligible Auction-Rate securities, there was no income statement impact for the three months ended September 30, 2010. During the three and nine months ended September 30, 2009, we recorded additional income of \$4.8 million and \$9.6 million, respectively, in Other income, net in the Condensed Consolidated Statements of Operations.

As a result of our fair value election for our auction-rate securities rights, the fair value of the auction-rate securities rights were re-measured each reporting period with the corresponding changes in fair value reported in earnings. Since the auction-rate securities rights were freestanding financial instruments, they did 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 acted as an economic hedge against further fair value changes in the Eligible Auction-Rate Securities. On June 30, 2010, our auction-rate securities rights were exercised. Accordingly, the related asset was written off with corresponding charges to Other income, net in the Condensed Consolidated Statement of Operations of \$15.7 million for the nine months ended September 30, 2010.

***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 life used for each remaining security, representing time to maturity is 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 September 30, 2010 was 4.54% 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 September 30, 2010, the base

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

rate for our securities applied to our securities was 197 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.

---

**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010**

At September 30, 2010, the fair value of our auction-rate securities, as determined by applying the above described discount rate adjustment technique, was approximately \$17.5 million, representing a seven percent (7%), or \$1.3 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 September 30, 2010 and December 31, 2009 were reduced by approximately \$1.3 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.

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 \$0.2 million loss and a \$0.6 million gain in shareholders' equity in accumulated other comprehensive loss as of September 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 September 30, 2010 and 2009 (in thousands):

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

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)		
	Auction-rate Securities	Auction-rate Securities Rights	Total
Balance at July 1, 2010	\$ 17,695	\$	\$ 17,695
Securities sold or redeemed			
Securities purchased or acquired			
Transfers in and/or (out) of Level 3			
Changes in fair value recorded in earnings			
Unrealized loss included in other comprehensive loss	(190)		(190)
Balance at September 30, 2010	\$ 17,505	\$	\$ 17,505

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)

## FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3) Acquisition-related Contingent Consideration	
<b>Liabilities:</b>		
Balance at July 1, 2010	\$	(59,590)
Amounts acquired or issued		
Transfers in and/or (out) of Level 3		
Changes in fair value recorded in earnings		(1,030)
Balance at September 30, 2010	\$	(60,620)

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)		
	Auction-rate Securities	Auction-rate Securities Rights	Total
Balance at July 1, 2009	\$ 237,770	\$ 24,808	\$ 262,578
Securities sold or redeemed	(1,075)		(1,075)
Securities purchased or acquired			
Transfers in and/or (out) of Level 3	(400)		(400)
Changes in fair value recorded in earnings	4,830	(5,128)	(298)
Unrealized gain included in other comprehensive loss	150		150
Balance at September 30, 2009	\$ 241,275	\$ 19,680	\$ 260,955

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)

## FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3) Acquisition-related Contingent Consideration	
<b>Liabilities:</b>		
Balance at July 1, 2009	\$	(212,490)
Amounts acquired or issued		
Transfers in and/or (out) of Level 3		
Changes in fair value recorded in earnings		22,690
Balance at September 30, 2009	\$	(189,800)

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 nine months ended September 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 loss included in other comprehensive loss	(199)		(199)
Balance at September 30, 2010	\$ 17,505	\$	\$ 17,505

	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		(2,150)
Balance at September 30, 2010	\$	(60,620)



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

	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	(2,475)		(2,475)
Securities purchased or acquired			
Transfers in and/or (out) of Level 3	(400)		(400)
Changes in fair value recorded in earnings	9,646	(7,641)	2,005
Unrealized gain included in other comprehensive loss	499		499
Balance at September 30, 2009	\$ 241,275	\$ 19,680	\$ 260,955

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)

## FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

	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	(186,560)
Transfers in and/or (out) of Level 3	
Changes in fair value recorded in earnings	(3,240)
Balance at September 30, 2009	\$ (189,800)

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

	Amortized Cost	Available-for-sale Gross Unrealized Gains	Gross Unrealized (Losses)	Fair Value
<b>September 30, 2010:</b>				
Money market funds	\$ 314,019	\$	\$	\$ 314,019
<i>Total included in cash and cash equivalents</i>	314,019			314,019
Corporate commercial paper	250			250
<i>Total other short-term available-for-sale securities</i>	250			250
Auction-rate securities	18,800		(1,295)	17,505
Equity securities	5,564		(887)	4,677
<i>Long-term available-for-sale securities</i>	24,364		(2,182)	22,182
<i>Total available-for-sale securities</i>	\$ 338,633	\$	\$ (2,182)	\$ 336,451

	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

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

<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

During the nine-month period ended September 30, 2010, we sold \$230.3 million of auction-rate securities at par value. During the three-month period ended September 30, 2010, there were no sales of auction-rate securities. 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 September 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.

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)

## FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

The following table sets forth the fair value of our long-term auction-rate securities by type of security and underlying credit rating as of September 30, 2010 and December 31, 2009 (in thousands):

	Underlying Credit Rating(1)					Total
	AAA	A	B2	Ba2	Baa3	
<b>As of September 30, 2010:</b>						
<i>Underlying security:</i>						
Student loans	\$ 17,505	\$	\$	\$	\$	\$ 17,505
<i>Total auction-rate securities included in long-term marketable securities</i>	\$ 17,505	\$	\$	\$	\$	\$ 17,505
	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 September 30, 2010, the yields on our long-term auction-rate securities ranged from 0.50% to 0.60%. These yields represent the predetermined maximum reset rates that occur upon auction failures according to the specific terms within each security's prospectus. As of September 30, 2010, the weighted average yield for our long-term auction-rate securities was 0.55%. Total interest recognized on our auction-rate securities during the nine-months ended September 30, 2010 and 2009 was \$0.6 million and \$2.0 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.

	September 30, 2010		December 31, 2009	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
<b>Available-for-sale debt securities:</b>				
Due in less than 1 year	\$ 250	\$ 250	\$	\$
Due in 1 to 5 years				
Due in 5 to 10 years				
Due after 10 years	18,800	17,505	18,800	17,704

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

Equity securities	5,564	4,677	5,564	4,458
<b>Total</b>	<b>\$ 24,614</b>	<b>\$ 22,432</b>	<b>\$ 24,364</b>	<b>\$ 22,162</b>

**NOTE 4. INVENTORIES**

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

	<b>September 30, 2010</b>	<b>December 31, 2009</b>
Raw materials	\$ 19,912	\$ 8,510
Work-in-process	15,010	25,799
Finished goods	59,870	50,584
<b>Total</b>	<b>\$ 94,792</b>	<b>\$ 84,893</b>

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)

## FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 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):

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

As of September 30, 2010 and December 31, 2009, the fair value of the contingent consideration is \$60.6 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> 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

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

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.

**ENDO PHARMACEUTICALS HOLDINGS INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)****FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 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, 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 \$7.3 million and \$7.5 million at September 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 \$44.5 million and \$42.5 million at September 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 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



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

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.

**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010**

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 \$8.8 million and \$8.5 million at September 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 September 30, 2010, the aggregate fair values of the three acquisition-related contingent consideration liabilities increased by approximately \$2.2 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.

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)

## FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

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:

	<b>Valuation (in millions)</b>	<b>Amortization Period (in years)</b>
<b>In Process Research &amp; Development:</b>		
Valstar <sup>®(1)</sup>	\$ 88.0	n/a
Aveed <sup>™ (2)</sup>	100.0	n/a
Octreotide	31.0	n/a
Pagoclone <sup>(3)</sup>	21.0	n/a

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

Pro2000 <sup>(4)</sup>	4.0	n/a
Other	11.9	n/a
Total	\$ 255.9	n/a
License Rights:		
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.

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

- (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.

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)

## FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

- (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 \$0.5 million in expense and \$20.2 million of income for Indevus acquisition-related items for the three-month period ended September 30, 2010 and September 30, 2009, respectively. The Company recognized \$2.0 million and \$41.2 million of Indevus acquisition-related costs that were expensed for the nine-month periods ended September 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):

	Acquisition-related Costs	
	Three Months Ended September 30, 2010	Three Months Ended September 30, 2009
Investment bank fees, includes Endo and Indevus	\$	\$
Legal, separation and other costs	(574)	2,484
Changes in fair value of acquisition-related contingent consideration	1,030	(22,690)
Total	\$ 456	\$ (20,206)

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

	Acquisition-related Costs	
	Nine Months	Nine Months
	Ended September 30, 2010	Ended September 30, 2009
Investment bank fees, includes Endo and Indevus	\$	\$ 13,030
Legal, separation and other costs	(122)	24,952
Changes in fair value of acquisition-related contingent consideration	2,150	3,240
Total	\$ 2,028	\$ 41,222

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)

## FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

The amounts of revenue and net loss of Indevus included in the Company's Condensed Consolidated Statements of Operations for the three months ended September 30, 2009 and from the Acquisition date to the period ending September 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 September 30, 2009	Revenue and Losses included in the Condensed Consolidated Statements of Operations from February 23, 2009 to September 30, 2009
Revenue	\$ 18,194	\$ 42,628
Net loss	\$ (18,233)	\$ (53,625)
Basic and diluted loss per share	\$ (0.16)	\$ (0.46)

The following supplemental pro forma information presents the financial results as if the acquisition of Indevus had occurred January 1, 2009 for the nine months ended September 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.

	Nine Months ended September 30, 2009
<b>Pro forma consolidated results (in thousands, except per share data):</b>	
Revenue	\$ 1,079,735
Net income	\$ 95,488
Basic earnings per share	\$ 0.82
Diluted earnings per share	\$ 0.81

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.

**HealthTronics, Inc.**

On July 2, 2010 (the HealthTronics Acquisition Date), the Company completed its initial tender offer for all outstanding shares of common stock of HealthTronics. On July 12, 2010, Endo completed its acquisition of HealthTronics for approximately \$214.8 million in aggregate cash consideration for 100% of the outstanding shares, at which time HealthTronics became a wholly-owned subsidiary of the Company. The HealthTronics Shares were purchased at a price of \$4.85 per HealthTronics Share. In addition, Endo paid \$40 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 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.

---

**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010**

*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, which provides laboratory detection and diagnosis services to urologists throughout the United States. In addition, in July 2008, HealthTronics acquired Uropath LLC, now referred to as HealthTronics Laboratory Solutions, which managed pathology laboratories located at Uropath sites for physician practice groups located in Texas, Florida and Pennsylvania. Through HealthTronics Laboratory Solutions, 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 HealthTronics Laboratory Solutions 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.

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.

The operating results of HealthTronics from July 2, 2010 are included in the accompanying condensed consolidated statements of operations. The consolidated balance sheet as of September 30, 2010 reflects the acquisition of HealthTronics, effective July 2, 2010, the date the Company obtained control of HealthTronics.



## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)

## FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

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

	<b>July 2, 2010</b>
Cash and cash equivalents	\$ 6,769
Accounts receivable	33,111
Other receivables	1,006
Inventories	12,399
Prepaid expenses and other current assets	5,204
Deferred income taxes	43,737
Property and equipment	30,687
Other intangible assets	65,866
Other assets	5,210
 Total identifiable assets	 \$ 203,989
 Accounts payable	 \$ (3,084)
Accrued expenses	(11,551)
Deferred income taxes	(20,377)
Long-term debt	(44,751)
Other liabilities	(1,434)
 Total liabilities assumed	 \$ (81,197)
 Net identifiable assets acquired	 \$ 122,792
Noncontrolling interests	\$ (60,119)
Goodwill	\$ 152,170
 Net assets acquired	 \$ 214,843

The above estimated fair values of assets acquired and liabilities assumed are provisional and are based on the information that was available as of the HealthTronics Acquisition Date to estimate the fair value of assets acquired and liabilities assumed. The Company believes that information provides a reasonable basis for estimating the fair values but the Company is waiting for additional information necessary to finalize those amounts. Thus, the provisional measurements of fair value reflected are subject to change. Such changes could be significant. The Company expects to finalize the valuation and complete the purchase price allocation as soon as practicable but no later than one-year from the HealthTronics Acquisition Date.

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

Valuation (in millions)	Amortization Period (in years)
-------------------------------	--------------------------------------

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

Endocare Developed Technology	\$ 46.3	10
HealthTronics Tradename	14.6	15
Service Contract	5.0	15
Total	\$ 65.9	n/a

The fair value of the developed technology assets 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 assumed to extend through the patent life of the purchased technology. The fair value of the HealthTronics Tradename 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 Tradename. Thus, we derived the hypothetical royalty income from the projected revenues of HealthTronics' services.

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

HealthTronics has investments in partnerships and limited liability companies (LLCs) where we, as the general partner or managing member, exercise effective control. Accordingly, we consolidate various entities where we do not own 100% of the entity in accordance with the accounting consolidation principles. As a result, we are required to fair value the noncontrolling interests as part of our purchase price allocation. To calculate fair value, the Company used historical transactions which represented level 2 data points within the fair value hierarchy to calculate applicable multiples of each respective noncontrolling interest in the partnerships and LLCs.

The \$152.2 million of goodwill was assigned to our Devices and Services segment, which was established in July 2010 pursuant to our acquisition of HealthTronics. The goodwill recognized is attributable primarily to strategic and synergistic opportunities across the HealthTronics network of urology partnerships, expected corporate synergies, the assembled workforce of HealthTronics and other factors. Approximately \$33.6 million of goodwill is expected to be deductible for income tax purposes.

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)

## FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

The deferred tax assets of \$43.7 million are related primarily to federal net operating loss and credit carryforwards of HealthTronics and its subsidiaries. The deferred tax liabilities of \$20.4 million are related primarily to the difference between the book basis and tax basis of identifiable intangible assets.

The Company recognized \$15.3 million and \$20.0 million of HealthTronics acquisition-related costs that were expensed for the three and nine month periods ended September 30, 2010, 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):

	Acquisition-related Costs	
	Three Months	Nine Months
	Ended September 30, 2010	Ended September 30, 2010
Investment bank fees, includes Endo and HealthTronics	\$ 5,230	\$ 5,230
Acceleration of outstanding HealthTronics stock-based compensation	7,924	7,924
Legal, separation and other costs	2,113	6,866
Total	\$ 15,267	\$ 20,020

The amounts of revenue and net loss of HealthTronics included in the Company's Condensed Consolidated Statements of Operations from the Acquisition date to September 30, 2010 are as follows (in thousands, except per share data):

	Revenue and Losses included in the Condensed Consolidated Statements of Operations from July 2, 2010 to September 30, 2010
Revenue	\$ 51,686
Net loss attributable to Endo Pharmaceuticals Holdings Inc.	\$ (460)
Basic and diluted loss per share	\$ (0.00)

The following supplemental pro forma information presents the financial results as if the acquisition of HealthTronics had occurred on January 1, 2010 and January 1, 2009 for the nine months ended September 30, 2010 and the three and nine months ended September 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, 2010 or January 1, 2009, nor are they indicative of any future results.

Nine Months  
Ended  
September 30, 2010

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

**Pro forma consolidated results (in thousands, except per share data):**

Revenue	\$	1,303,728
Net income attributable to Endo Pharmaceuticals Holdings Inc	\$	171,180
Basic earnings per share	\$	1.47
Diluted earnings per share	\$	1.46

	<b>Three Months Ended September 30, 2009</b>	<b>Nine Months Ended September 30, 2009</b>
<b>Pro forma consolidated results (in thousands, except per share data):</b>		
Revenue	\$ 408,310	\$ 1,204,486
Net income attributable to Endo Pharmaceuticals Holdings Inc	\$ 48,445	\$ 117,354
Basic earnings per share	\$ 0.41	\$ 1.00
Diluted earnings per share	\$ 0.41	\$ 1.00

These amounts have been calculated after applying the Company's accounting policies and adjusting the results of HealthTronics to reflect the additional depreciation and amortization that would have been charged assuming the fair value adjustments primarily to property, plant and equipment, and intangible assets, had been applied on January 1, 2010 and 2009, as applicable, together with the consequential tax effects.



## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)

## FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

*Penwest Pharmaceuticals Co.*

On September 20, 2010 (the Penwest Acquisition Date), the Company completed its tender offer for the outstanding shares of common stock of Penwest, at which time Penwest became a majority-owned subsidiary of the Company. The Penwest shares were purchased at a price of \$5.00 per share. Endo paid approximately \$147.6 million in aggregate cash consideration for the outstanding shares. Currently, Endo owns approximately 90.56% of Penwest's common stock. We anticipate closing the acquisition following the Penwest Shareholders meeting on November 4, 2010. Due to our obligation to close at a price of \$5 per share, we have reflected the remaining payment of approximately \$21 million to existing holders of outstanding Penwest shares and share equivalents within Accrued expenses on the condensed consolidated balance sheet as of September 30, 2010.

This transaction contributes to Endo's core Pain Management franchise and permits us to maximize the value of our Oxymorphone franchise.

The operating results of Penwest from September 20, 2010 are included in the accompanying condensed consolidated statements of operations. The consolidated balance sheet as of September 30, 2010 reflects the acquisition of Penwest, effective September 20, 2010, the date the Company obtained control of Penwest.

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

	September 20, 2010
Cash and cash equivalents	\$ 22,343
Marketable securities	800
Accounts receivable	10,885
Other receivables	132
Inventories	396
Prepaid expenses and other current assets	716
Deferred income taxes	27,175
Property and equipment	1,115
Other intangible assets	111,200
Other assets	2,104
<b>Total identifiable assets</b>	<b>\$ 176,866</b>
Accounts payable	\$ (229)
Income taxes payable	(347)
Penwest shareholder liability	(20,815)
Accrued expenses	(1,455)
Deferred income taxes	(39,951)
Other liabilities	(4,403)
<b>Total liabilities assumed</b>	<b>\$ (67,200)</b>
<b>Net identifiable assets acquired</b>	<b>\$ 109,666</b>
Goodwill	\$ 37,952

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

Net assets acquired	\$ 147,618
---------------------	------------

The above estimated fair values of assets acquired and liabilities assumed are provisional and are based on the information that was available as of the Penwest Acquisition Date to estimate the fair value of assets acquired and liabilities assumed. The Company believes that information provides a reasonable basis for estimating the fair values but the Company is waiting for additional information necessary to finalize those amounts. Thus, the provisional measurements of fair value reflected are subject to change. Such changes could be significant. The Company expects to finalize the valuation and complete the purchase price allocation as soon as practicable but no later than one-year from the Penwest Acquisition Date.

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)

## FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

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

	Valuation (in millions)	Amortization Period (in years)
<b>In Process Research &amp; Development:</b>		
Otsuka	\$ 5.5	n/a
A0001	1.6	n/a
Total	\$ 7.1	n/a
<b>Developed Technology:</b>		
Opana <sup>®</sup> ER	\$ 104.1	10
Total	\$ 104.1	n/a
Total other intangibles	\$ 111.2	n/a

The fair values of the in-process research and development assets and developed technology asset 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 the asset. The Company believes that the level and timing of cash flows appropriately reflect market participant assumptions. Cash flows were assumed to extend through the patent life of our purchased technology.

The \$38.0 million of goodwill was assigned to our Pharmaceutical Products segment. The goodwill recognized is attributable primarily to the control premium associated with our Oxymorphone Franchise and other factors. None of the goodwill is expected to be deductible for income tax purposes.

The deferred tax assets of \$27.2 million are related primarily to federal net operating loss and credit carryforwards of Penwest. The deferred tax liabilities of \$40.0 million are related primarily to the difference between the book basis and tax basis of the identifiable intangible assets.

The Company recognized \$6.9 million of Penwest acquisition-related costs that were expensed for both the three and nine month periods ended September 30, 2010, 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):

	Acquisition-related Costs Three and nine months Ended September 30, 2010	
Investment bank fees, includes Endo and Penwest	\$	3,660
Legal and other costs		3,255

Total	\$	6,915
-------	----	-------

Due to the pro forma impacts of eliminating the pre-existing intercompany royalties between Penwest and Endo, which were determined to be at fair value, we have not provided supplemental pro forma information as amounts are not material to the condensed consolidated statements of operations. We have also considered the impacts of Penwest, since the date we obtained a majority interest, on our condensed consolidated statement of operations and concluded amounts were not material.

#### *Qualitest Pharmaceuticals*

On September 28, 2010, Endo announced that it has entered into a definitive agreement to acquire Qualitest Pharmaceuticals (referred to as Qualitest), a leading, privately-held generics company in the U.S., for approximately \$1.2 billion in cash, of which approximately \$400 million will be utilized to extinguish existing indebtedness. Consummation of the acquisition is subject to certain conditions, including, among others, (i) absence of certain legal impediments to the consummation of the acquisition, (ii) the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, (iii) the accuracy of the representations and warranties made by each party, respectively, in each case, subject to certain material adverse effect qualifications, and (iv) compliance by each party with their respective obligations under the stock purchase agreement, in each case, subject to certain materiality qualifications.

**NOTE 6. SEGMENT RESULTS**

As a result of our recent acquisition of HealthTronics during the third quarter ended September 30, 2010, the Company has realigned its internal management reporting to reflect a total of two reportable segments. These segments reflect the level at which executive management regularly reviews financial information to assess performance and to make decisions about resources to be allocated.

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)

## FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

The two reportable business segments in which the Company now operates include: (1) Pharmaceuticals Products and (2) Devices and Services. Each segment derives revenue from the sales or licensing of their respective products or services and is discussed below.

**Pharmaceutical Products**

This group of products includes a variety of branded and generic prescription products related to treating and managing pain as well as our Urology, Endocrinology and Oncology products. The established products that are included in this operating segment includes Lidoderm<sup>®</sup>, Opana<sup>®</sup> ER and Opana<sup>®</sup>, Percocet<sup>®</sup>, Voltaren<sup>®</sup> Gel, Frova<sup>®</sup>, Supprelin<sup>®</sup> LA, Vantas<sup>®</sup>, Valstar<sup>®</sup>, and Sanctura<sup>®</sup> and Sanctura XR<sup>®</sup>.

This segment also includes our non-branded generic portfolio, which mainly focuses on selective generics related to pain that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing. Included in this segment, as well as many other products, are Endocet<sup>®</sup> and Morphine Sulfate.

**Devices and Services**

The Devices and Services operating segment provides urological services, products, and support systems to urologists, hospitals, surgery centers and clinics across the United States. These services and products are sold through the following five HealthTronics<sup>®</sup> business lines: *Lithotripsy services, Prostate treatment services, Radiation therapy services, Anatomical pathology services, and Medical products manufacturing, sales and maintenance*. These business lines are discussed in greater detail within Note 5.

The Company evaluates segment performance based on net sales and income before income taxes and income attributable to noncontrolling interests. Certain costs, such as acquisition-related costs, cost reduction initiatives, unallocated corporate general administrative expense, interest expense, net, and other income, net are included within Corporate unallocated. The following represents selected information for the Company's reportable segments for the three and nine months ended September 30, 2010 and 2009 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Net revenues to external customers				
Pharmaceutical Products	\$ 392,417	\$ 361,027	\$ 1,153,353	\$ 1,069,435
Devices and Services	51,686		51,686	
Total consolidated net revenues to external customers	\$ 444,103	\$ 361,027	\$ 1,205,039	\$ 1,069,435
Income (loss) before income taxes				
Pharmaceutical Products	\$ 179,907	\$ 120,732	\$ 487,566	\$ 410,806
Devices and Services	19,084 <sup>(1)</sup>		19,084 <sup>(1)</sup>	
Corporate unallocated	(95,979) <sup>(2)</sup>	(41,403) <sup>(3)</sup>	(223,094) <sup>(4)</sup>	(206,694) <sup>(5)</sup>
Total consolidated income before income taxes	\$ 103,012	\$ 79,329	\$ 283,556	\$ 204,112

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

- (1) Included within Devices and Services is \$15.3 million in income attributable to noncontrolling interests
- (2) Included in Corporate unallocated income before income tax is: acquisition-related costs of \$25.0 million, cost reduction initiatives of \$1.1 million, corporate general administrative expense of \$55.7 million, inventory step-up of \$1.3 million, interest income of \$0.2 million, interest expense of \$13.1 million, and other income, net, of \$0.1 million.
- (3) Included in Corporate unallocated income before income tax is: acquisition-related gains of \$20.2 million, cost reduction initiatives of \$2.5 million, corporate general administrative expense of \$54.0 million, inventory step-up of \$0.01 million, interest income of \$0.7 million, interest expense of \$11.0 million, other income, net, of \$1.2 million, and gain on extinguishment of debt of \$4.0 million.
- (4) Included in Corporate unallocated income before income tax is: acquisition-related costs of \$31.3 million, cost reduction initiatives of \$10.6 million, corporate general administrative expense of \$147.5 million, inventory step-up of \$1.4 million, interest income of \$1.0 million, interest expense of \$33.8 million, and other income, net, of \$0.5 million.
- (5) Included in Corporate unallocated income before income tax is: acquisition-related costs of \$41.2 million, cost reduction initiatives of \$2.5 million, corporate general administrative expense of \$129.2 million, inventory step-up of \$11.1, interest income of \$2.9 million, interest expense of \$31.2 million, other income, net, of \$1.6 million, and gain on extinguishment of debt of \$4.0 million.

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)

## FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

The following represents additional selected financial information for our reportable segments:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Depreciation expense:				
Pharmaceutical Products	\$ 4,138	\$ 4,947	\$ 12,619	\$ 12,318
Devices and Services	3,060		3,060	
Total depreciation expense	\$ 7,198	\$ 4,947	\$ 15,679	\$ 12,318
Amortization expense:				
Pharmaceutical Products	\$ 18,208	\$ 16,888	\$ 52,779	\$ 44,164
Devices and Services	1,401		1,401	
Total amortization expense	\$ 19,609	\$ 16,888	\$ 54,180	\$ 44,164

Asset information by reportable segment is not accounted for at the segment level and consequently is not reviewed or included within our internal management reporting. Therefore, the Company has not disclosed asset information for each reportable segment.

**NOTE 7. INCOME TAXES**

The effective income tax rate on earnings from continuing operations before income taxes was 32.6% and 36.1% for the three and nine months ended September 30, 2010 compared to 37.7% and 41.9% for the three and nine months ended September 30, 2009.

The decrease in the effective income tax rate in the three and nine months ended September 30, 2010, was due to:

A \$7.3 million benefit relating to net income associated with the noncontrolling interests assumed as part of the HealthTronics acquisition which were not taxable at the corporate level; and

A decline in our state income taxes and uncertain tax positions by \$6.7 million and \$7.8 million for the three and nine-months periods, respectively, as compared to the prior year periods.

Partially offset by:

A favorable impact from the research and development tax credit on the prior year rate of \$1.7 million and \$3.3 million for the three and nine month periods ended September 30, 2009. This credit expired on December 31, 2009.

**NOTE 8. 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<sup>®</sup> 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<sup>®</sup> Gel (Voltaren<sup>®</sup> Gel or Licensed Product). Voltaren<sup>®</sup> 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<sup>®</sup> Gel has been granted marketing exclusivity in the U.S. as a prescription medicine until at least October 2010.

Under the terms of the five-year Voltaren<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> Gel Agreement year. No royalty payments were payable to Novartis during the nine months ended September 30, 2010 or 2009. Novartis is also eligible to receive a one-time milestone payment of \$25 million if annual net sales of Voltaren<sup>®</sup> 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<sup>®</sup> Gel. We are amortizing this intangible asset into cost of revenues over its estimated five-year useful life.

---

**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010**

Endo is 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 is 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 nine-month periods ended September 30, 2010 and 2009 we recorded \$63.7 million and \$62.1 million for these royalties to Hind, respectively. At September 30, 2010 and December 31, 2009, we had recorded \$21.8 million and \$22.6 million, respectively, as a royalty payable included in accounts payable in the accompanying balance sheets. In March 2002, we extended this license with Hind to cover Lidoderm® in Canada and Mexico.



---

**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 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 would 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 were summarized as follows:

With respect to U.S. sales of Opana® ER, Endo's royalty payments to Penwest would 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 could increase to a maximum of 30%.

No royalty payments would 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 was 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 agreed that Penwest's share of these unfunded development costs would be fixed at \$28 million and would be recouped by Endo through a temporary 50% reduction in royalties payable to Penwest. Endo recouped the full \$28 million of these unfunded development costs during the first half of 2010.

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 nine months ended September 30, 2010, we recorded in cost of revenues, royalties on the net sales of Opana® ER of approximately \$10.2 million and \$29.8 million, respectively. During the three and nine month ended September 30, 2009, we recorded in cost of revenues, royalties on the net sales of Opana® ER of approximately \$4.9 million and \$13.7 million, respectively.

On June 8, 2010, the Company and Penwest entered into an amendment (the Fifth Amendment) to the 2002 Agreement, as amended. Under the terms of the Fifth Amendment, the royalty rate on net sales of Opana® ER was 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.

On August 9, 2010, the Company and Penwest entered into an amendment (the Sixth Amendment) to the 2002 Agreement, as amended. Under the terms of the Sixth Amendment, from and after September 20, 2010, Endo obtained sole discretion with respect to all decisions and actions

pertaining to Opana® ER.

See Note 5 for discussion of our Penwest Acquisition which will effectively eliminate this third-party relationship for future impacts on the consolidated statement of operations.

*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. Prior to Endo's acquisition of the majority of common stock of Penwest, under the terms of the collaboration agreement between Penwest and Endo, the two companies shared 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 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. We capitalized the \$30 million up-front payment and the present value of the two \$15 million anniversary payments. 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.

---

ENDO PHARMACEUTICALS HOLDINGS INC.

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

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 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>. 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.

In February 2008, we entered into Amendment No. 4 to the Vernalis License Agreement (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.

*Allergan/Esprit*

In September 2007, Indevus (now, Endo Pharmaceuticals Solutions Inc.) 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 15).

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.





---

**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010**

*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 hydrogel 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 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.

---

**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 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 \$26 million at September 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.

In December 2007, we entered into a license, development and supply agreement with Grünenthal for the exclusive clinical development and commercialization rights in Canada and the United States for a new oral formulation of long-acting oxymorphone, which is designed to be crush resistant. Under the terms of this agreement Grünenthal is responsible for development efforts to conduct pharmaceutical formulation development and will manufacture any such product or products which obtain FDA approval. Endo is 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 September 30, 2010. Additional payments of approximately 65.0 million Euros (approximately \$88 million at September 30, 2010) may become due upon achievement of predetermined regulatory and commercial milestones. Endo will also make payments to Grünenthal based on net sales of any such product or products commercialized under this agreement.

*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<sup>®</sup> in the U.S. (the ProStrakan Agreement). Fortesta<sup>®</sup>, 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 receive up to approximately \$200 million in additional payments linked to the achievement of future regulatory and commercial milestones related to Fortesta<sup>®</sup>. ProStrakan will exclusively supply Fortesta<sup>®</sup> 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.

---

**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 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.

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

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

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.

---

**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010**

*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<sup>®</sup> 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<sup>®</sup> BP product. Under this Agreement, we made an upfront payment to EpiCept of \$7.5 million which we capitalized as an intangible asset representing the fair value of the exclusive right and the patents. We are amortizing this intangible asset over its useful life of thirteen (13) years. EpiCept has also retained an option to co-promote the LidoPAIN<sup>®</sup> 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<sup>®</sup> BP. However, the Company intends to maintain its patent rights conveyed by the EpiCept Agreement.

*Other*

We have 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. 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 nine months ended September 30, 2010, \$1.6 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 October 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 September 30, 2010, our investment in the privately-held company was \$21.6 million, representing our maximum exposure to loss.

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)

## FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

## NOTE 9. GOODWILL AND OTHER INTANGIBLES

Changes in the carrying amount of our goodwill for the nine months ended September 30, 2010, are as follows:

(in thousands)	Gross carrying amount
Balance at December 31, 2009	\$ 302,534
Goodwill acquired during the period (see Note 5)	190,122
Balance at September 30, 2010	\$ 492,656

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

	September 30, 2010	December 31, 2009
Indefinite-lived intangibles:		
In process research and development	\$ 95,000	\$ 100,900
Definite-lived intangibles:		
Licenses	625,242	625,242
Trade names	14,600	
Developed technology	150,400	
Service contract	4,966	
Less accumulated amortization	(170,413)	(116,233)
	624,795	509,009
Other intangibles, net	\$ 719,795	\$ 609,909

Changes in the gross carrying amount of our other intangible assets for the nine months ended September 30, 2010, are as follows:

(in thousands)	Gross carrying amount
Balance at December 31, 2009:	\$ 726,142
HealthTronics acquisition	65,866
Penwest acquisition	111,200
Pagoclone impairment	(13,000)
Balance at September 30, 2010	\$ 890,208



## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)

## FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

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. In May 2010, following the completion of the phase IIb study, Teva terminated the Teva agreement and all rights to pagoclone were returned to the Company.

As of June 30, 2010, 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 model 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 reflected 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 during the nine months ended September 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.

Amortization expense for the nine month periods ended September 30, 2010 and 2009 was \$54.2 million and \$44.2 million, respectively. As of September 30, 2010, the weighted average amortization period for our definite lived intangible assets in total was approximately 11 years.

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

2010	\$ 81,256
2011	\$ 108,307
2012	\$ 108,307
2013	\$ 66,321
2014	\$ 53,429

**NOTE 10. COMPREHENSIVE INCOME**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Consolidated net income	\$ 69,472	\$ 49,422	\$ 181,287	\$ 118,488
Other comprehensive income (loss):				
Unrealized gain (loss) on securities, net of tax	36	375	(62)	(233)
Consolidated total comprehensive income	69,508	49,797	181,225	118,255

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

Less: Total comprehensive income attributable to noncontrolling interests	(15,266)		(15,266)	
Comprehensive income attributable to Endo Pharmaceuticals Holdings Inc.	\$ 54,242	\$ 49,797	\$ 165,959	\$ 118,255

---

**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010**

**NOTE 11. 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 September 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 \$6.4 million and \$16.8 million, during the three and nine months ended September 30, 2010 and \$6.8 million and \$14.6 million during the three and nine months ended September 30, 2009, respectively. As of September 30, 2010, the total remaining unrecognized compensation cost related to all non-vested stock-based compensation awards amounted to \$68.0 million. This expected cost does not include the impact of any future stock-based compensation awards.

*Stock Options*

For all of the Company's stock-based compensation plans, the fair value of each option grant was estimated at the date of grant using the Black-Scholes option-pricing model. Black-Scholes utilizes assumptions related to volatility, the risk-free interest rate, the dividend yield (which is assumed to be zero, as the Company has not paid cash dividends to date and does not currently expect to pay cash dividends) and the expected term of the option. Expected volatilities utilized in the model are based mainly on the historical volatility of the Company's stock price over a period commensurate with the expected life of the share option as well as other factors. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. We estimate the expected term of options granted based on our historical experience with our employees' exercise of stock options and other factors.

A summary of the activity under 2000, 2004 and 2007 Stock Incentive Plans for the nine months ended September 30, 2010 is as follows:

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

	<b>Number of Shares</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term</b>	<b>Aggregate Intrinsic Value</b>
Outstanding, January 1, 2010	5,158,541	\$ 22.84		
Granted	2,063,009	\$ 21.22		
Exercised	(439,117)	\$ 19.86		
Forfeited	(283,198)	\$ 21.74		
Expired	(196,367)	\$ 30.55		

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)

## FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding, September 30, 2010	6,302,868	\$ 22.32	7.56	\$ 67,639,068
Vested and expected to vest, September 30, 2010	5,835,164	\$ 22.44	7.44	\$ 61,967,053
Exercisable, September 30, 2010	2,416,611	\$ 24.07	5.58	\$ 21,707,656

The total intrinsic value of options exercised during the nine months ended September 30, 2010 and 2009 was \$2.3 million and \$3.4 million, respectively. The weighted-average grant date fair value of the stock options granted in the nine months ended September 30, 2010 and 2009 was \$7.38 per option and \$7.47 per option, respectively, determined using the following assumptions:

	2010	2009
Average expected term (years)	5.3	5.22
Risk-free interest rate	2.5%	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 2.5 years.

*Restricted Stock Units*

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

	Number of Shares	Aggregate Intrinsic Value
Outstanding, January 1, 2010	1,477,241	
Granted	1,355,792	
Forfeited	(295,794)	
Vested	(356,302)	
Outstanding, September 30, 2010	2,180,937	\$ 72,090,437
Vested and expected to vest, September 30, 2010	1,876,773	\$ 61,653,345

The weighted average remaining requisite service period of the non-vested restricted stock units was 2.6 years. The weighted-average grant date fair value of the restricted stock units granted during the nine months ended September 30, 2010 was \$20.78 per unit.

*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 nine months ended September 30, 2010 totaled 163,000. As of September 30, 2010, there was approximately \$2.6 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.

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

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.

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)

## FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

During 2010, pursuant to the existing share repurchase program, we purchased approximately 2.5 million shares of our common stock during the period ended September 30, 2010 totaling \$59.0 million. We did not purchase any shares of our common stock during the year ended December 31, 2009.

*Changes in Stockholders' Equity*

The following table displays a reconciliation of our beginning and ending balances in stockholders' equity for the nine months ended September 30, 2010 (dollars in thousands):

	Endo Pharmaceuticals Holdings Inc.	Attributable to: Noncontrolling interests	Total Stockholders Equity
Stockholders' equity at January 1, 2010	\$ 1,497,411	\$	\$ 1,497,411
Net income	166,021	15,266	181,287
Other comprehensive income	(62)		(62)
Compensation related to stock-based awards	16,753		16,753
Exercise of options	8,887		8,887
Common stock purchased	(58,974)		(58,974)
Noncontrolling interests acquired in business combinations		60,119	60,119
Distributions to noncontrolling interests		(13,971)	(13,971)
Buy-out of noncontrolling interests, net of contributions		(725)	(725)
Other	(1,530)		(1,530)
Stockholders' equity at September 30, 2010	\$ 1,628,506	\$ 60,689	\$ 1,689,195

**NOTE 12. 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 in 2010 and approximately \$21 million in 2011. Either party may terminate this agreement on three-years' notice, effective at any time after the initial five-year term. Either party may also terminate this agreement on account of a material breach by the other.



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

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

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

As part of the Voltaren® Gel Agreement, we also agreed to undertake advertising and promotion of Voltaren® Gel (A&P Expenditures), subject to certain thresholds set forth in the Voltaren® Gel Agreement. We agreed to spend a minimum of \$15.0 million on A&P Expenditures during the first Voltaren® Gel Agreement Year which ended on June 30, 2009. During the second Voltaren® 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® 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® Gel Agreement are determined based on a percentage of net sales of Voltaren® Gel.

---

**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 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® 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® for a period of time after which the price will be adjusted at future dates certain based on a price index defined in the Amended Agreement. Since future price changes are unknown, we have used prices currently existing under the Amended Agreement, and estimated our minimum purchase requirement to be approximately \$32 million per year through 2012. The minimum purchase requirement shall remain in effect subsequent to 2012, except that Endo has the right to terminate the Amended Agreement after 2012, if we fail to meet the annual minimum requirement.

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

The Amended Agreement will expire on December 31, 2021, unless terminated in accordance with its terms. Either party may terminate this Agreement, upon thirty (30) days written notice, in the event that Endo fails to purchase the annual minimum quantity for each year after 2012 (e.g., 2013 through 2021) upon thirty (30) days written notice. Notwithstanding the foregoing, after December 31, 2021, the Amended Agreement shall be automatically renewed on the first day of January each year unless (i) we and Teikoku agree to terminate the Amended Agreement upon mutual written agreement or (ii) either we or Teikoku terminates the Amended Agreement with 180-day written notice to the other party, which notice shall not in any event be effective prior to July 1, 2022.

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.

Effective November 1, 2010, the parties amended the Teikoku Agreement. Pursuant to this amendment, Teikoku has agreed to supply additional product at no cost to Endo in each of 2011, 2012 and 2013 in the event Endo's firm orders of Product exceed certain thresholds in those years.

*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.

---

**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 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 \$3.4 million and \$9.1 million for the three and nine months ended September 30, 2010, respectively. The expenses incurred with respect to Ventiv under the Ventiv Agreement were \$2.7 million and \$19.3 million for the three and nine months ended September 30, 2009.

The term of the Ventiv Agreement which was originally set to expire on August 10, 2010, was extended until the first to occur of the following: (i) Endo and Ventiv entering into the new services agreement or (ii) November 30, 2010.

*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.

---

**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010**

*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 8 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*

In the ordinary course of its business, the Company is involved in various claims and legal proceedings, including product liability, intellectual property, and commercial litigation. While we cannot predict the outcome of our ongoing legal proceedings 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

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

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.

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.

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

### *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.



---

ENDO PHARMACEUTICALS HOLDINGS INC.

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

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

*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.*

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.

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 plaintiff 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.*

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

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.

---

**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010**

The Company intends to contest the unresolved 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. In October 2010, Teikoku Pharma USA listed U.S. Patent No. 5,741,510 in the FDA's Orange Book, and this patent expires in March 2014. This patent has not yet been challenged. Endo intends, and has been advised by Teikoku that they too intend, to 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. However, there can be no assurance that we will be successful. Additionally, we cannot predict or determine the timing or outcome of any of this litigation 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'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.

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 Company and Penwest timely filed lawsuits against IMPAX in the United States District Court for the District of Delaware in connection with IMPAX's ANDAs.

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 or earlier under certain circumstances.

In February 2008, the Company 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).

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. The Company and Penwest timely filed lawsuits against Actavis in the United States District Court for the District of New Jersey.

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

On February 20, 2009, Endo and Penwest settled all of the Actavis litigation. 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 on July 15, 2011, or earlier under certain circumstances. 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.

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

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.

---

**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010**

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 Company and Penwest timely filed lawsuits against Sandoz in the United States District Court for the District of Delaware.

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. 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. The Company and Penwest timely filed lawsuits against Barr in the United States District Court for the District of Delaware 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 Opana® ER. Endo and Penwest agreed to grant Barr a license permitting the production and sale of all strengths of Opana® ER commencing on September 15, 2012, or earlier under certain circumstances.

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. 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. The Company and Penwest timely filed lawsuits 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 October 4, 2010, Endo and Penwest settled all of the Watson litigation. Under the terms of the settlement, Watson agreed not to challenge the validity or enforceability of Penwest's patents relating to Opana® ER. Endo and Penwest agreed to grant Watson a license permitting the production and sale of all strengths of Opana® ER commencing on 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.

We 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.

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

### *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 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 prevented final approval of any ANDA by the FDA until the exclusivity expired on August 3, 2010.

---

**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 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 July 23, 2010, Watson filed an amended and supplemental answer and counterclaims to our complaint. On August 19, 2010, we filed an answer to Watson's counterclaims.

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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> product has new dosage form exclusivity that prevented final approval of any ANDA by the FDA until the exclusivity expired 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> product has new dosage form exclusivity that prevented final approval of any ANDA by the FDA until the exclusivity expired 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.

On July 7, 2010, Paddock filed an answer and counterclaims to our complaint. On August 2, 2010, we filed an answer to Paddock's counterclaims. On September 21, 2010, the Court consolidated the actions against Watson, Sandoz, and Paddock. We have amended the complaint against Paddock to add Paddock's supplier as a defendant.

On August 18, 2010, we received an amended paragraph 4 invalidity and noninfringement Hatch-Waxman Act certification from Watson indicating that Watson had filed an ANDA seeking approval of a generic form of Sanctura XR<sup>®</sup>. In their certification, Watson contends that U.S. Patent Nos. 7,759,359 and 7,763,635 listed in the Orange Book under Sanctura XR<sup>®</sup>, are invalid and/or not infringed by the proposed Watson product. On September 13, 2010, we received an amended paragraph 4 invalidity and noninfringement Hatch-Waxman Act certification from Watson indicating that Watson had filed an ANDA seeking approval of a generic form of Sanctura XR<sup>®</sup>. In their certification, Watson contends that U.S. Patent Nos. 7,781,448 and 7,781,449 listed in the Orange Book under Sanctura XR<sup>®</sup>, are invalid and/or not infringed by the proposed



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

Watson product. In October 2010, we, Endo and Supernus filed a complaint against Watson for patent infringement to assert U.S. Patent Nos. 7,781,448 and 7,781,449.

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

On August 19, 2010, we received an amended paragraph 4 invalidity and noninfringement Hatch-Waxman Act certification from Paddock indicating that Paddock had filed an ANDA seeking approval of a generic form of Sanctura XR<sup>®</sup>. In their certification, Paddock contends that U.S. Patent Nos. 7,759,359 and 7,763,635 listed in the Orange Book under Sanctura XR<sup>®</sup>, are invalid and/or not infringed by the proposed Paddock product. On September 14, 2010, we received an amended PIV certification from Paddock indicating that Paddock had filed an ANDA seeking approval of a generic form of Sanctura XR<sup>®</sup>. In their certification, Paddock contends that U.S. Patent Nos. 7,781,448 and 7,781,449 listed in the Orange Book under Sanctura XR<sup>®</sup>, are invalid and/or not infringed by the proposed Paddock product. On September 21, 2010, the court consolidated the Watson action and the Sandoz action with the Paddock action. On October 5, 2010, Endo Pharmaceuticals Solutions and Supernus filed a complaint against Paddock for patent infringement to assert U.S. Patent Nos. 7,781,448 and 7,781,449.

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)

## FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

*Legal Proceedings Regarding the Penwest Offer and Merger*

As a result of our acquisition of Penwest, multiple purported shareholders of Penwest filed lawsuits on behalf of a putative class of holders of Penwest common stock. The actions name Penwest, Penwest's Board, Tang Capital Partners, L.P., Perceptive Life Sciences Master Fund Ltd. and Endo as defendants. The actions challenge the proposed sale of Penwest to Endo and generally allege, among other things, that Penwest and the Penwest Board violated various fiduciary duties in approving the proposed transaction with Endo and that Endo aided and abetted such violations.

Endo and Penwest have denied, and continue to deny, that either of them has committed or aided and abetted in the commission of any violation of law or any kind or engaged in any wrongful acts alleged in the above-referenced actions. However, Endo and Penwest anticipate resolving these cases solely to eliminate the uncertainties, burden and expense of further protracted litigation. Such a resolution would be for amounts considered immaterial to the consolidated financial statements.

*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 13. 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 September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
<b>Numerator:</b>				
Net income attributable to Endo Pharmaceuticals Holdings Inc. common stockholders	\$ 54,206	\$ 49,422	\$ 166,021	\$ 118,488
<b>Denominator:</b>				
For basic per share data weighted average shares	115,469	117,207	116,292	117,062
Effect of dilutive stock options	1,128	436	804	339
For diluted per share data weighted average shares	116,597	117,643	117,096	117,401
Basic net income per share attributable to Endo Pharmaceuticals Holdings Inc.	\$ 0.47	\$ 0.42	\$ 1.43	\$ 1.01
Diluted net income per share attributable to Endo Pharmaceuticals Holdings Inc.	\$ 0.46	\$ 0.42	\$ 1.42	\$ 1.01

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.

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

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.

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 warrants are 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 if the warrants were exercised is approximately 13 million.

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)

## FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

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 nine months ended September 30 (in thousands):

	2010	2009
Weighted average shares excluded:		
1.75% Convertible senior subordinated notes due 2015 and warrants(1)	25,993	25,993
Employee stock-based awards	5,220	4,703
	31,213	30,696

(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 14. COST OF REVENUES**

The components of cost of revenues for the three and nine months ended September 30, 2010 and 2009 are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Cost of net sales	\$ 107,414	\$ 97,307	\$ 308,703	\$ 275,385
Cost of device, service and other revenues	26,506		26,506	
<b>Total cost of revenues</b>	<b>\$ 133,920</b>	<b>\$ 97,307</b>	<b>\$ 335,209</b>	<b>\$ 275,385</b>

**NOTE 15. 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

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

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 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.

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)

## FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

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.

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 September 30, 2010 and December 31, 2009 are as follows (in thousands):

	September 30, 2010	December 31, 2009
Principal amount of Convertible Notes	\$ 379,500	\$ 379,500
Unamortized discount related to the debt component(1)	(105,422)	(119,221)
<b>Net carrying amount of the debt component</b>	<b>\$ 274,078</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 \$21.5 million and \$17.7 million of interest expense for the nine months ended September 30, 2010 and 2009, respectively. For the amounts recognized in 2010, \$7.7 million related to the contractual interest payments and \$13.8 million related to the amortization of the debt discount and certain other costs of the offering. This compared to \$5.0 million of contractual interest payments and \$12.7 million related to the amortization of the debt discount and certain other costs of the offering for the nine months ended September 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

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

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 8) 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.

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)

## FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

Unless repaid or redeemed earlier, 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 September 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 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, \$1.2 million and \$1.3 million with our February 2010, May 2010, and August 2010 quarterly interest payments, respectively.

During the third quarter of 2010, Endo notified the Holders of its intent to exercise its option to redeem the \$57 million of principal at 108% for approximately \$61.6 million (which amount excludes accrued and unpaid interest) on November 5, 2010. Accordingly, we have reclassified the remaining carrying value of the Non-Recourse of approximately \$62.0 million to a current liability in our Condensed Consolidated Balance Sheet as of September 30, 2010. A gain will be recognized during the fourth quarter of 2010 when the Non-Recourse Notes are extinguished. The gain will not be material to the consolidated financial statements.

The Non-recourse Notes are subject to redemption at the option of Royalty Sub. The redemption price is 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%

*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 is available for letters of credit, working capital and general corporate purposes. The Credit Facility was amended on October 25, 2010 to permit up to \$500 million of additional revolving or term loan commitments from one or more of the existing lenders or other lenders.

---

**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010**

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 and the subsidiary guarantors. 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 accrue interest at 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.

***Debt Acquired from HealthTronics***

In connection with our acquisition of HealthTronics, we assumed \$40 million in outstanding debt drawn under the HealthTronics Senior Credit Facility. The Company repaid those amounts, including unpaid interest, on July 2, 2010 and the HealthTronics Senior Credit Facility was terminated as a result of the acquisition.

Upon our acquisition of HealthTronics, we also assumed \$4.6 million in notes related to equipment purchased by HealthTronics' limited partnerships, which indebtedness we believe will be repaid from the cash flows of the partnerships. During the third quarter of 2010, our partnerships repaid certain of these notes and financed additional purchases of equipment by obtaining additional similar notes. The carrying amount of our partnership's notes associated with the purchase of equipment is \$5.8 million at September 30, 2010. These notes bear interest at either a fixed rate of five to eight percent or LIBOR or prime plus a certain premium and are due over the next four years.

**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 U.S.-based, specialty healthcare solutions company, focused on high-value branded products and specialty generics. Endo is redefining its position in the healthcare marketplace by anticipating and embracing the evolution of health decisions based on the need for high-quality and cost-effective care. We aim to be the premier partner to healthcare professionals and payment providers, delivering an innovative suite of complementary diagnostics, drugs, devices and clinical data to meet the needs of patients in areas such as pain, urology, oncology and endocrinology.

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 88% of our revenues for the nine months ended September 30, 2010, with 48% of our revenues coming from Lidoderm<sup>®</sup>. Our non-branded generic portfolio, which accounted for 7% of revenues for the nine months ended September 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 459 pharmaceutical sales representatives focusing primarily on pain products, 80 sales representatives focusing primarily on urology and oncology, 46 sales representatives focusing primarily on managed markets, 28 medical center representatives and a contract sales force of approximately 250 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 provider of healthcare services and manufacturer of medical devices, primarily for the urology community. Additionally, on September 20, 2010, we acquired a majority interest in Penwest Pharmaceuticals Co., a drug development company. We anticipate closing this acquisition immediately following a special meeting of shareholders of Penwest to consider and vote upon a proposal to approve the merger, which is scheduled to be held on November 4, 2010.

**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.

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.

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 (the HealthTronics Acquisition Date), the Company completed its initial tender offer for all outstanding shares of common stock of HealthTronics. On July 12, 2010, Endo completed its acquisition of HealthTronics for approximately \$214.8 million in aggregate cash consideration for 100% of the outstanding shares, at which time HealthTronics became a wholly-owned subsidiary of the Company. The HealthTronics Shares were purchased at a price of \$4.85 per HealthTronics Share. In addition, Endo paid \$40 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.

#### ***Penwest Acquisition***

On September 20, 2010 (the Penwest Acquisition Date), the Company completed its tender offer for the outstanding shares of common stock of Penwest, at which time Penwest became a majority-owned subsidiary of the Company. The Penwest shares were purchased at a price of \$5.00 per share. Endo paid approximately \$147.6 million in aggregate cash consideration for the outstanding shares. Currently, Endo owns approximately 90.56% of Penwest's common stock.

This transaction contributes to Endo's core Pain Management franchise and permits us to maximize the value of our Oxymorphone franchise.

#### ***Qualitest Pharmaceuticals***

On September 28, 2010, Endo announced that it has entered into a definitive agreement to acquire Qualitest Pharmaceuticals (referred to as Qualitest), a leading, privately-held generics company in the U.S., for approximately \$1.2 billion in cash, of which approximately \$400 million will be utilized to extinguish existing indebtedness. Consummation of the acquisition is subject to certain conditions, including, among others, (i) absence of certain legal impediments to the consummation of the acquisition, (ii) the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, (iii) the accuracy of the representations and warranties made by each party, respectively, in each case, subject to certain material adverse effect qualifications, and (iv) compliance by each party with their respective obligations under the stock purchase agreement, in each case, subject to certain materiality qualifications.

The combined company will deliver more comprehensive healthcare solutions across its diversified businesses in Branded Pharmaceuticals, Generics, Devices & Services in key therapeutic areas including pain and urology. Qualitest, the sixth largest U.S. generics company as measured by prescriptions filled, is focused on cost competitive, high quality manufactured products with high barriers to entry. Endo believes Qualitest brings critical mass to Endo's current generics business, further diversifies its business lines and product offerings and enhances Endo's portfolio of pain management products.

Endo intends to finance the purchase with existing cash, by utilizing all or a portion of our existing \$300 million revolving credit facility and/or with the proceeds of one or more new financings, which may include a new term loan financing of up to \$400 million pursuant to financing commitments that have been previously obtained by Endo.

#### ***Pipeline Developments***

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

In September 2010, we received notification from the U.S. Food and Drug Administration (FDA) that Endo's new drug application (NDA) for its new oral formulation of long-acting oxymorphone, which is designed to be crush resistant, has been granted priority review status. The FDA has set the action date under the Prescription Drug User Fee Act (PDUFA) for January 7, 2011.



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<sup>®</sup> in the U.S. Fortesta<sup>®</sup>, 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<sup>®</sup> 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 pargolone (the Teva Agreement). Under the terms of the Teva Agreement, the Company would conduct, and Teva would reimburse expenses for, a Phase IIb 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 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.

## **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 nine months ended September 30, 2010 increased 23% to \$444.1 million and 13% to \$1,205.0 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. Included in the nine months ended September 30, 2010 are the revenues from our recently acquired products, including Supprelin<sup>®</sup> LA and other brands, from our acquisition of Indevus Pharmaceuticals, Inc. This compares to a partial nine months in 2009 as the revenue from Indevus was included from February 23, 2009 through September 30, 2009. Additionally, included within the three and nine months ended September 30, 2010 are revenues from our recently acquired devices and services from our acquisition of HealthTronics. For the

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

nine months ended September 30, 2010, increased sales volume on net sales contributed 10% of the total revenue growth of 13% while price contributed 2%.

The following table displays our revenues by reportable segment and as a percentage of total revenues for the three and nine months ended September 30, 2010 and 2009 (dollars in thousands):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2010		2009		2010		2009	
	\$	%	\$	%	\$	%	\$	%
Pharmaceutical Products	\$ 392,417	88	\$ 361,027	100	\$ 1,153,353	96	\$ 1,069,435	100
Devices and Services	51,686	12			51,686	4		
<b>Total revenues</b>	<b>\$ 444,103</b>	<b>100</b>	<b>\$ 361,027</b>	<b>100</b>	<b>\$ 1,205,039</b>	<b>100</b>	<b>\$ 1,069,435</b>	<b>100</b>

*Pharmaceutical Products.* Net sales for the three and nine months ended September 30, 2010 increased 9% to \$392.4 million and 8% to \$1,153.4 million, respectively from the comparable 2009 periods.

*Devices and Services.* Net sales of for the three and nine months ended September 30, 2010 of \$51.7 resulted from the acquisition of HealthTronics.

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

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2010		2009		2010		2009	
	\$	%	\$	%	\$	%	\$	%
Lidoderm®	\$ 196,263	44	\$ 192,738	53	\$ 574,960	48	\$ 559,846	52
Opana® ER and Opana®	75,951	17	58,894	16	215,946	18	166,878	16
Percocet®	29,950	7	30,690	9	90,428	8	96,394	9
Voltaren® Gel	26,947	6	19,584	5	73,632	6	57,437	5
Frova®	14,136	3	15,000	4	43,898	4	42,479	4
Supprelin® LA	11,018	2	8,092	2	33,814	3	18,091	2
Other brands	7,568	2	10,418	3	30,065	2	26,242	2
<b>Total brands*</b>	<b>361,833</b>	<b>81</b>	<b>335,416</b>	<b>93*</b>	<b>1,062,743</b>	<b>88*</b>	<b>967,367</b>	<b>90</b>
Total generics	27,431	6	22,928	6	80,991	7	95,605	9
Total devices and service revenue	51,686	12			51,686	4		
Total royalty and other revenue	3,153	1	2,683	1	9,619	1	6,463	1
<b>Total revenues*</b>	<b>\$ 444,103</b>	<b>100</b>	<b>\$ 361,027</b>	<b>100*</b>	<b>\$ 1,205,039</b>	<b>100</b>	<b>\$ 1,069,435</b>	<b>100</b>

\* Total percentages may not sum due to rounding.

*Lidoderm®.* Net sales of Lidoderm® for the three months ended September 30, 2010 increased by \$3.5 million, or 2%, from the comparable 2009 period. Net sales of Lidoderm® for the nine months ended September 30, 2010 increased by \$15.1 million, or 3%, from the comparable 2009 period. During the three and nine months ended September 30, 2010, the increases in Lidoderm® are attributable to volumes compared to the same period in 2009.

*Opana® ER and Opana®.* Net sales of Opana® ER and Opana® for the three months ended September 30, 2010 increased by \$17.1 million, or 29% from the comparable 2009 period. Net sales of Opana® ER and Opana® for the nine months ended September 30, 2010 increased by \$49.1 million, or 29% 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

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

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 September 30, 2010 decreased by \$0.7 million, or 2% from the comparable 2009 period. Net sales of Percocet<sup>®</sup> for the nine months ended September 30, 2010 decreased by \$6.0 million, or 6% from the comparable 2009 period. The decreases are primarily attributable to decreased volumes during the first nine-months of 2010 as compared to 2009 partially offset due to price increases.

*Voltaren*<sup>®</sup> Gel. Net sales of Voltaren<sup>®</sup> Gel for the three months ended September 30, 2010 increased by \$7.4 million or 38% from the comparable 2009 period. Net sales of Voltaren<sup>®</sup> Gel for the nine months ended September 30, 2010 increased by \$16.2 million or 28% compared to from the comparable 2009 period. The 2010 increases were driven by volume. The Company launched Voltaren<sup>®</sup> Gel in March 2008 and we believe the growth of Voltaren<sup>®</sup> 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.

*Frova*<sup>®</sup>. Net sales of Frova<sup>®</sup> for the three months ended September 30, 2010 decreased by \$0.9 million or 6% from the comparable 2009 period. Net sales of Frova<sup>®</sup> for the nine months ended September 30, 2010 increased by \$1.4 million or 3%. The decline for the three months ended September 30, 2010 were driven primarily by decreases in volume. For the nine months ended September 30, 2010, price increases more than offset the decline in volumes.

*Supprelin*<sup>®</sup> LA. Net sales of Supprelin<sup>®</sup> LA for the three months ended September 30, 2010 increased by \$2.9 million or 36% from the comparable 2009 period. Net sales of Supprelin<sup>®</sup> LA for the nine months ended September 30, 2010 increased by \$15.7 million or 87% 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 nine months ended 2010 was driven by our February 2009 acquisition of Indevus, which contributed a full nine 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 September 30, 2010 decreased by \$2.9 million from the comparable 2009 period. Net sales of our other branded products for the nine months ended September 30, 2010 increased by \$3.8 million from the comparable 2009 period. These fluctuations are primarily driven by our February 2009 acquisition of Indevus, which contributed approximately \$7.6 million and \$14.2 million of net sales during the three months ended September 30, 2009 and the period from February 23, 2009 through September 30, 2009, respectively. This compares to \$6.3 million and \$26.0 million for the full three and nine months ended September 30, 2010, which also included revenues from our launch of Valstar<sup>™</sup> in the third quarter of 2009.

*Generics*. Net sales of our generic products for the three months ended September 30, 2010 increased by \$4.5 million, or 20% from the comparable 2009 period. Net sales of our generic products for the nine months ended September 30, 2010 decreased by \$14.6 million, or 15% from the comparable 2009 period. The decrease in sales for the nine months ended September 30, 2010 is primarily attributable to a shortage of other competing generic opioids in the market during the first half of 2009, which was an anomaly and did not recur during 2010, partially offset by increased volumes during the three months ended September 30, 2010 as compared to 2009.

*Device and service revenues*. Service revenue was \$51.7 million for the three and nine months ended September 30, 2010. These amounts consist of revenues from the acquisition of HealthTronics.

*Other revenues*. Royalty and other revenues for the three and nine months ended September 30, 2010 were \$3.2 million and \$9.6 million, respectively. Royalty and other revenues for the three and nine months ended September 30, 2009 were \$2.7 million and \$6.5 million, respectively. These amounts consist primarily of royalties earned on net sales of Sanctura<sup>®</sup> and Sanctura XR<sup>®</sup>.

### **Gross Margin, Costs and Expenses**

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

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2010		2009		2010		2009	
	\$	% of Revenues	\$	% of Revenues	\$	% of Revenues	\$	% of Revenues
Cost of revenues	\$ 133,920	30%	\$ 97,307	27%	\$ 335,209	28%	\$ 275,385	26%
Selling, general and administrative	137,816	31	139,922	39	404,402	34	389,520	36
Research and development	31,445	7	59,690	17	105,269	9	136,612	13
Acquisition related items	24,990	6	(20,206)	(6)	31,315	3	41,222	4
Impairment of other intangible assets					13,000	1		
Total costs and expenses	\$ 328,171	74%	\$ 276,713	77%	\$ 889,195	74%*	\$ 842,739	79%

\* Total percentages may not sum due to rounding.

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

**Cost of Revenues and Gross Margin.** Cost of revenues for the three months ended September 30, 2010 increased by \$36.6 million or 38%, to \$133.9 million from \$97.3 million in the comparable 2009 period. Cost of revenues for the nine months ended September 30, 2010 increased by \$59.8 million or 22%, to \$335.2 million from \$275.4 million in the comparable 2009 period. These increases were primarily attributable to increased revenues as well as increased cost of revenues as a percent of revenue, primarily attributable to our July 2, 2010 acquisition of HealthTronics. Gross profit margins for the three months ended September 30, 2010 and 2009 were 70% and 73%, respectively. Gross profit margins for the nine months ended September 30, 2010 and 2009 were 72% and 74%, respectively. The reduction in gross profit margins is primarily due to the acquisition of HealthTronics, which has contributed a lower gross profit percentage than Endo's pharmaceutical product net sales, as well as the increased amortization expense in 2010 compared to the 2009 period as a result of a full nine months of amortization on the acquired Indevus intangible assets and an increase in royalty expense recorded on net sales of Opana<sup>®</sup> ER for the three and nine months ended September 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 September 30, 2010 decreased to \$137.8 million from \$139.9 million in the comparable 2009 period. Selling, general and administrative expenses for the nine months ended September 30, 2010 increased to \$404.4 million from \$389.5 million in the comparable 2009 period. The increase in selling, general and administrative expenses for the nine months ended September 30, 2010 compared to the comparable 2009 period is primarily attributable to our acquisition of Indevus during the first quarter of 2009 and the recognition of a full nine months of Indevus expenses during the nine months ended September 30, 2010 as well as approximately \$10.0 million of certain costs incurred in connection with continued efforts to enhance the cost structure of the Company and \$6.0 million in start-up costs associated with our contract sales organization. The decrease in selling, general and administrative expenses for the three months ended September 30, 2010 compared to the comparable 2009 period is primarily attributable to efficiency measures taken in 2010 around corporate discretionary spending partially offset by increases relating to HealthTronics since July 2, 2010.

**Research and Development Expenses.** Research and development expenses for the three months ended September 30, 2010 decreased to \$31.4 million from \$59.7 million in the comparable 2009 period. Research and development expenses for the nine months ended September 30, 2010 decreased to \$105.3 million from \$136.6 million in the comparable 2009 period. These decreases are primarily a result of less upfront and milestone payments in 2010 as compared to 2009.

**Acquisition Related Items.** Acquisition related items for the three months ended September 30, 2010 and 2009 increased to \$25.0 million in expense from \$20.2 million in income in the comparable 2009 period. Acquisition-related items for the nine months ended September 30, 2010 and 2009 decreased to \$31.3 million in expense from \$41.2 million in expense in the comparable 2009 period. As a result of our acquisition of Indevus Pharmaceuticals, Inc. in the first three quarters of 2009, we incurred \$41.2 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 \$31.3 million in the comparable 2010 period primarily reflecting changes in the fair value of the Indevus acquisition-related contingent consideration of \$2.2 million and other expenses, including transaction fees, accelerated vesting of HealthTronics stock-based compensation, and legal and accounting fees, for the acquisition of HealthTronics, Penwest, and Qualitest incurred during the three months ended September 30, 2010.

#### **Interest Expense, net**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Interest expense	\$ 13,147	\$ 10,950	\$ 33,782	\$ 31,154
Interest income	(168)	(746)	(1,015)	(2,941)
Interest expense, net	\$ 12,979	\$ 10,204	\$ 32,767	\$ 28,213

Interest expense for the three months ended September 30, 2010 increased to \$13.1 million from \$11.0 million in the comparable 2009 period. For the nine months ended September 30, 2010, interest expense increased to \$33.8 million from \$31.2 million in the comparable 2009 period. This increase for the nine months ended September 30, 2010 is primarily due to the amortization of our deferred financing fees associated with our Credit Facility. Additionally, for the three and nine months ended September 30, 2010, we incurred an additional 50 basis-point expense or \$2.7 million relating to our outstanding convertible debt. Interest income decreased to \$0.2 million and \$1.0 million for the three and nine months ended September 30, 2010, respectively, compared to \$0.7 million and \$2.9 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 nine months ended September 30, 2010 and 2009 are as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2010	September 30, 2009	September 30, 2010	September 30, 2009
Gain on trading securities	\$	\$ (4,830)	\$ (15,420)	\$ (9,646)
Loss on auction-rate securities rights		5,128	15,659	7,641
Other (income) expense	(59)	(1,492)	(718)	401
Other income, net	\$ (59)	\$ (1,194)	\$ (479)	\$ (1,604)

During the three and nine months ended September 30, 2010, the value of our trading auction-rate securities increased by \$0 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 \$0 million and \$15.7 million, respectively, for the three and nine-months ended September 30, 2010. During the three and nine months ended September 30, 2009, the value of our trading auction-rate securities increased by \$4.8 million and \$9.6 million, respectively. During the three and nine months ended September 30, 2009, decreases in the fair value of our auction-rate securities rights were \$5.1 million and \$7.6 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**

Income tax for the three months ended September 30, 2010 increased to \$33.5 million from \$29.9 million in the comparable period in 2009. For the nine months ended September 30, 2010, income tax increased to \$102.3 million from \$85.6 million. The increases for the three and nine months ended September 30, 2010 are 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 32.6% and 36.1% for the three and nine months ended September 30, 2010, respectively, from 37.7% and 41.9% in the comparable 2009 periods. The decrease in the effective income tax rate is partially attributable to lower state income taxes and the impacts of the noncontrolling interests on our consolidated limited partnerships and limited liability companies assumed with the HealthTronics acquisition, which are not taxable to Endo and favorably impacted the three and nine month periods ended September 30, 2010 by \$5.1 million. These decreases were partially offset in the three-months ended September 30, 2010 by an increase in non-deductible transaction costs which unfavorably impacted tax expense by \$2.8 million, compared to \$0 in the prior year period and the absence of \$3.4 million of a credit relating to gains on contingent consideration. In addition, the 2010 effective tax rate was slightly impacted due to the absence of the research and development tax credit benefit which is not effective as of September 30, 2010.

**Net Income Attributable to Noncontrolling Interests**

Net income attributable to noncontrolling interests for the three and nine month periods ended September 30, 2010 increased to \$15.3 million due primarily to the acquisition of HealthTronics during the third quarter ended September 30, 2010 and their related non wholly-owned consolidated partnerships and limited liability companies that we assumed with the acquisition.

**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 Lidoderm®, Opana® ER and Voltaren® 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 nine months of royalties on the 2010 net sales of Opana® ER as well as three months of amortization expense associated with the Penwest acquisition, the consolidation of six months of HealthTronics results, 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



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

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, licenses, milestone payments, capital expenditures and debt service payments. The Company continues to maintain a sufficient level of working capital, which was approximately \$808.9 million at September 30, 2010, increasing from \$808.4 million at December 31, 2009. Cash, cash equivalents and current marketable securities were approximately \$774.3 million at September 30, 2010 compared to \$733.7 million at December 31, 2009.

In 2010, we expect that sales of our currently marketed products and HealthTronics device and services will allow us to continue to generate positive cash flow from operations. 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, general corporate expenses, the payment of contractual obligations, including scheduled interest payments on our Convertible Notes, principal and interest payments on the remaining \$57.0 million of Non-recourse Notes expected in November 2010, and any regulatory and/or sales milestones that may become due. As a result of our recently announced acquisition of Qualitest Pharmaceuticals, we are contemplating incurring up to \$400 million of additional long-term debt and drawing up to \$300 million from our existing revolving credit facility, discussed below, during the fourth quarter of 2010 to finance the acquisition. Additionally, we may refinance existing debt or debt commitments, incur additional debt or issue equity or convertible securities 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.

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 new indebtedness and our revolver, 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.

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. We are currently contemplating increasing the size of the facility as well as extending its term. The Credit Facility is available for letters of credit, working capital and general corporate purposes. The Credit Facility was amended on October 25, 2010 to permit up to \$500 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 and the subsidiary guarantors. 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 accrue interest at 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. Pursuant to the existing share repurchase program, we purchased approximately 2.5 million shares of our common stock during the nine-month period ended September 30, 2010 totaling \$59.0 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 September 30, 2010, \$17.5 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 September 30, 2010 and December 31, 2009 (in thousands):

	Underlying Credit Rating(1)					Total
	AAA	A	B2	Ba2	Baa3	
<b>As of September 30, 2010:</b>						
<i>Underlying security:</i>						
Student loans	\$ 17,505	\$	\$	\$	\$	\$ 17,505
<i>Total auction-rate securities included in long-term marketable securities</i>	\$ 17,505	\$	\$	\$	\$	\$ 17,505
<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. During the nine months ended September 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.

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

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 September 30, 2010, the yields on our long-term auction-rate securities ranged from 0.50% to 0.60%. These yields represent the predetermined maximum reset rates that occur upon auction failures according to the specific terms within each security's prospectus. As of September 30, 2010, the weighted average yield for our long-term auction-rate securities was 0.55%. Total interest recognized on our auction-rate securities during the nine-months ended September 30, 2010, and 2009 was \$0.6 million and \$2.0 million, respectively. The issuers have been making interest payments promptly.

At September 30, 2010, the fair value of our auction-rate securities, as determined by applying the above described discount rate adjustment technique, was approximately \$17.5 million, representing a seven percent (7%), or \$1.3 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 September 30, 2010, the resultant discount to the original purchase price or par value would have been \$1.0 million and \$1.6 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 \$808.9 million as of September 30, 2010 from \$808.4 million as of December 31, 2009. The components of our working capital as of September 30, 2010 and December 31, 2009 are below:

	September 30, 2010	December 31, 2009
Total current assets	\$ 1,410,697	\$ 1,280,581
Less: Total current liabilities	(601,770)	(472,180)
<b>Working capital</b>	<b>\$ 808,927</b>	<b>\$ 808,401</b>

Working capital increased primarily due to the operational results and consolidating impacts of both HealthTronics and Penwest as well as the impacts from increased revenues as compared to the prior year. In addition, the sale of \$230.3 million in auction-rate securities, including \$205.0 million which were non-current assets as of December 31, 2009 had favorable impacts on working capital. These increases were largely offset by our cash used to acquire Penwest and HealthTronics, including our \$40 million payment to retire the HealthTronics senior credit facility. Additionally, we had negative impacts on working capital related to cash outflows of \$59.0 million for share repurchases and \$11.3 million for capital expenditures during the nine months ended September 30, 2010.

The following table summarizes our statement of cash flows and liquidity for the nine months ended September 30, 2010 and 2009 (in thousands):

	Nine Months Ended September 30,	
	2010	2009
Net cash flow provided by (used in):		
Operating activities	\$ 282,984	\$ 219,015
Investing activities	(115,448)	(425,449)
Financing activities	(101,923)	(112,506)
Net increase (decrease) in cash and cash equivalents	65,613	(318,940)
Cash and cash equivalents, beginning of period	708,462	775,693
Cash and cash equivalents, end of period	\$ 774,075	\$ 456,753
Current ratio	2.3:1	1.9:1
Days sales outstanding	47	47

**Net Cash Provided by Operating Activities.** Net cash provided by operating activities was \$283.0 million for the nine months ended September 30, 2010 compared to \$219.0 million for the nine months ended September 30, 2009. Significant components of our operating cash flows for the nine months ended September 30, 2010 and 2009 are as follows:

	Nine Months Ended September 30,	
	2010	2009
<b>Cash Flow Data-Operating Activities:</b>		
Net income	\$ 181,287	\$ 118,488
Depreciation and amortization	69,859	56,482
Stock-based compensation	16,753	14,626
Change in fair value of contingent consideration	2,150	3,240
Impairment of other intangible assets	13,000	
Loss on auction-rate securities rights	15,659	7,641
Unrealized gain on trading securities	(15,420)	(9,646)
Gain on extinguishment of debt		(4,025)
Changes in assets and liabilities which (used) provided cash:	(4,470)	48,730
Other, net	4,166	(16,521)
 Net cash provided by operating activities	 \$ 282,984	 \$ 219,015

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 partially offset by the transaction costs of \$29.2 million to fund the HealthTronics and Penwest acquisitions compared to \$38.0 million in 2009 for Indevus.

**Net Cash Used in Investing Activities.** Net cash used in investing activities was \$115.4 million for the nine months ended September 30, 2010 compared to net cash used in investing activities of \$425.4 million during the same period of 2009. The change is primarily related to the proceeds received during 2010 from the \$230.9 million in sales of our auction-rate and available for sale securities compared to \$9.0 million in the prior year. Additionally, cash used in acquisitions, net, including the funding of the acquisition-related escrow pursuant to the terms of the Avede Contingent Cash Consideration Agreement exceeded the cash used for acquisitions in 2010 by \$92.0 million.

**Net Cash Used in Financing Activities.** Net cash used in financing activities was \$101.9 million for the nine months ended September 30, 2010 compared to net cash used in financing activities of \$112.5 million during the nine months ended September 30, 2009. The change to cash used in financing activities was primarily a result of the Company's share repurchase of \$59.0 million during the nine months ended September 30, 2010 as well as \$40 million in principal payments in July of 2010 to retire the HealthTronics Senior Credit Facility. Additionally, during the first nine months of 2010, the exercise of equity awards provided \$8.7 million of cash flows from financing activities compared to \$7.4 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.

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

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

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 12 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 8, and Note 12 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.

Sanctura XR® (trospium chloride extended release capsules) is a 60 mg, once-daily formulation of Sanctura®, 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® is currently promoted in the U.S. by Allergan Inc. and by Madaus AG in Europe.

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

Vantas® (histrelin) was launched in the U.S. in November 2004. Vantas® 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

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

advanced prostate cancer. The product utilizes our patented Hydron® Polymer Technology that allows for a controlled delivery of medicine over a 12-month period. In November 2005, Vantas® 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® was approved in Thailand, Singapore, and Malaysia and approval is pending in Taiwan, Korea, Hong Kong and China. Additionally, Vantas® received approval in Argentina in January 2007 and is currently being marketed in that country.

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

Hydron® Implant is a subcutaneous, retrievable, non-biodegradable, hydrogel reservoir drug delivery device. The Hydron® Implant is designed to provide sustained release of a broad spectrum of drugs continuously, at constant, predetermined rates. The Hydron® 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® and Supprelin® LA.

Valstar® (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®, 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® and in February 2009 obtained FDA approval of its sNDA for Valstar®. In September 2009, we launched Valstar® 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 September 30, 2010, primary development products included the following from the Indevus acquisition:

Aveed™ (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™ had historically been referred to as Nebido®. On May 6, 2009, we received notice from the FDA that Nebido® was unacceptable as a proprietary name for testosterone undecanoate. In August 2009, we received approval from FDA to use the name Aveed™. 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™ 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™ intramuscular injection. On December 2, 2009, we received a complete response letter from the FDA regarding Aveed™ 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.

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

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

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):

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

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>

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

Goodwill	\$ 121,455
Net assets acquired	\$ 540,894

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:

	Valuation (in millions)	Amortization Period (in years)
<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
Supprelin <sup>®</sup> LA	124.0	10
Other	1.0	4
<b>Total</b>	<b>\$ 277.0</b>	<b>11</b>
<b>Total other intangible assets</b>	<b>\$ 532.9</b>	

- (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.
- (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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> Polymer Technology is currently used in the following products: Vantas<sup>®</sup>, Supprelin<sup>®</sup> LA and octreotide. Thus, we derived the hypothetical royalty income from the projected revenues of those drugs. The fair value of the Hydron<sup>®</sup> 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<sup>®</sup> 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.

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

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 September 30, 2010 and December 31, 2009, the fair value of the contingent consideration is \$60.6 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> 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<sup>TM</sup> Contingent Cash Consideration Agreement.

Further, in the event that the Aveed<sup>TM</sup> Without Label approval is received and subsequently, Endo and its subsidiaries publicly report audited financial statements which reflect cumulative net sales of Aveed<sup>TM</sup> 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<sup>TM</sup> (Aveed<sup>TM</sup> 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<sup>TM</sup> Net Sales Event does not occur prior to the fifth anniversary of the date of the first commercial sale of Aveed<sup>TM</sup> then the Company will not pay, and former Indevus stockholders will not receive, any additional amounts under the Aveed<sup>TM</sup> Contingent Cash Consideration Agreement.

The range of the undiscounted amounts the Company could pay under the Aveed<sup>TM</sup> Contingent Cash Consideration Agreement is between \$0 and approximately \$175 million. The fair value of the contractual obligation to pay the Aveed<sup>TM</sup> contingent consideration recognized on the Acquisition Date was \$133.1 million. We determined the fair value of the obligation to pay the Aveed<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> With Label approval, (2) obtaining an Aveed<sup>TM</sup> 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<sup>TM</sup> should the Aveed<sup>TM</sup> Without Label approval be obtained. The fourth scenario is Aveed<sup>TM</sup> 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<sup>TM</sup>. 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, the results of which could materially impact the fair value of the Aveed<sup>TM</sup> contingent consideration liability due to the potential to pay in the range of \$0 to the maximum amount of \$175 million under the Aveed<sup>TM</sup> Contingent Cash Consideration Agreement. The fair value of the contractual obligation to pay the Aveed<sup>TM</sup> contingent consideration was \$7.3 million and \$7.5 million at September 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.

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

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 \$44.5 million and \$42.5 million at September 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 \$8.8 million and \$8.5 million at September 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 September 30, 2010, the aggregate fair values of the three acquisition-related contingent consideration liabilities increased by approximately \$2.2 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 for all outstanding shares of common stock, par value \$0.01 per share, 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 \$214.8 million in aggregate cash consideration for 100% of the outstanding shares. In July of 2010, Endo also paid \$40 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 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, which provides laboratory detection and diagnosis services to urologists throughout the United States. In addition, in July 2008, HealthTronics acquired Uropath LLC, now referred to as HealthTronics Laboratory Solutions, which managed pathology laboratories located at Uropath sites for physician practice groups located in Texas, Florida and Pennsylvania. Through HealthTronics Laboratory Solutions, 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 HealthTronics Laboratory Solutions 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.

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 deals with 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.

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

The operating results of HealthTronics from July 2, 2010 are included in the accompanying condensed consolidated statements of operations. The consolidated balance sheet as of September 30, 2010 reflects the acquisition of HealthTronics, effective July 2, 2010, the date the Company obtained control of HealthTronics.

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

	<b>July 2, 2010</b>
Cash and cash equivalents	\$ 6,769
Accounts receivable	33,111
Other receivables	1,006
Inventories	12,399
Prepaid expenses and other current assets	5,204
Deferred income taxes	43,737
Property and equipment	30,687
Other intangible assets	65,866
Other assets	5,210
<b>Total identifiable assets</b>	<b>\$ 203,989</b>
Accounts payable	\$ (3,084)
Accrued expenses	(11,551)
Deferred income taxes	(20,377)
Long-term debt	(44,751)
Other liabilities	(1,434)
<b>Total liabilities assumed</b>	<b>\$ (81,197)</b>
<b>Net identifiable assets acquired</b>	<b>\$ 122,792</b>
Noncontrolling interests	\$ (60,119)
Goodwill	\$ 152,170
<b>Net assets acquired</b>	<b>\$ 214,843</b>

The above estimated fair values of assets acquired and liabilities assumed are provisional and are based on the information that was available as of the HealthTronics Acquisition Date to estimate the fair value of assets acquired and liabilities assumed. The Company believes that information provides a reasonable basis for estimating the fair values but the Company is waiting for additional information necessary to finalize those amounts. Thus, the provisional measurements of fair value reflected are subject to change. Such changes could be significant. The Company expects to finalize the valuation and complete the purchase price allocation as soon as practicable but no later than one-year from the HealthTronics Acquisition Date.

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>
Endocare Developed Technology	\$ 46.3	10
HealthTronics Tradename	14.6	15
Service Contract	5.0	15
<b>Total</b>	<b>\$ 65.9</b>	<b>n/a</b>

The fair value of the developed technology assets 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

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

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 assumed to extend through the patent life of the purchased technology. The fair value of the HealthTronics Tradename 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 Tradename. Thus, we derived the hypothetical royalty income from the projected revenues of HealthTronics services.

HealthTronics has investments in partnerships and limited liability companies (LLCs) where we, as the general partner or managing member, exercise effective control. Accordingly, we consolidate various entities where we do not own 100% of the entity in accordance with the accounting consolidation principles. As a result, we are required to fair value the noncontrolling interests as part of our purchase price allocation. To calculate fair value, the Company used historical transactions which represented level 2 data points within the fair value hierarchy to calculate applicable multiples of each respective noncontrolling interest in the partnerships and LLCs.

The \$152.2 million of goodwill was assigned to our Devices and Services segment, which was established in July 2010 pursuant to our acquisition of HealthTronics. The goodwill recognized is attributable primarily to the strategic and synergistic opportunities across the HealthTronics network of urology partnerships, expected corporate synergies, the assembled workforce of HealthTronics and other factors. Approximately \$33.6 million of goodwill is expected to be deductible for income tax purposes.

The deferred tax assets of \$43.7 million are related primarily to federal net operating loss and credit carryforwards of HealthTronics and its subsidiaries. The deferred tax liabilities of \$20.4 million are related primarily to the difference between the book basis and tax basis of identifiable intangible assets.

The Company recognized \$15.3 million and \$20.0 million of HealthTronics acquisition-related costs that were expensed for the three and nine month periods ended September 30, 2010, 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):

	Acquisition-related Costs	
	Three Months Ended September 30, 2010	Nine Months Ended September 30, 2010
Investment bank fees, includes Endo and HealthTronics	\$ 5,230	\$ 5,230
Acceleration of outstanding HealthTronics stock-based compensation	7,924	7,924
Legal, separation and other costs	2,113	6,866
<b>Total</b>	<b>\$ 15,267</b>	<b>\$ 20,020</b>

The amounts of revenue and net loss of HealthTronics included in the Company's Condensed Consolidated Statements of Operations from the Acquisition date to September 30, 2010 are as follows (in thousands, except per share data):

	Revenue and Losses included in the Condensed Consolidated Statements of Operations from July 2, 2010 to September 30, 2010
Revenue	\$ 51,686
Net loss attributable to Endo Pharmaceuticals Holdings Inc.	\$ (460)
Basic and diluted loss per share	\$ (0.00)

The following supplemental pro forma information presents the financial results as if the acquisition of HealthTronics had occurred on January 1, 2010 and January 1, 2009 for the nine months ended September 30, 2010 and the three and nine months ended September 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, 2010 or January 1, 2009, nor are they indicative of any future results.

	Nine Months Ended September 30, 2010
<b>Pro forma consolidated results (in thousands, except per share data):</b>	
Revenue	\$ 1,303,728
Net income attributable to Endo Pharmaceuticals Holdings Inc.	\$ 171,180
Basic earnings per share	\$ 1.47
Diluted earnings per share	\$ 1.46



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

	Three Months Ended September 30, 2009	Nine Months Ended September 30, 2009
<b>Pro forma consolidated results (in thousands, except per share data):</b>		
Revenue	\$ 408,310	\$ 1,204,486
Net income attributable to Endo Pharmaceuticals Holdings Inc.	\$ 48,445	\$ 117,354
Basic earnings per share	\$ 0.41	\$ 1.00
Diluted earnings per share	\$ 0.41	\$ 1.00

These amounts have been calculated after applying the Company's accounting policies and adjusting the results of HealthTronics to reflect the additional depreciation and amortization that would have been charged assuming the fair value adjustments primarily to property, plant and equipment, and intangible assets, had been applied on January 1, 2010 and 2009, as applicable, together with the consequential tax effects.

#### *Acquisition of Penwest Pharmaceuticals Co.*

On September 20, 2010 (the Penwest Acquisition Date), the Company completed its tender offer for the outstanding shares of common stock of Penwest, at which time Penwest became a majority-owned subsidiary of the Company. The Penwest shares were purchased at a price of \$5.00 per share. Endo paid approximately \$147.6 million in aggregate cash consideration for the outstanding shares. Currently, Endo owns approximately 90.56% of Penwest's common stock. We anticipate closing the acquisition following the Penwest Shareholders meeting on November 4, 2010. Due to our obligation to close at a price of \$5 per share, we have reflected the remaining payment of approximately \$21 million to existing holders of outstanding Penwest shares and share equivalents within Accrued expenses on the condensed consolidated balance sheet as of September 30, 2010.

This transaction contributes to Endo's core Pain Management franchise and permits us to maximize the value of our Oxymorphone franchise.

The operating results of Penwest from September 20, 2010 are included in the accompanying condensed consolidated statements of operations. The consolidated balance sheet as of September 30, 2010 reflects the acquisition of Penwest, effective September 20, 2010, the date the Company obtained control of Penwest.

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

	<b>September 20, 2010</b>
Cash and cash equivalents	\$ 22,343
Marketable securities	800
Accounts receivable	10,885
Other receivables	132
Inventories	396
Prepaid expenses and other current assets	716
Deferred income taxes	27,175
Property and equipment	1,115
Other intangible assets	111,200
Other assets	2,104
<b>Total identifiable assets</b>	<b>\$ 176,866</b>
Accounts payable	\$ (229)
Income taxes payable	(347)
Penwest shareholder liability	(20,815)
Accrued expenses	(1,455)
Deferred income taxes	(39,951)
Other liabilities	(4,403)
<b>Total liabilities assumed</b>	<b>\$ (67,200)</b>
<b>Net identifiable assets acquired</b>	<b>\$ 109,666</b>
Goodwill	\$ 37,952
<b>Net assets acquired</b>	<b>\$ 147,618</b>

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

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

provides a reasonable basis for estimating the fair values but the Company is waiting for additional information necessary to finalize those amounts. Thus, the provisional measurements of fair value reflected are subject to change. Such changes could be significant. The Company expects to finalize the valuation and complete the purchase price allocation as soon as practicable but no later than one-year from the Penwest Acquisition Date.

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

	Valuation (in millions)	Amortization Period (in years)
<b>In Process Research &amp; Development:</b>		
Otsuka	\$ 5.5	n/a
A0001	1.6	n/a
Total	\$ 7.1	n/a
<b>Developed Technology:</b>		
Opana <sup>®</sup> ER	\$ 104.1	10
Total	\$ 104.1	n/a
Total other intangibles	\$ 111.2	n/a

The fair values of the in-process research and development assets and developed technology asset 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 the asset. The Company believes that the level and timing of cash flows appropriately reflect market participant assumptions. Cash flows were assumed to extend through the patent life of our purchased technology.

The \$38.0 million of goodwill was assigned to our Pharmaceutical Products segment. The goodwill recognized is attributable primarily to the control premium associated with our Oxymorphone Franchise and other factors. None of the goodwill is expected to be deductible for income tax purposes.

The deferred tax assets of \$27.2 million are related primarily to federal net operating loss and credit carryforwards of Penwest. The deferred tax liabilities of \$40.0 million are related primarily to the difference between the book basis and tax basis of the identifiable intangible assets.

The Company recognized \$6.9 million of Penwest acquisition-related costs that were expensed for both the three and nine month periods ended September 30, 2010, 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):

	Acquisition-related Costs Three and nine months Ended September 30, 2010	
Investment bank fees, includes Endo and Penwest	\$	3,660
Legal and other costs		3,255
Total	\$	6,915

Due to the pro forma impacts of eliminating the pre-existing intercompany royalties between Penwest and Endo, which were determined to be at fair value, we have not provided supplemental pro forma information as amounts are not material to the condensed consolidated statements of operations. We have also considered the impacts of Penwest, since the date we obtained a majority interest, on our condensed consolidated statement of operations and concluded amounts were not material.

*Qualitest Pharmaceuticals*

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

On September 28, 2010, Endo announced that it has entered into a definitive agreement to acquire Qualitest Pharmaceuticals (referred to as Qualitest), a leading, privately-held generics company in the U.S., for approximately \$1.2 billion in cash, of which approximately \$400 million will be utilized to extinguish existing indebtedness. Consummation of the acquisition is subject to certain conditions, including, among others, (i) absence of certain legal impediments to the consummation of the acquisition, (ii) the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, (iii) the accuracy of the representations and warranties made by each party, respectively, in each case, subject to certain material adverse effect qualifications, and (iv) compliance by each party with their respective obligations under the stock purchase agreement, in each case, subject to certain materiality qualifications.

The combined company will deliver more comprehensive healthcare solutions across its diversified businesses in Branded Pharmaceuticals, Generics, Devices & Services in key therapeutic areas including pain and urology. Qualitest, the sixth largest U.S. generics company as measured by prescriptions filled, is focused on cost competitive, high quality manufactured products with high barriers to entry. Endo believes Qualitest brings critical mass to Endo's current generics business, further diversifies its business lines and product offerings and enhances Endo's portfolio of pain management products.

Endo intends to finance the purchase with existing cash, by utilizing all or a portion of our existing \$300 million revolving credit facility and/or with the proceeds of one or more new financings, which may include a new term loan financing of up to \$400 million pursuant to financing commitments that have been previously obtained by Endo.

**Convertible Notes due 2009.** As discussed in Note 15 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 15 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 15 to the Condensed Consolidated Financial Statements in Part I, Item 1 of this Report, 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 8 of the Condensed Consolidated Financial Statements in Part I, Item 1 of this Report) for sales in the U.S. of Sanctura® and Sanctura XR®. 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.

Unless repaid or redeemed earlier, 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 September 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 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.

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.

During the third quarter of 2010, Endo notified the Holders of its intent to exercise its option to redeem the \$57 million of principal at 108% for approximately \$61.6 million (amount excludes accrued and unpaid interest) on November 5, 2010. Accordingly, we have reclassified the remaining carrying value of the Non-Recourse of approximately \$62.0 million to a current liability in our Condensed Consolidated Balance Sheet as of September 30, 2010. A gain will be recognized during the fourth quarter of 2010 when the Non-Recourse Notes are extinguished. The gain will not be material to the consolidated financial statements.

The Non-recourse Notes are subject to redemption at the option of Royalty Sub. The redemption price of the Non-recourse Notes is 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 12 of the Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.



**Expected Cash Requirements for Contractual Obligations.** The following table presents our expected cash requirements for contractual obligations for the remainder of 2010 as well as for each of the following years ending subsequent to December 31, 2010 (in thousands). It has been updated from our Annual Report on Form 10-K for the year ended December 31, 2009 to include contractual obligations assumed in connection with the HealthTronics and Penwest acquisitions:

Contractual Obligations	Total	Payment Due by Period					
		Three months ended December 31, 2010	2011	2012	2013	2014	Thereafter
Operating lease obligations	\$ 33,915	\$ 3,179	\$ 8,307	\$ 6,166	\$ 5,987	\$ 5,650	\$ 4,626
Convertible Senior Subordinated Notes	379,500						379,500
Interest payments on Convertible Senior Subordinated Notes	32,581	4,080	6,641	6,641	6,641	6,641	1,937
Non-recourse Notes	61,560	61,560					
Interest on Non-recourse Notes	2,280	2,280					
Minimum purchase commitments to Novartis	21,000		21,000				
Minimum purchase commitments to Teikoku(1)	64,000		32,000	32,000			
Minimum Voltaren® royalty obligations due to Novartis(2)	60,000		15,000	30,000	15,000		
Minimum advertising and promotion spend(3)	9,266	2,689	6,577				
Shire minimum payments(4)	1,500		1,500				
Other obligations(5)	16,546	6,144	5,293	2,656	559	435	1,459
<b>Total</b>	<b>\$ 682,148</b>	<b>\$ 79,932</b>	<b>\$ 96,318</b>	<b>\$ 77,463</b>	<b>\$ 28,187</b>	<b>\$ 12,726</b>	<b>\$ 387,522</b>

- (1) On April 24, 2007, we amended our Supply and Manufacturing Agreement with Teikoku Seiyaku Co., Ltd. / Teikoku Pharma USA, Inc. (collectively, "Teikoku") dated as of November 23, 1998, pursuant to which Teikoku manufactures and supplies Lidoderm® (lidocaine patch 5%) (referred to as the Product) to Endo. This amendment is referred to as the Amended Agreement. Under the terms of the Amended Agreement, Endo has agreed to purchase a minimum number of Lidoderm® patches per year through 2012, representing the noncancelable portion of the Amended Agreement. The minimum purchase requirement shall remain in effect subsequent to 2012, except that Endo has the right to terminate the Amended Agreement after 2012, if we fail to meet the annual minimum requirement. Teikoku has agreed to fix the supply price of Lidoderm® for a specified period of time after which the price will be adjusted at future dates certain based on a price index defined in the Amended Agreement. Since future price changes are unknown, for purposes of this contractual obligations table, all amounts scheduled above represent the minimum patch quantities at the price currently existing under the Amended Agreement. We will update the Teikoku purchase commitments upon future price changes made in accordance with the Amended Agreement.
- (2) Under the terms of the five-year Voltaren® Gel Agreement, Endo made an up-front 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 all as defined in the Voltaren® Gel Agreement. In addition, Endo has agreed to make certain guaranteed minimum annual royalty payments beginning in the fourth year of the Voltaren® Gel Agreement, subject to certain limitations as defined in the Voltaren® Gel Agreement. These guaranteed minimum royalties will be creditable against royalty payments on a Voltaren® Gel Agreement year basis such that Endo's obligation with respect to each Voltaren® Gel Agreement year is to pay the greater of (i) royalties payable based on annual net sales of the Licensed Product or (ii) the guaranteed minimum royalty for such Agreement year.
- (3) Under the terms of the five-year Voltaren® Gel Agreement, Endo has agreed to certain minimum advertising and promotional spending, subject to certain thresholds as defined in the Voltaren® Gel Agreement. Subsequent to June 30, 2010, the minimum advertising and promotional spending are determined based on a percentage of net sales of the licensed product.
- (4) In April 2008, Indevus entered into an agreement to terminate its manufacturing and supply agreement with Shire Pharmaceuticals Group plc (Shire) related to Vantas®. Under this termination agreement, Shire relinquished its right to receive royalties on net sales of Vantas® or a percentage of royalties and other consideration received in connection with a sublicense of Vantas® selling and marketing rights granted by Shire. The termination agreement provided for Indevus to pay Shire a total of \$5.0 million. The final remaining payment to be made to Shire of \$1.5 million is payable in January 2011.
- (5)

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

This amount is comprised of obligations assumed primarily in connection with our acquisition of HealthTronics and Penwest, including debt obligations of the HealthTronics partnerships and certain costs associated with Penwest's collaborative discovery agreements. Additionally, amounts include commitment fees on our credit facility.

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

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

As of September 30, 2010, our liability for unrecognized tax benefits amounted to \$36.3 million (including interest and penalties). Due to the nature and timing of the ultimate outcome of these uncertain tax positions, we cannot make a reasonably reliable estimate of the amount and period of related future payments. Therefore, our liability has been excluded from the above contractual obligations table.

**Fluctuations.** Our quarterly results have fluctuated in the past, and may continue to fluctuate. These fluctuations may be due to the timing of new product launches, purchasing patterns of our customers, market acceptance of our products, the impact of competitive products and pricing, 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.

**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.

### **Consolidation**

As a result of the HealthTronics acquisition, we now own interests in various partnerships and limited liability companies (LLCs). We consolidate our investments in these partnerships or LLCs, where we, as the general partner or managing member, exercise effective control, even though our ownership is less than 50%. The consolidated financial statements include our accounts, our wholly-owned subsidiaries, and entities more than 50% owned and limited partnerships or LLCs where we, as the general partner or managing member, exercise effective control, even though our ownership is less than 50%. The related agreements, where we have concluded we exercise effective control, provide us with broad operating decision-making powers. The other parties and limited partners do not participate in the management of the entity and do not have the substantial ability to remove us. Investment in entities in which our investment is less than 50% ownership and we do not have significant control are accounted for by the equity method if ownership is between 20% - 50%, or by the cost method if ownership is less than 20%. We have reviewed each of the underlying agreements and determined we have effective control; however, if it was determined this control did not exist; these investments would be reflected on the equity or cost method of accounting. Although this would change individual line items within our consolidated financial statements, it would have no effect on our net income and/or total stockholders' equity attributable to Endo shareholders.

### **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 September 30, 2010. Based on that evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective as of September 30, 2010.

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

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

## PART II

### OTHER INFORMATION

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

The disclosures under Note 12. 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 in light of our recent business development and related financing activities.

#### **We face intense competition, in particular from companies that develop rival products to our branded products and from companies with which we compete to acquire rights to intellectual property assets.**

The pharmaceutical industry is intensely competitive, and we face competition across the full range of our activities. If we fail to compete successfully in any of these areas, our business, results of operations, financial condition and cash flows could be adversely affected. Our competitors include many of the major brand name and generic manufacturers of pharmaceuticals, especially those doing business in the United States. In the market for branded pharmaceutical products, our competitors, including Abbott Laboratories, Johnson & Johnson, King Pharmaceuticals Inc., Cephalon, Inc., Pfizer, Inc., Purdue Pharma, L.P., Allergan, Inc., and Watson Pharmaceuticals Inc., vary depending on product category, dosage strength and drug-delivery systems. In addition to product safety, development and efficacy, other competitive factors in the branded pharmaceutical market include product quality and price, reputation, service and access to scientific and technical information. It is possible that developments by our competitors will make our products or technologies uncompetitive or obsolete. Because we are smaller than many of our national competitors in the branded pharmaceutical products sector, we may lack the financial and other resources needed to maintain our profit margins and market share in this sector.

The intensely competitive environment of the branded products business requires an ongoing, extensive search for medical and technological innovations and the ability to market products effectively, including the ability to communicate the effectiveness, safety and value of branded products for their intended uses to healthcare professionals in private practice, group practices and managed care organizations. There can be no assurance that we will be able to successfully develop medical or technological innovations or that we will be able to effectively market existing products or new products we develop.

Our branded products face competition from generic versions. Generic versions are generally significantly cheaper than the branded version, and, where available, may be required or encouraged in preference to the branded version under third party reimbursement programs, or substituted by pharmacies for branded versions by law. The entrance of generic competition to our branded products generally reduces our market share and adversely affects our profitability and cash flows. Generic competition with our branded products, including Percocet<sup>®</sup>, has had and will continue to have a material adverse effect on the net sales and profitability of our branded products.

Additionally, we compete to acquire the intellectual property assets that we require to continue to develop and broaden our product range. In addition to our in-house research and development efforts, we seek to acquire rights to new intellectual property through corporate acquisitions, asset acquisitions, licensing and joint venture arrangements. Competitors with greater resources may acquire assets that we seek, and even where we are successful, competition may increase the acquisition price of such assets or prevent us from capitalizing on such acquisitions or licensing opportunities. If we fail to compete successfully, our growth may be limited.

#### **If generic manufacturers use litigation and regulatory means to obtain approval for generic versions of our branded drugs, our sales may suffer.**

Under the Hatch-Waxman Act, the FDA can approve an ANDA, for a generic version of a branded drug, and what is referred to as a Section 505(b)(2) NDA, for a branded variation of an existing branded drug, without undertaking the clinical testing necessary to obtain approval to market a new drug. We refer to this process as the "ANDA process". In place of such clinical studies, an ANDA applicant usually

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

needs only to submit data demonstrating that its product has the same active ingredient(s) and is bioequivalent to the branded product, in addition to any data necessary to establish that any difference in strength, dosage form, inactive ingredients, or delivery mechanism does not result in different safety or efficacy profiles, as compared to the reference drug.



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

The Hatch-Waxman Act requires an applicant for a drug that relies, at least in part, on the patent of one of our branded drugs to notify us of their application and potential infringement of our patent rights. Upon receipt of this notice we have 45 days to bring a patent infringement suit in federal district court against the company seeking approval of a product covered by one of our patents. If such a suit is commenced, the FDA is generally prohibited from granting approval of the ANDA or Section 505(b)(2) NDA until the earliest of 30 months from the date the FDA accepted the application for filing, the conclusion of litigation in the generic's favor or expiration of the patent(s). If the litigation is resolved in favor of the applicant or the challenged patent expires during the 30-month stay period, the stay is lifted and the FDA may thereafter approve the application based on the standards for approval of ANDAs and Section 505(b)(2) NDAs. Frequently, the unpredictable nature and significant costs of patent litigation leads the parties to settle to remove this uncertainty. Settlement agreements between branded companies and generic applicants may allow, among other things, a generic product to enter the market prior to the expiration of any or all of the applicable patents covering the branded product, either through the introduction of an authorized generic or by providing a license to the patents in suit.

On January 15, 2010, the Company and the holders of the Lidoderm<sup>®</sup> NDA and relevant patent, Teikoku Seiyaku Co., Ltd. and Teikoku Pharma USA, Inc. (together, Teikoku) received a Paragraph IV Certification Notice under 21 U.S.C. 355(j) from Watson Laboratories, Inc. (Watson) advising of the filing of an Abbreviated New Drug Application (ANDA) for a generic version of Lidoderm<sup>®</sup> (lidocaine topical patch 5%). The Paragraph IV Certification Notice refers to U.S. Patent No. 5,827,529 (the 529 patent), which covers the formulation of Lidoderm<sup>®</sup>, 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 and Teikoku filed a lawsuit against Watson, in the United States District Court of the District of Delaware. Because the suit was filed within the 45-day period under the Hatch-Waxman Act for filing a patent infringement action, we believe that it triggered an automatic 30-month stay of approval under the Act, which would expire in June 2012. On March 4, 2010, Watson filed an Answer and Counterclaims, claiming the 529 patent is invalid or not infringed. Litigation is inherently uncertain and we cannot predict the outcome of our case against Watson. If Watson wins this lawsuit and is able to obtain FDA approval of its product, it may be able to launch its generic version of Lidoderm<sup>®</sup> prior to the 529 patent's expiration in 2015. Additionally, it is possible that another generic manufacturer would seek to launch a generic version of Lidoderm<sup>®</sup> and challenge the 529 patent. For a complete description of the related legal proceeding see Note 12 of the Condensed Consolidated Financial Statements included in Part I, Item 1 of this Report.

In October 2010, Teikoku obtained a license to U.S. Patent No. 5,741,510 (the 510 patent) and subsequently listed this patent in the FDA's Orange Book. The 510 patent expires in March 2014. The 510 patent is currently the subject of litigation in the United States District Court for the Eastern District of Texas (*LecTec Corporation v. Chattem, Inc., et al.*, Civil Action No. 5:08-CV-00130-DF), and although neither the Company nor Teikoku is a party to that litigation, if the litigation is decided in a manner adverse to the 510 patent (i.e., the patent is found invalid), the 510 patent may be of limited utility to us in the future in preventing the introduction of generic versions of Lidoderm<sup>®</sup>. Likewise, if Watson or any other generic manufacturer certifies against the 510 patent and subsequently succeeds in proving noninfringement, invalidity, or unenforceability of the 510 patent and is able to obtain FDA approval of its product, such manufacturer may be able to launch its generic version of Lidoderm<sup>®</sup> prior to the 510 patent's expiration in 2014. In addition to the 529 and 510 patents, the Company also holds a license from Hind Health Care, Inc. to U.S. Patent Nos. 5,411,738 and 5,601,838 (the Hind patents), both of which are listed in the FDA's Orange Book for Lidoderm<sup>®</sup>. The Hind patents will expire in May 2012. Watson submitted a Paragraph III certification with respect to the Hind patents, which indicated that it would not introduce its generic Lidoderm<sup>®</sup> product prior to the expiration of those patents. It is possible, however, that another generic manufacturer seeking approval of a generic version of Lidoderm<sup>®</sup> could challenge the Hind patents.

Notwithstanding the foregoing patent litigation, even if Watson or any other generic manufacturer were to be successful with respect to the 510 and 529 patents, no generic version of Lidoderm<sup>®</sup> can be marketed without the approval of the FDA of the respective ANDA for a generic version of Lidoderm<sup>®</sup>. In December 2006, the Division of Bioequivalence, Office of Generic Drugs, Center for Drug Evaluation and Research (referred to as OGD), issued draft guidance making recommendations regarding establishing bioequivalence with our patent-protected product, Lidoderm<sup>®</sup> (lidocaine topical patch 5%), pursuant to which a party could seek ANDA approval of a generic version of that product. In that draft guidance, OGD has recommended a bioequivalence study characterizing the pharmacokinetic profile of lidocaine as well as a skin irritation/sensitization study of any lidocaine-containing patch formulation. This recommendation deviates from our understanding of the applicable regulations and of OGD's past practices, which, for a topically acting product such as Lidoderm<sup>®</sup>, would require demonstration of bioequivalence through a comparative clinical equivalency study rather than through a pharmacokinetic study.

On December 19, 2006, we submitted a Citizen Petition to the FDA requesting that the FDA apply existing bioequivalence regulations to any ANDA seeking regulatory approval of a generic drug product that references Lidoderm<sup>®</sup>. We submitted an amendment to that filing in August 2007 in order to provide additional data. Our Citizen Petition emphasizes that the FDA's recommendation deviates from applicable regulations and OGD's past practices, both of which contemplate demonstration of bioequivalence for a topically acting product like Lidoderm<sup>®</sup> through a comparative clinical efficacy study. We believe blood levels of the active ingredient, lidocaine, cannot properly be used as the key measure in proving bioequivalence. To appropriately assess the efficacy and safety of any generic version of Lidoderm<sup>®</sup>, we believe that it is critical that the FDA require any ANDA applicant relying on Lidoderm<sup>®</sup> as its reference listed drug satisfy the regulations by conducting comparative clinical studies demonstrating (1) bioequivalence between the generic version and Lidoderm<sup>®</sup>, and (2) that the generic version produces the same local analgesic effect as Lidoderm<sup>®</sup> without producing a complete sensory block, in order to assure that the generic product has the same labeling, efficacy and safety profile as Lidoderm<sup>®</sup>. The FDA has not acted on our Citizen Petition, and it is unclear whether or not the FDA will agree with our position. In addition to this Petition, on September 28, 2007, we filed comments with the FDA regarding the draft guidance; those comments reiterated our position as set forth in the Citizen Petition, referencing the Citizen Petition and supporting data. The draft guidance remains available and has not been updated or revised since being issued.

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, business and regulatory avenues in defense of Lidoderm®, including enforcement of the product's intellectual property rights and approved labeling. However, there can be no assurance that our defense will be successful. Additionally, we cannot predict or determine the timing or outcome of the paragraph IV litigation discussed above but will explore all options as appropriate in the best interests of the Company.

We currently anticipate that Lidoderm will represent a decreasing percentage of our annual sales without taking into account any potential future business development transactions but including our pending acquisition of Qualitest. However, if a generic version of Lidoderm were introduced to the market before 2015, our revenues from Lidoderm would decrease significantly and, depending on the timing of such introduction and its effect on Lidoderm pricing, could have a material adverse effect on our business, results of operations, financial condition and cash flows as well as our stock price.

The Company is also aware of various ANDA filings containing Paragraph IV certifications under 21 U.S.C. Section 355(j) with respect to oxymorphone hydrochloride extended-release tablets. For a complete description of these and other legal proceedings see Note 12 of the Condensed Consolidated Financial Statements included in Part I, Item 1 of this Report.

**Patent litigation which is often time-consuming and expensive could have a material adverse effect on our business, results of operations, financial condition and cash flows.**

The discovery, trial and appeals process in patent litigation can take several years. Regardless of FDA approval, should we commence a lawsuit against a third party for patent infringement or should there be a lawsuit commenced against us with respect to any alleged patent infringement by us, whether because of the filing of an ANDA or otherwise, the cost of such litigation as well as the ultimate outcome of such litigation, if commenced, whether or not we are successful, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

**Most of our total revenues come from a small number of products.**

The following table displays our revenues by product category and as a percentage of total revenues for the years ended December 31, 2009 and the nine months ended September 30, 2010 (dollars in thousands):

	Nine Months Ended September 30, 2010		Twelve Months Ended December 31, 2009		Twelve Months Ended December 31, 2008		Twelve Months Ended December 31, 2007	
	\$	%	\$	%	\$	%	\$	%
Lidoderm®	\$ 574,960	48%	\$ 763,698	52	\$ 765,097	61	\$ 705,587	65
Opana® ER and Opana®	215,946	18	230,631	16	180,429	14	107,143	10
Percocet®	90,428	8	127,090	9	129,966	10	121,742	11
Voltaren® Gel	73,632	6	78,868	5	23,791	2		
Frova®	43,898	4	57,924	4	58,017	5	52,437	5
Other brands	63,879	5	68,635	5	10,904	1	11,065	1
<b>Total brands*</b>	<b>1,062,743</b>	<b>*88</b>	<b>1,326,846</b>	<b>91</b>	<b>1,168,204</b>	<b>93</b>	<b>997,974</b>	<b>92</b>
Total generics	80,991	7	124,731	9	92,332	7	87,634	8
Total devices and service revenue	51,686	4						
Total royalty and other revenue	9,619	1	9,264	1				
<b>Total revenues*</b>	<b>\$ 1,205,039</b>	<b>100</b>	<b>\$ 1,460,841</b>	<b>*100</b>	<b>\$ 1,260,536</b>	<b>100</b>	<b>\$ 1,085,608</b>	<b>100</b>

\* Total percentages may not sum due to rounding.

If we are unable to continue to market any of our products, if any of them were to lose market share, for example, as the result of the entry of new competitors, particularly from generic versions of branded drugs, or if the prices of any of these products were to decline significantly, our total revenues, profitability and cash flows would be materially adversely affected.



**Our ability to protect our proprietary technology, which is vital to our business, is uncertain.**

Our success, competitive position and amount of future income will depend in part on our ability to obtain patent protection relating to the technologies, processes and products we are currently developing and that we may develop in the future. Our policy is to seek patent protection and enforce the intellectual property rights we own and license. We cannot assure you that patent applications we submit and have submitted will result in patents being issued. If an advance is made that qualifies as a joint invention, the joint inventor or his or her employer may have rights in the invention. We cannot assure you that a third party will not infringe upon, design around or develop uses not covered by any patent issued or licensed to us or that these patents will otherwise be commercially viable. In this regard, the patent position of pharmaceutical compounds and compositions is particularly uncertain. Even issued patents may later be modified or revoked by the U.S. Patent and Trademark Office (PTO) or in legal proceedings. Moreover, we believe that obtaining foreign patents may be more difficult than obtaining domestic patents because of differences in patent laws and, accordingly, our patent position may be stronger in the United States than abroad. Foreign patents may be more difficult to protect and/or the remedies available may be less extensive than in the United States. Various countries limit the subject matter that can be patented and limit the ability of a patent owner to enforce patents in the medical field. This may limit our ability to obtain or utilize those patents internationally. Because unissued U.S. patent applications are maintained in secrecy for a period of eighteen months and U.S. patent applications filed prior to November 29, 2000 are not disclosed until such patents are issued, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first creator of the inventions covered by pending patent applications or the first to file patent applications on those inventions. Several drug companies and research and academic institutions have developed technologies, filed patent applications or received patents for technologies that may be related to our business. Others may file patent applications and may receive patents that may conflict with patents or patent applications we have obtained or licensed for our use, either by claiming the same methods or compounds or by claiming methods or compounds that could dominate those owned by or licensed to us. We cannot assure you that any of our pending patent applications will be allowed, or, if allowed, whether the scope of the claims allowed will be sufficient to protect our products. Litigation to establish the validity of patents, to defend against patent infringement claims of others and to assert patent infringement claims against others can be expensive and time-consuming even if the outcome is favorable to us. If the outcome is unfavorable to us, this could have a material adverse effect on our business. We have taken and may, in the future, take steps to enhance our patent protection, but we cannot assure you that these steps will be successful or that, if unsuccessful, our patent protection will be adequate.

We also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. We attempt to protect our proprietary technology in large part by confidentiality agreements with our employees, consultants and other contractors. We cannot assure you, however, that these agreements will not be breached, that we would have adequate remedies for any breach or that competitors will not know of, or independently discover, our trade secrets. We cannot assure you that others will not independently develop substantially equivalent proprietary information or be issued patents that may prevent the sale of our products or know-how or require licensing and the payment of significant fees or royalties by us in order to produce our products. Moreover, we cannot assure you that our technology does not infringe upon any valid claims of patents that other parties own.

In the future, if we were found to be infringing on a patent, we might have to seek a license to use the patented technology. We cannot assure you that, if required, we would be able to obtain such a license on terms acceptable to us, if at all. If a third party brought a legal action against us or our licensors, we could incur substantial costs in defending ourselves, and we cannot assure you that such an action would be resolved in our favor. If such a dispute were to be resolved against us, we could be subject to significant damages, and the testing, manufacture or sale of one or more of our technologies or proposed products, if developed, could be enjoined.

We cannot assure you as to the degree of protection any patents will afford, whether the PTO will issue patents or whether we will be able to avoid violating or infringing upon patents issued to others or that others will not manufacture and distribute our patented products upon expiration of the applicable patents. Despite the use of confidentiality agreements and non-compete agreements, which themselves may be of limited effectiveness, it may be difficult for us to protect our trade secrets.

**We may incur significant liability if it is determined that we are promoting or have in the past promoted the off-label use of drugs.**

Companies may not promote drugs for off-label uses that is, uses that are not described in the product's labeling and that differ from those approved by the FDA. Physicians may prescribe drug products for off-label uses, and such off-label uses are common across some medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the Federal Food, Drug and Cosmetics Act and FDA regulations restrict communications on the subject of off-label uses of drug products by pharmaceutical companies. The Office of Inspector General of the Department of Health and Human Services (referred to as OIG), the FDA, and the Department of Justice (referred to as DOJ) all actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including criminal fines and penalties, civil fines, penalties and damages, exclusion from federal healthcare programs and other collateral administrative consequences. Conduct giving rise to such liability could also form the basis for private civil litigation by third-party payors or other persons allegedly harmed by such conduct.

Notwithstanding the regulatory restrictions on off-label promotion, the OIG, the FDA, and DOJ allow companies to engage in some forms of truthful, non-misleading, and non-promotional speech concerning their products. The Company has endeavored to establish extensive compliance programs in order to instruct employees as to how to comply with the relevant legal requirements. Nonetheless, the OIG or the FDA may take the position that the Company is not in compliance with such requirements, and, if such non-compliance is proven, we may be subject to significant liability, including civil and administrative remedies, as well as criminal sanctions. In addition, management's attention could be diverted from our business operations and our reputation could be damaged.

In January 2007, we received a subpoena issued by the OIG. The subpoena requests documents relating to Lidoderm® (lidocaine patch 5%) that are focused primarily on the sale, marketing and promotion of Lidoderm®. We are cooperating with the government. At this time, we cannot predict or determine the outcome of the above matter or reasonably estimate the amount or range of amounts of fines or penalties that might result from a settlement or an adverse outcome. However, should the government choose to initiate action against us, we could face substantial penalties, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

**We have significant goodwill and other intangible assets. Consequently, potential impairment of goodwill and other intangibles may significantly impact our profitability.**

Goodwill and other intangibles represent a significant portion of our assets. As of September 30, 2010, goodwill and other intangibles comprised approximately 44% of our total assets. Goodwill and other intangible assets are subject to an impairment analysis whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Additionally, goodwill and indefinite-lived assets are subject to an impairment test at least annually.

Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. As a result of the significance of goodwill and other intangible assets, our results of operations and financial position in a future period could be negatively impacted should an impairment of goodwill or other intangible assets occur.

**We may incur liability if our continuing medical or health education programs and/or product promotions are determined, or are perceived, to be inconsistent with regulatory guidelines.**

The FDA provides guidelines with respect to appropriate promotion and continuing medical and health education activities. Although we endeavor to follow these guidelines, should it be determined that we have not appropriately followed these guidelines, the government may initiate an action against us which may result in significant liability, including civil and administrative remedies as well as criminal sanctions. Such penalties could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, management's attention could be diverted and our reputation could be damaged.

**We are subject to various regulations pertaining to the marketing of our products and services.**

We are subject to various federal and state laws pertaining to healthcare fraud and abuse, including prohibitions on the offer of payment or acceptance of kickbacks or other remuneration for the purchase of our products and services. Specifically, these anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, or pay any remuneration in exchange for purchasing, leasing or ordering any service or items including the purchase or prescription of a particular drug for which payment may be made under a federal healthcare program. Because of the sweeping language of the federal anti-kickback statute, many potentially beneficial business arrangements would be prohibited if the statute were strictly applied. To avoid this outcome, the U.S. Department of Health and Human Services has published regulations known as "safe harbors" that identify exceptions or exemptions to the statute's prohibitions. Arrangements that do not fit within the safe harbors are not automatically deemed to be illegal, but must be evaluated on a case-by-case basis for compliance with the statute. We seek to comply with anti-kickback statutes and to fit within one of the defined "safe harbors"; we are unaware of any violations of these laws. However, due to the breadth of the statutory provisions and the absence of uniform guidance in the form of regulations or court decisions, there can be no assurance that our practices will not be challenged under anti-kickback or similar laws. Violations of such restrictions may be punishable by civil and/or criminal sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from U.S. federal healthcare programs (including Medicaid and Medicare). Any such violations could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In addition, the FDA has the authority to regulate the claims we make in marketing our prescription drug products to ensure that such claims are true, not misleading, supported by scientific evidence and consistent with the labeled use of the drug. Failure to comply with FDA requirements in this regard could result in, among other things, suspensions of approvals, seizures or recalls of products, injunctions against a product's manufacture, distribution, sales and marketing, operating restrictions, civil penalties and criminal prosecutions.





**Many of our core products contain narcotic ingredients. As a result of reports of misuse or abuse of prescription narcotics, the sale of such drugs may be subject to new regulation, including the development and implementation of REMS, which may prove difficult or expensive to comply with, and we and other pharmaceutical companies may face lawsuits.**

Many of our core products contain narcotic ingredients. Misuse or abuse of such drugs can lead to physical or other harm. For example, in the past, reportedly widespread misuse or abuse of OxyContin®, a product of Purdue Pharma L.P., or Purdue, containing the narcotic oxycodone, resulted in the strengthening of warnings on its labeling. In addition, we believe that Purdue, the manufacturer of OxyContin®, faces or did face numerous lawsuits, including class action lawsuits, related to OxyContin® misuse or abuse. We may be subject to litigation similar to the OxyContin® suits related to any narcotic-containing product that we market.

The FDA or the DEA may impose new regulations concerning the manufacture, storage, transportation and sale of prescription narcotics. Such regulations may include new labeling requirements, the development and implementation of formal Risk Evaluation and Mitigation Strategy (REMS), restrictions on prescription and sale of these products and mandatory reformulation of our products in order to make abuse more difficult. On September 27, 2007, Congress passed legislation authorizing the FDA to require companies to undertake post-approval studies in order to assess known or signaled potential serious safety risks and to make any labeling changes necessary to address safety risks. Congress also empowered the FDA to require companies to formulate REMS to ensure a drug's benefits outweigh its risks. In addition, state health departments and boards of pharmacy have authority to regulate distribution and may modify their regulations with respect to prescription narcotics in an attempt to curb abuse. In either case, any such new regulations or requirements may be difficult and expensive for us to comply with, may delay our introduction of new products, may adversely affect our total revenues and may have a material adverse effect on our business, results of operations, financial condition and cash flows.

**The pharmaceutical industry is heavily regulated, which creates uncertainty about our ability to bring new products to market and imposes substantial compliance costs on our business.**

Federal, state and local governmental authorities in the United States, principally the FDA, impose substantial requirements on the development, manufacture, labeling, sale, distribution, marketing, advertising, promotion and introduction of therapeutic pharmaceutical products through lengthy and detailed laboratory and clinical testing and other costly and time-consuming procedures. The submission of an NDA or ANDA to the FDA alone does not guarantee that the FDA will grant approval to market the product. Satisfaction of FDA requirements typically takes a number of years, varies substantially based upon the type, complexity and novelty of the pharmaceutical product and is subject to uncertainty. The NDA approval process for a new product varies in time, generally requiring a minimum of 10 months, but could also take several years from the date of application. The timing for the ANDA approval process for generic products is difficult to estimate and can vary significantly.

NDA approvals, if granted, may not include all uses for which a company may seek to market a product. The FDA actively enforces regulations prohibiting marketing of products for unapproved uses. The FDA also requires companies to undertake post-approval surveillance regarding their drug products and to report any adverse events. Failure to comply with applicable regulatory requirements in this regard can result in, among other things, suspensions or withdrawals of approvals, seizures or recalls of products, injunctions against a product's manufacture, distribution, sales and marketing, operating restrictions, civil penalties and criminal prosecutions. Furthermore, changes in existing regulations or the adoption of new regulations could prevent us from obtaining, or affect the timing of, future regulatory approvals. The effect of government regulation may be to delay marketing of our new products for a considerable period of time, to impose costly procedures upon our activities and to furnish a competitive advantage to larger companies that compete against us.

We cannot assure you that the FDA or other regulatory agencies will approve any products developed by us, on a timely basis, if at all, or, if granted, that approval will not entail limiting the indicated uses for which we may market the product, which could limit the potential market for any of these products.

The current FDA standards of approving new pharmaceutical products are more stringent than those that were applied in the past. These standards were not applied to many established products currently on the market, including certain opioid products. As a result, the FDA does not have as extensive safety databases on these products as on some products developed more recently. Accordingly, we believe the FDA has recently expressed an intention to develop such databases for certain of these products, including many opioids.

In particular, the FDA has expressed interest in specific chemical structures that may be present as impurities in a number of opioid narcotic active pharmaceutical ingredients, such as oxycodone, which based on certain structural characteristics and laboratory tests may indicate the potential for having mutagenic effects.

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

More stringent controls of the levels of these impurities have been required and may continue to be required for FDA approval of products containing these impurities. Also, labeling revisions, formulation or manufacturing changes and/or product modifications may be necessary for new or existing products containing such impurities. The FDA's more stringent requirements together with any additional testing or remedial measures that may be necessary could result in increased costs for, or delays in, obtaining approval for certain of our products in development. Although we do not believe that the FDA would seek to remove a currently marketed product from the market unless such mutagenic effects are believed to indicate a significant risk to patient health, we cannot make any such assurance.

In addition, on September 27, 2007, through passage of the Food and Drug Administration Amendments Act of 2007, Congress enacted legislation authorizing the FDA to require companies to undertake post-approval studies in order to assess known or signaled potential serious safety risks and to make any labeling changes necessary to address safety risks. Congress also empowered the FDA to require companies to formulate REMS to ensure a drug's benefits outweigh its risks.

The FDA and the DEA have important and complementary responsibilities with respect to our business. The FDA administers an application and post-approval monitoring process to assure that marketed products are safe, effective and consistently of uniform, high quality. The DEA administers registration, drug allotment and accountability systems to assure against loss and diversion of controlled substances. Both agencies have trained investigators that routinely, or for cause, conduct inspections, and both have authority to enforce their statutory authority and regulations using administrative remedies as well as civil and criminal sanctions.

The FDA regulates the facilities and procedures used to manufacture pharmaceutical products in the United States or for sale in the United States. Such facilities must be registered with the FDA and all products made in such facilities must be manufactured in accordance with current good manufacturing practices, or cGMP, regulations enforced by the FDA. Compliance with cGMP regulations requires the dedication of substantial resources and requires significant expenditures. The FDA periodically inspects both our third party and owned manufacturing facilities and procedures to assure compliance. The FDA may cause a recall or withdrawal of product approvals if regulatory standards are not maintained. The FDA approval to manufacture a drug is site-specific. In the event an approved manufacturing facility for a particular drug is required by the FDA to cease or curtail operations, or otherwise becomes inoperable, or the manufacturing contract applicable thereto terminates, obtaining the required FDA approval to manufacture such drug at a different manufacturing site could result in production delays, which could adversely affect our business, results of operations, financial condition and cash flow.

The stringent DEA regulations on our use of controlled substances include restrictions on their use in research, manufacture, distribution and storage. A breach of these regulations could result in imposition of civil penalties, refusal to renew or action to revoke necessary registrations, or other restrictions on operations involving controlled substances. See also The DEA limits the availability of the active ingredients used in many of our current products and products in development and, as a result, our procurement quota may not be sufficient to meet commercial demand or complete clinical trials.

We cannot determine what effect changes in regulations or legal interpretations, when and if promulgated, may have on our business in the future. Changes could, among other things, require different labeling, monitoring of patients or physicians, education programs for patients or physicians, or curtailment of supplies or limitations on distribution. These changes, or others required by the FDA could have an adverse effect on the sales of these products. On February 6, 2009, the FDA sent letters to manufacturers of certain opioid drug products, indicating that these drugs will be required to have a REMS to ensure that the benefits of the drugs continue to outweigh the risks. The FDA has authority to require a REMS under the FDAAA when necessary to address whether the benefits of these products continue to outweigh the risks. On September 27, 2007, Congress enacted new requirements for testing drug products in children, which may increase the time and cost necessary for new drug development. The evolving and complex nature of regulatory requirements, the broad authority and discretion of the FDA and the generally high level of regulatory oversight results in a continuing possibility that from time to time, we will be adversely affected by regulatory actions despite ongoing efforts and commitment to achieve and maintain full compliance with all regulatory requirements.

**Implementation by the FDA of certain specific public advisory committee recommendations regarding acetaminophen use in both over-the-counter and prescription products could have an adverse material impact on our net sales of Percocet® and Endocet®.**

The FDA held a public advisory committee meeting in June 2009 to discuss acetaminophen use in both over-the-counter and prescription products, the potential for liver injury, and potential interventions to reduce the incidence of liver injury. The panel's recommendations included the banning of certain prescription painkillers which combine acetaminophen with an opiate narcotic, and lowering the maximum dose of over-the-counter painkillers containing acetaminophen. These recommendations were made following the release in May 2009 of a FDA report that found severe liver damage, and even death, can result from a lack of consumer awareness that acetaminophen can cause such injury. These recommendations are advisory in nature and the FDA is not bound to follow these recommendations. At this time, the FDA has not made any decisions regarding acetaminophen-containing products, but has stated that it is reviewing the recommendations of the advisory committee, all available safety and efficacy data as well as public input before making a final decision. Therefore it is unclear what actions the FDA may take in response to the panel's recommendations. Implementation by the FDA of certain specific panel recommendations could result in (1) a black box warning on the labels of prescription acetaminophen combination products or (2) the removal of several products from the marketplace including certain, or even all, strengths of Percocet® and Endocet®. The recommendation does not change the safety and efficacy of Percocet® and Endocet®, which remain FDA approved. Endo remains committed to working with the FDA so that these products are prescribed in the best interest of patients, and we will continue to closely monitor this issue. Any action taken by the FDA to implement certain of the recommendations of the panel, or take other measures to address concerns raised by the panel, could have a material adverse effect on our business, financial condition, results of operations and cash flows.



**Timing and results of clinical trials to demonstrate the safety and efficacy of products as well as the FDA's approval of products are uncertain.**

Before obtaining regulatory approvals for the sale of any of our products, other than generic products, we must demonstrate through preclinical studies and clinical trials that the product is safe and effective for each intended use. Preclinical and clinical studies may fail to demonstrate the safety and effectiveness of a product. Even promising results from preclinical and early clinical studies do not always accurately predict results in later, large scale trials. A failure to demonstrate safety and efficacy would result in our failure to obtain regulatory approvals.

The rate of patient enrollment sometimes delays completion of clinical studies. There is substantial competition to enroll patients in clinical trials and such competition has delayed clinical development of our products in the past. Delays in planned patient enrollment can result in increased development costs and delays in regulatory approval. In addition, we rely on collaboration partners that may control or make changes in trial protocol and design enhancements that may also delay clinical trials. We cannot assure you that we will not experience delays or undesired results in these or any other of our clinical trials.

We cannot assure you that the FDA or other regulatory agencies will approve any products developed by us, on a timely basis, if at all, or, if granted, that such approval will not subject the marketing of our products to certain limits on indicated use. Any limitation on use imposed by the FDA or delay in or failure to obtain FDA approvals of products developed by us would adversely affect the marketing of these products and our ability to generate product revenue, as well as adversely affect the price of our common stock.

Before obtaining regulatory approvals for certain generic products, we must conduct limited clinical or other trials to show comparability to the branded products. A failure to obtain satisfactory results in these trials would prevent us from obtaining required regulatory approvals.

**The success of our acquisition and licensing strategy is subject to uncertainty and any completed acquisitions or licenses may reduce our earnings, be difficult to integrate, not perform as expected or require us to obtain additional financing.**

We regularly evaluate selective acquisitions and look to continue to enhance our product line by acquiring rights to additional products and compounds. Such acquisitions may be carried out through the purchase of assets, joint ventures and licenses or by acquiring other companies. However, we cannot assure you that we will be able to complete acquisitions that meet our target criteria on satisfactory terms, if at all. In particular, we may not be able to identify suitable acquisition candidates, and we may have to compete for acquisition candidates.

Our competitors may have greater resources than us and therefore be better able to complete acquisitions or may cause the ultimate price we pay for acquisitions to increase. If we fail to achieve our acquisition goals, our growth may be limited.

Acquisitions, such as the recent Indevus, HealthTronics and Penwest acquisitions, may expose us to additional risks and may have a material adverse effect on our profitability and cash flows. Any acquisitions we make may:

fail to accomplish our strategic objectives;

not be successfully combined with our operations;

not perform as expected; and

expose us to cross border risks.

In addition, based on current acquisition prices in the pharmaceutical industry, acquisitions could decrease our net income per share and add significant intangible assets and related amortization or impairment charges. Our acquisition strategy may require us to obtain additional debt or equity financing, resulting in leverage, increased debt obligations as compared to equity, or dilution of ownership. We may not be able to finance acquisitions on terms satisfactory to us.

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

Further, if we are unable to maintain, on commercially reasonable terms, product, compound or other licenses that we have acquired, our ability to develop or commercially exploit our products may be inhibited.

**Our growth and development will depend on developing, commercializing and marketing new products, including both our own products and those developed with our collaboration partners. If we do not do so successfully, our growth and development will be impaired.**

Our future revenues and profitability will depend, to a significant extent, upon our ability to successfully commercialize new branded and generic pharmaceutical products in a timely manner. As a result, we must continually develop, test and manufacture new products, and these new products must meet regulatory standards and receive requisite regulatory approvals. Products we are currently developing may or may not receive the regulatory approvals necessary for us to market them. Furthermore, the development and commercialization process is time-consuming and costly, and we cannot assure you that any of our products, if and when developed and approved, can be successfully commercialized. Some of our collaboration partners may decide to make substantial changes to a product's formulation or design, may experience financial difficulties or have limited financial resources, any of which may delay the development, commercialization and/or marketing of new products. In addition, if a co-developer on a new product terminates our collaboration agreement or does not perform under the agreement, we may experience delays and, possibly, additional costs in developing and marketing that product.

We conduct research and development primarily to enable us to manufacture and market FDA-approved pharmaceuticals in accordance with FDA regulations. Much of our development effort is focused on technically difficult-to-formulate products and/or products that require advanced manufacturing technology. Typically, research expenses related to the development of innovative compounds and the filing of NDAs for these products are significantly greater than those expenses associated with ANDAs for generic products. As we continue to develop new products, our research expenses will likely increase. Because of the inherent risk associated with research and development efforts in our industry, particularly with respect to new drugs, our research and development expenditures may not result in the successful introduction of FDA approved new pharmaceutical products. Also, after we submit an NDA or ANDA, the FDA may require that we conduct additional studies, including, depending on the product, studies to assess the product's interaction with alcohol, and as a result, we may be unable to reasonably predict the total research and development costs to develop a particular product. Indeed, on September 27, 2007, Congress passed legislation authorizing the FDA to require companies to undertake post-approval studies in order to assess known or signaled potential serious safety risks and to make any labeling changes necessary to address safety risks. Congress also empowered the FDA to require companies to formulate REMS to ensure a drug's benefits outweigh its risks.

**We face intense competition from brand-name companies that sell or license their own generic versions of our generic products or seek to delay the introduction of our generic products.**

Brand-name pharmaceutical companies have taken aggressive steps to thwart competition from generic equivalents of their brand-name products. In particular, brand-name companies sell directly to the generics market or license their products for sale to the generics market through licensing arrangements or strategic alliances with generic pharmaceutical companies (so-called "authorized generics"). No significant regulatory approvals are currently required for a brand-name manufacturer to sell directly or through a third party to the generic market. Brand-name manufacturers do not face any other significant barriers to entry into such market. The introductions of these so-called "authorized generics" have had and may continue to have an adverse effect by reducing our market share and adversely affecting our profitability and cash flows.

In addition, brand-name companies continually seek new ways to delay generic introduction and decrease the impact of generic competition, such as filing new patents on drugs whose original patent protection is about to expire; filing an increasing number of patents that are more complex and costly to challenge; filing suits for patent infringement that automatically delay approval by the FDA; developing patented controlled release or other next generation products, which often reduces the demand for the generic version of the existing product for which we may be seeking approval; changing product claims and product labeling; developing and marketing as over-the-counter products those branded products that are about to face generic competition; or filing Citizens' Petitions with the FDA seeking restraints on our products or seeking to prevent them from coming to market. These strategies may increase the costs and risks associated with our efforts to introduce generic products and may delay or prevent such introduction altogether.

**We face intense competition from other manufacturers of generic versions of our generic products.**

Our generic products compete with branded products and with generic versions made by or for other manufacturers, such as Mallinckrodt Inc. and Watson Pharmaceuticals, Inc. When additional versions of one of our generic products enter the market, we generally lose market share and our selling prices and margins on the product decline. Because we are smaller than many of our full-line competitors in the generic pharmaceutical products sector, we may lack the financial and other resources needed to maintain our profit margins and market share in this sector.





**If the efforts of manufacturers of branded pharmaceuticals to use litigation and legislative and regulatory means to limit the use of generics and certain other products are successful, sales of our generic products may suffer.**

Pharmaceutical companies that produce patented brand products are increasingly employing a range of legal and regulatory strategies to delay the introduction of competing generics and certain other products to which we do not have a right of reference to all necessary preclinical and clinical data. Opposing such measures can be costly and time-consuming and result in delays in the introduction of our products.

The products for which we are developing generic versions may be claimed by their manufacturer to be protected by one or more patents. If we file an ANDA to seek FDA approval of our generic version of such a drug, we are required to certify that any patent or patents listed as covering the approved listed drug are invalid, unenforceable or will not be infringed by our generic version. Similar certification requirements apply to new drug applications filed under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, where we rely on information to which we do not have a right of reference. Once the FDA accepts our ANDA or Section 505(b)(2) NDA, we are required to notify the brand manufacturer of this fact. The brand manufacturer then has 45 days from the receipt of the notice in which to sue us for patent infringement. If it does so, the FDA is generally prevented from granting approval of the ANDA or Section 505(b)(2) NDA until the earliest of 30 months from the date the FDA accepted the application for filing, the conclusion of litigation in the generic's favor or expiration of the patent(s).

**We may be the subject of product liability claims or product recalls, and we may be unable to obtain or maintain insurance adequate to cover potential liabilities. We will be subject to product liability claims following consummation of our acquisition of Qualitest Pharmaceuticals.**

Our business exposes us to potential liability risks that arise from the testing, manufacturing, marketing and sale of our products. In addition to direct expenditures for damages, settlement and defense costs, there is a possibility of adverse publicity as a result of product liability claims. Product liability is a significant commercial risk for us. Some plaintiffs have received substantial damage awards in some jurisdictions against pharmaceutical companies based upon claims for injuries allegedly caused by the use of their products. In addition, it may be necessary for us to recall products that do not meet approved specifications or which subsequent data demonstrate may be unsafe or ineffective, which would also result in adverse publicity, as well as resulting in costs connected to the recall and loss of revenue.

We have signed an agreement to purchase Qualitest Pharmaceuticals (Qualitest), and Qualitest is named as a defendant in a number of cases that have been filed in various state and federal courts that allege plaintiffs experienced injuries as a result of ingesting the prescription medicine metoclopramide, which is and has been manufactured and marketed by Qualitest. Many of these cases are in the discovery phase of the litigation, and certain cases have been scheduled for trial in the Spring and Fall of 2011. Following the completion of the acquisition of Qualitest, we may be subject to liabilities arising out of these cases, and will be responsible for the cost of managing these cases. We intend to contest all of these cases vigorously. Additional litigation similar to that described above may also be brought by other plaintiffs in various jurisdictions in the future. However, we cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against Qualitest. Subject to certain terms and conditions, we will be indemnified by the former owners of Qualitest with respect to metoclopramide litigation arising out of the sales of the product by Qualitest between January 1, 2006 and the date on which the acquisition is completed, subject to an overall liability cap of \$100 million for all claims arising out of or related to the acquisition, including the claims described above.

We cannot assure you that a product liability claim or series of claims brought against us would not have an adverse effect on our business, financial condition, results of operations and cash flows. If any claim is brought against us, regardless of the success or failure of the claim, we cannot assure you that we will be able to obtain or maintain product liability insurance in the future on acceptable terms or with adequate coverage against potential liabilities or the cost of a recall.

**We may incur liabilities as the result of over-time cases which, if ultimately determined adverse to the industry, could have a material adverse effect on our business, financial condition, results of operations and cash flows.**

A number of pharmaceutical companies are defendants in litigation brought by their own current and former pharmaceutical sales representatives, alleging that the companies violated wage and hour laws by misclassifying the sales representatives as exempt employees, and by failing to pay overtime compensation. We are and may in the future be the subject of similar cases. Depending on developments in the ongoing and any future litigation, there is a possibility that we will suffer an adverse decision or verdicts of substantial amounts, or that we will enter into monetary settlements. Any unfavorable outcome as a result of such litigation could have a material adverse effect on our business, financial condition, results of operations and cash flows.

**The availability of third party reimbursement for our products is uncertain, and thus we may find it difficult to maintain current price levels. Additionally, the market may not accept those products for which third party reimbursement is not adequately provided.**

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

Our ability to commercialize our products depends, in part, on the extent to which reimbursement for the costs of these products is available from government healthcare programs, private health insurers and others. We cannot assure you that third party payment for our products will be adequate for us to maintain price levels sufficient for realization of an appropriate return on our investment. Government, private insurers and other third party payers are increasingly attempting to contain healthcare costs by (1) limiting both coverage and the level of reimbursement (including adjusting co-pays) for products approved for marketing by the FDA, (2) refusing, in some cases, to provide any coverage for uses of approved products for indications for which the FDA has not granted marketing approval and (3) requiring or encouraging, through more favorable reimbursement levels or otherwise, the substitution of generic alternatives to branded products.

On December 8, 2003, President Bush signed into law the Medicare Prescription Drug Improvement and Modernization Act (Medicare Modernization Act) of 2003. The Medicare Modernization Act created a new prescription drug coverage program for people with Medicare through a new system of private market insurance providers; the program began in January 2006. This new benefit has resulted in an increased use of formularies (listings of prescription drugs approved for use) such that, in the event a Medicare beneficiary's medications are not listed on the applicable formulary, such Medicare beneficiary may not receive reimbursement for such medications. Moreover, once these formularies are established, Medicare is not obligated to pay for drugs omitted from a formulary, and the cost of these non-covered drugs will not be counted towards the \$3,600 annual out-of-pocket beneficiary deductible established by the Medicare Modernization Act. Further, since 2006, Medicare prescription drug program beneficiaries are not permitted to purchase private insurance policies, known as Medigap policies, to cover the cost of off-formulary medications. If our products are or become excluded from these formularies, demand for our products might decrease and we may be forced to lower prices for our products, which may adversely affect our business, financial condition, results of operations and cash flows.

From time to time, state Medicaid programs review our products to assess whether such products should be subject to a prior authorization process, which processes vary state-by-state but generally require physicians prescribing the products to answer several questions prior to the product being dispensed. The institution of a prior authorization process may adversely impact the sales of the related product in the state and depending on the state, may adversely affect our business and results of operations. On February 20, 2008, in connection with its Clinical Drug Review Program, the Pharmacy and Therapeutics Committee of the New York State Department of Health reviewed our product Lidoderm® and recommended that it be subject to a prior authorization process. As a result, on July 31, 2008, the New York State Department of Health placed Lidoderm® in its Clinical Drug Review Program, which is a specific program within its prior authorization program. There can be no assurance that such a process, or the institution thereof, in New York State or elsewhere would not have a material adverse effect on our business, financial condition, results of operations and cash flows.

If government and third party payers do not provide adequate coverage and reimbursement levels for users of our products, the market acceptance of these products could be adversely affected. In addition, the following factors could significantly influence the purchase of pharmaceutical products, which would result in lower prices and a reduced demand for our products that might force us to reduce the price of these products to remain competitive:

the trend toward managed healthcare in the United States;

the growth of organizations such as HMOs and managed care organizations;

legislative proposals to reform healthcare and government insurance programs; and

price controls and non-reimbursement of new and highly priced medicines for which the economic therapeutic rationales are not established.

On February 17, 2009, President Obama signed into law the American Recovery and Reinvestment Act of 2009, which appropriates \$1.1 billion to fund comparative effectiveness research (referred to as CER) relating to healthcare treatments. Although the concept of CER now has significant momentum, numerous unresolved and potentially contentious issues remain, and stakeholders are following implementation of this new law closely. Depending on whether and, if so, how CER is implemented, CER could possibly present regulatory, and reimbursement issues under certain circumstances. On February 26, 2009, President Obama released his fiscal 2010 budget, which included approximately \$43 billion in new revenue from biopharmaceutical companies. The impact of the President's proposed budget on the Company's business, financial condition, results of operations and cash flows is not yet known. President Obama released his fiscal year (FY) 2011 budget which proposes \$3.8 trillion in spending. The President's budget serves as an important marker for policy proposals and the Administration's preferences. The FY 2011 budget includes a \$743 billion allowance for health insurance reform. This allowance demonstrates the Administration's commitment to enacting fundamental reforms to the U.S. health care delivery system, which may have an impact on the Company's business.

**Our reporting and payment obligations under the Medicaid rebate program and other governmental pricing programs are complex and may involve subjective decisions. Any failure to comply with those obligations could subject us to penalties and sanctions.**

We are subject to various federal and state laws pertaining to healthcare fraud and abuse, including prohibitions on the offer of payment or acceptance of kickbacks or other remuneration in return for the purchase of our products. Sanctions for violating these laws include criminal

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

penalties and civil sanctions and possible exclusion from the Medicare, Medicaid, and other government healthcare programs. There can be no assurance that our practices will not be challenged under these laws in the future or that such a challenge would not have a material adverse effect on our business or results of operations.

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

We also are subject to federal and state laws prohibiting the presentation (or the causing to be presented) of claims for payment (by Medicare, Medicaid, or other third-party payers) that are determined to be false, fraudulent, or for an item or service that was not provided as claimed. These false claims statutes include the Federal Civil and Criminal False Claims Acts, which allow any person to bring suit in the name of the government alleging false or fraudulent claims presented to or paid by the government (or other violations of the statutes) and to share in any amounts paid by the entity to the government in fines or settlement. Such suits, known as qui tam actions, have increased significantly in the healthcare industry in recent years. These actions against healthcare companies may result in payment of fines or exclusion from the Medicare, Medicaid, and/or other government healthcare programs.

We and other pharmaceutical companies are defendants in a number of lawsuits filed by local and state government entities, alleging generally that we and numerous other pharmaceutical companies reported false pricing information in connection with certain drugs that are reimbursable under Medicaid. We intend to defend these lawsuits vigorously. Depending on developments in the litigation however, as with all litigation, there is a possibility that we will suffer adverse decisions or verdicts of substantial amounts, or that we will enter into monetary settlements in one or more of these actions as we recently did with a number of New York counties. See *Legal proceedings* in Note 12 of the Condensed Consolidated Financial Statements included in Part I, Item 1 of this Report. Any unfavorable outcomes as a result of such litigation could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Government regulations regarding reporting and payment obligations are complex and we are continually evaluating the methods we use to calculate and report the amounts owed with respect to Medicaid and other government pricing programs. Our calculations are subject to review and challenge by various government agencies and authorities and it is possible that any such review could result either in material changes to the method used for calculating the amounts owed to the pertinent government agency (or agencies), or to the amounts themselves. In addition, because our processes for these calculations and our judgments supporting these calculations involve, and will continue to involve, subjective decisions, these calculations are subject to the risk of errors. As noted above, any governmental agency that commences an action, if successful, could impose, based on a claim of violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal healthcare programs (including Medicaid and Medicare). Some of the applicable laws impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity with regard to how to properly calculate and report payments and even in the absence of such ambiguity a governmental authority may take a position contrary to a position we have taken, and may impose civil and/or criminal sanctions. Any such penalties or sanctions could have a material adverse effect on our business, financial position, results of operations and cash flows, and could cause the market value of our common stock to decline.

**Once approved, there is no guarantee that the market will accept our future products, and regulatory requirements could limit the commercial usage of our products.**

Even if we obtain regulatory approvals, uncertainty exists as to whether the market will accept our products. A number of factors may limit the market acceptance of our products, including the timing of regulatory approvals and market entry relative to competitive products, the availability of alternative products, the price of our products relative to alternative products, the availability of third party reimbursement and the extent of marketing efforts by third party distributors or agents that we retain. We cannot assure you that our products will receive market acceptance in a commercially viable period of time, if at all. We cannot be certain that any investment made in developing products will be recovered, even if we are successful in commercialization. To the extent that we expend significant resources on research and development efforts and are not able, ultimately, to introduce successful new products as a result of those efforts, our business, financial position, results of operations and cash flows may be materially adversely affected, and the market value of our common stock could decline. In addition, many of our products contain narcotic ingredients that carry stringent record keeping obligations, strict storage requirements and other limitations on these products' availability, which could limit the commercial usage of these products.

We sell our products to a limited number of wholesale drug distributors and large pharmacy chains. In turn, these wholesale drug distributors and large pharmacy chains supply products to pharmacies, hospitals, governmental agencies and physicians. Net sales to customers who accounted for 10% or more of our net sales during the years ended December 31 and the nine months ended September 30, 2010 were as follows:

	September 30, 2010	2009	December 31, 2008	2007
Cardinal Health, Inc.	33%	35%	36%	34%
McKesson Corporation	29%	29%	31%	31%
AmerisourceBergen Corporation	15%	16%	15%	15%

If we were to lose the business of any of these customers, or if any were to experience difficulty in paying us on a timely basis, our net sales, profitability and cash flows could be materially and adversely affected.

**We are dependent on outside manufacturers for the manufacture of our products; therefore, we will have limited control of the manufacturing process and related costs. Certain of our manufacturers currently constitute the sole source of one or more of our products, including Teikoku, our sole source of Lidoderm®.**

Third party manufacturers currently manufacture substantially all of our products pursuant to contractual arrangements. Certain of our manufacturers currently constitute the sole source of one or more of our products. Because of contractual restraints and the lead-time necessary to obtain FDA approval, and possibly DEA registration, of a new manufacturer, replacement of any of these manufacturers may be expensive and time consuming and may cause interruptions in our supply of products to customers. As a result, any such delay could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Because all of our products are manufactured by third parties, we have a limited ability to control the manufacturing process or costs related to this process. Increases in the prices we pay our manufacturers, interruptions in our supply of products or lapses in quality could adversely impact our margins, profitability and cash flows. We are reliant on our third party manufacturers to maintain the facilities at which they manufacture our products in compliance with FDA, DEA, state and local regulations. If they fail to maintain compliance with FDA, DEA or other critical regulations, they could be ordered to cease manufacturing which would have a material adverse impact on our business, results of operations, financial condition and cash flows. In addition to FDA and DEA regulation, violation of standards enforced by the Environmental Protection Agency (referred to as the EPA), and the Occupational Safety and Health Administration (referred to as OSHA), and their counterpart agencies at the state level, could slow down or curtail operations of third party manufacturers.

We have entered into minimum purchase requirement contracts with some of our third party manufacturers. In May 2001, we entered into a long-term manufacturing and development agreement with Novartis Consumer Health, Inc. pursuant to which Novartis Consumer Health Inc. has agreed to manufacture certain of our commercial products in addition to products in development. As of December 31, 2009, we are required to purchase a minimum of approximately \$20 million in 2010 and approximately \$21 million of product from Novartis Consumer Health Inc. in 2011.

We also have a long-term contract with Teikoku Seiyaku Co., Ltd., under which Teikoku manufactures Lidoderm® at its Japanese facility for commercial sale by us in the United States. We agreed to purchase a minimum number of patches per year from Teikoku through 2012, representing the noncancelable portion of the Teikoku agreement. Teikoku has agreed to fix the supply price of Lidoderm® for a period of time after which the price will be adjusted at future set dates based on a price index defined in the Teikoku agreement. Since future price changes are unknown, we have used prices currently existing under the Teikoku 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 we have the right to terminate the Teikoku agreement after 2012, if we fail to meet the annual minimum requirement.

In addition, we may consider entering into additional manufacturing arrangements with third party manufacturers. In each case, we will incur significant costs in obtaining the regulatory approvals and taking the other steps necessary to begin commercial production by these manufacturers. If the market for the products manufactured by these third parties substantially contracts or disappears, we will continue to be financially obligated under these contracts, an obligation which could have a material adverse effect on our business.

**We are dependent on third parties to supply all raw materials used in our products and to provide services for certain core aspects of our business. Any interruption or failure by these suppliers, distributors and collaboration partners to meet their obligations pursuant to various agreements with us could have a material adverse effect on our business, results of operations, financial condition and cash flows.**

We rely on third parties to supply all raw materials used in our products. In addition, we rely on third party suppliers, distributors and collaboration partners to provide services for certain core aspects of our business, including manufacturing, warehousing, distribution, customer service support, medical affairs services, clinical studies, sales and other technical and financial services. All third party suppliers and contractors are subject to FDA, and very often DEA, requirements. Our business and financial viability are dependent on the regulatory compliance of these third parties, and on the strength, validity and terms of our various contracts with these third party manufacturers, distributors and collaboration partners. Any interruption or failure by these suppliers, distributors and collaboration partners to meet their obligations pursuant to various agreements with us could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In addition, we have entered into minimum purchase requirement contracts with some of our third party raw material suppliers. If the market for the products that utilize these raw materials substantially contracts or disappears, we will continue to be financially obligated under these contracts and meeting such obligations could have a material adverse effect on our business.

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

We are dependent upon third parties to provide us with various estimates as a basis for our financial reporting. While we undertake certain procedures to review the reasonableness of this information, we cannot obtain absolute assurance over the accounting methods and controls over the information provided to us by third parties. As a result we are at risk of them providing us with erroneous data which could have a material adverse impact on our business.



**The DEA limits the availability of the active ingredients used in many of our current products and products in development and, as a result, our procurement quota may not be sufficient to meet commercial demand or complete clinical trials.**

The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active ingredients in some of our current products and products in development, including oxycodone, oxymorphone, morphine, fentanyl, sufentanil and hydrocodone, are listed by the DEA as Schedule II or III substances under the Controlled Substances Act of 1970. Consequently, their manufacture, shipment, storage, sale and use are subject to a high degree of regulation. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

Furthermore, the DEA limits the availability of the active ingredients used in many of our current products and products in development and, as a result, our procurement quota of these active ingredients may not be sufficient to meet commercial demand or complete clinical trials. We must annually apply to the DEA for procurement quota in order to obtain these substances. Any delay or refusal by the DEA in establishing our procurement quota for controlled substances could delay or stop our clinical trials, product launches or could cause trade inventory disruptions for those products that have already been launched, which could have a material adverse effect on our business, financial position, results of operations and cash flows.

**We invest in securities that are subject to market risk and the recent issues in the financial markets could adversely affect the value of our assets.**

At September 30, 2010, \$18.8 million of our marketable securities portfolio was invested in AAA rated investments in auction-rate debt 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 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.

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

Throughout 2010, the auction-rate securities market has continued to be inactive. If credit and capital markets deteriorate further or we experience any additional ratings downgrades on any investments in our portfolio (including on our auction-rate securities), we may incur additional impairments in future periods, which could negatively affect our financial condition, cash flow or reported earnings.

Any of these events could materially affect our results of operations and our financial condition. In the event we need to access these funds, we could be required to sell these securities at an amount below our original purchase value. However, based on our ability to access our cash and cash equivalents and our other liquid investments, and our expected operating cash flows, we do not expect to be required to sell these securities at a loss. However, there can be no assurance that we will not have to sell these securities at a loss.

**Sales of our products may be adversely affected by the consolidation of the wholesale drug distribution and retail pharmacy industries, a trend which may continue.**

The network through which we sell our products has undergone significant consolidation marked by mergers and acquisitions among wholesale distributors and the growth of large retail drug store chains. As a result, a small number of large wholesale distributors control a significant share of the market, and the number of independent drug stores and small drug store chains has decreased. We expect that consolidation of drug wholesalers and retailers will place competitive pressures on drug manufacturers, including us. If we lose any of these customer accounts, or if our relationship with them were to deteriorate, our business could also be materially and adversely affected. Orders for our products may increase or decrease depending on the inventory levels held by our major customers. Significant increases and decreases in orders from our major customers could cause our operating results to vary significantly from quarter to quarter.



Retail availability of our products is greatly affected by the inventory levels our customers hold. We monitor wholesaler inventory of our products using a combination of methods, including tracking prescriptions filled at the pharmacy level to determine inventory amounts the wholesalers have sold to their customers. Pursuant to distribution service agreements with five of our significant wholesale customers, we receive inventory level reports. For other wholesalers where we do not receive inventory level reports, however, our estimates of wholesaler inventories may differ significantly from actual inventory levels. Significant differences between actual and estimated inventory levels may result in excessive inventory production, inadequate supplies of products in distribution channels, insufficient or excess product available at the retail level, and unexpected increases or decreases in orders from our major customers. Forward buying by wholesalers, for example, may result in significant and unexpected changes in customer orders from quarter to quarter. These changes may cause our revenues to fluctuate significantly from quarter to quarter, and in some cases may cause our operating results for a particular quarter to be below our expectations or internal projections. If our financial results are below expectations for a particular period, the market price of our securities may drop significantly.

**We may not be able to maintain our current insurance policies covering our business, assets, directors and officers and product liability claims and we may not be able to obtain new policies in the future.**

Property, product liability, directors and officers and general liability insurance represent significant costs to us. Since the events of September 11, 2001, and due to an increased focus on corporate governance in the United States, and product liability lawsuits related to pharmaceuticals, liability and other types of insurance have become more difficult and costly to obtain. As we continue to expand our portfolio of available products, we may experience an increase in the number of product liability claims against us. Moreover, we may be subject to claims that are not covered by insurance. In addition, products for which we currently have coverage may be excluded from coverage in the future. Certain claims may be subject to our self-insured retention, exceed our policy limits or relate to damages that are not covered by our policy. In addition, product liability coverage for pharmaceutical companies is becoming more expensive and increasingly difficult to obtain and, as a result, we may not be able to obtain the type and amount of coverage we desire or to maintain our current coverage. Unanticipated additional insurance costs could have a material adverse effect on our results of operations and cash flows. There can be no assurance that we will be able to maintain our existing insurance policies or obtain new policies in meaningful amounts or at a reasonable cost. Any failure to obtain or maintain any necessary insurance coverage could have a material adverse effect on our business, financial condition, results of operations and cash flows.

**If we are unable to retain our key personnel, and continue to attract additional professional staff, we may be unable to maintain or expand our business.**

Because of the specialized scientific nature of our business, our ability to develop products and to compete with our current and future competitors will remain highly dependent, in large part, upon our ability to attract and retain qualified scientific, technical and commercial personnel. The loss of key scientific, technical and commercial personnel or the failure to recruit additional key scientific, technical and commercial personnel could have a material adverse effect on our business. While we have consulting agreements with certain key individuals and institutions and have employment agreements with our key executives, we cannot assure you that we will succeed in retaining personnel or their services under existing agreements. There is intense competition for qualified personnel in the areas of our activities, and we cannot assure you that we will be able to continue to attract and retain the qualified personnel necessary for the development of our business.

**We are a holding company with no operations.**

We are a holding company with no direct operations. Our principal assets are the equity interests we hold in our operating subsidiaries. As a result, we are dependent on loans, dividends and other payments from our subsidiaries to generate the funds necessary to meet our financial obligations. Our subsidiaries are legally distinct from us and have no obligation to make funds available to us.

**Our revenues and operating results may fluctuate in future periods and we may fail to meet expectations, which may cause the price of our common stock to decline.**

Our quarterly operating results are difficult to predict and may fluctuate significantly from period to period. Accordingly, one cannot predict our quarterly financial results based on our full-year financial guidance. We cannot predict with certainty the timing or level of sales of our products in the future. If our quarterly sales or operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Our operating results may fluctuate due to various factors including those set forth above. As a result of these factors, we believe that period-to-period comparisons of our operating results are not a good indication of our future performance. For example, in 2010, we have assumed that our sales of Lidoderm®, Opana® ER, Voltaren® Gel, Supprelin® LA and Valstar® will grow over the course of the year, but there can be no assurance that sales of these products will grow at the rates anticipated, or at all.



**Our stock price may be volatile, and your investment in our common stock could decline in value.**

The market prices for securities of healthcare companies in general have been highly volatile and may continue to be highly volatile in the future. For the nine months ended September 30, 2010, our stock traded between \$19.19 and \$34.26 per share. The following factors, in addition to other risk factors described in this section, may cause the market price of our common stock to fluctuate:

FDA approval or disapproval of any of the drug applications we have submitted;

the success or failure of our clinical trials;

new data or new analyses of older data that raises potential safety or effectiveness issues concerning our approved products;

competitors announcing technological innovations or new commercial products;

introduction of generic substitutes for our products, including the filing of ANDAs with respect to generic versions of our branded products, such as Lidoderm®;

developments concerning our or others' proprietary rights, including patents;

competitors' publicity regarding actual or potential products under development;

regulatory developments in the United States and foreign countries, or announcements relating to these matters;

period-to-period fluctuations in our financial results;

new legislation in the United States relating to the development, sale or pricing of pharmaceuticals;

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;

litigation; and

economic and other external factors, including disasters and other crises.

**If our stockholders sell substantial amounts of our common stock, the market price of our common stock may fall.**

If our stockholders sell substantial amounts of our common stock, including shares issued upon the exercise of outstanding options, the market price of our common stock may fall. These sales also may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate.

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

Of the 8,483,805 shares that may be issued upon the exercise of options or vesting of restricted stock units outstanding as of September 30, 2010, 2,416,611 were vested, exercisable and eligible for sale.

**We have not paid, and may not pay, dividends and therefore, unless our stock appreciates in value, investors in our stock may not benefit from holding our stock.**

We have not paid any cash dividends since our inception. The payment of cash dividends is subject to the discretion of our Board of Directors and will be dependent on many factors, including our earnings, capital needs and general financial condition. Further, in October of 2009, we established a three-year senior secured revolving credit facility (referred to as the Credit Facility) with JP Morgan Chase Bank, Barclays Capital and certain other lenders. Subject to certain limitations, we are permitted to pay dividends under the Credit Facility. We anticipate that, for the foreseeable future, we will retain our earnings in order to finance investments in our business. As a result, investors in our stock may not be able to benefit from owning our stock unless the shares that these investors acquire appreciate in value.

**Our operations could be disrupted if our information systems fail or if we are unsuccessful in implementing necessary upgrades.**

Our business depends on the efficient and uninterrupted operation of our computer and communications systems and networks, hardware and software systems and our other information technology. If our systems were to fail or we are unable to successfully expand the capacity of these systems, or we are unable to integrate new technologies into our existing systems, our operations and financial results could suffer.

**The publication of negative results of studies or clinical trials may adversely impact our sales revenue.**

From time to time, studies or clinical trials on various aspects of pharmaceutical products are conducted by academics or others, including government agencies. The results of these studies or trials, when published, may have a dramatic effect on the market for the pharmaceutical product that is the subject of the study. The publication of negative results of studies or clinical trials related to our products or the therapeutic areas in which our products compete could adversely affect our sales, the prescription trends for our products and the reputation of our products. In the event of the publication of negative results of studies or clinical trials related to our products or the therapeutic areas in which our products compete, our business, financial condition, results of operations and cash flows could be materially adversely affected. In addition, on September 27, 2007, Congress enacted requirements that the results of studies and clinical trials be provided by the investigator to the National Institutes of Health (referred to as NIH) for inclusion in a publicly-available database registry of clinical trials. There is an exception for clinical research performed on behalf of a sponsor who has not yet submitted an NDA in connection with the drug being studied; however, it is unclear what impact the potential publication of clinical research data for our products will have.

**Actions that may be taken by significant stockholders may divert the time and attention of our board of directors and management from our business operations.**

Campaigns by significant investors to effect changes at publicly traded companies have increased in recent years. In August 2007, affiliates of D.E. Shaw & Co., L.P., which collectively currently beneficially own approximately 8.3 million shares of our outstanding common stock, sent letters to our Board of Directors suggesting, among other things, that the Company begin a process of evaluating strategic alternatives and explore a recapitalization. In April 2008, we reached an agreement with the D. E. Shaw group, pursuant to which Endo's Board of Directors nominated William F. Spengler at the 2008 Annual Meeting of Stockholders to serve as a member of the Company's Board of Directors. Mr. Spengler is an independent unaffiliated person who was recommended by D.E. Shaw to our Board of Directors. The D. E. Shaw group agreed to vote all of its shares in favor of the election of each of the Board's nominees at our 2008 Annual Meeting of Stockholders. At the 2008 Annual Meeting of Stockholders, the Company stockholders elected Mr. Spengler as a director of the Company. The D.E. Shaw group is no longer subject to any restrictions with respect to its shares in the Company.

If a proxy contest were to be pursued by any of our stockholders, it could result in substantial expense to the Company and consume significant attention of our management and Board of Directors. In addition, there can be no assurance that any stockholder will not pursue actions to effect changes in the management and strategic direction of the Company, including through the solicitation of proxies from the Company's stockholders.

**The regulatory approval process outside the U.S. varies depending on foreign regulatory requirements, and failure to obtain regulatory approval in foreign jurisdictions would prevent the marketing of our products in those jurisdictions.**

We have worldwide rights to market many of our products and product candidates. We intend to seek approval of and market certain of our products outside of the U.S. To market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. Approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to manufacturing or marketing that product in those countries. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process includes all of the risks associated with obtaining FDA approval set forth in this Report and approval by the FDA does not ensure approval by the regulatory authorities of any other country, nor does the approval by foreign regulatory authorities in one country ensure approval by regulatory authorities in other foreign countries or the FDA. Other than the approval of Vantas<sup>®</sup> for marketing in the European Union and certain other foreign jurisdictions, we may not be able to file for regulatory approvals or may not receive necessary approvals to commercialize our products in any foreign market. If we fail to comply with these regulatory requirements or obtain and maintain required approvals, our target market will be reduced and our ability to generate revenue from abroad will be adversely affected.

**If the indemnitors default on their obligations, the outcome of the Redux litigation could materially harm us.**

On September 15, 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, Indevus was named, together with other pharmaceutical companies, as a defendant in several thousand product liability legal actions, some of which purport to be class actions, in federal and state courts relating to the use of Redux and other weight loss drugs. The existence of such litigation may materially adversely affect our business. In addition, although we are unable to predict the outcome of any such litigation, if successful uninsured or insufficiently insured claims, or if a successful indemnification claim, were made against us, our business, financial condition and results of operations could be materially adversely affected. In addition, the uncertainties associated with these legal actions may have an adverse effect on the market price of our common stock and on our ability to obtain product liability insurance for other products at costs acceptable to us, or at all, which may materially adversely affect our business, financial condition and results of operations.

On May 30, 2001, Indevus entered into an Indemnity and Release Agreement with Wyeth, which provides for indemnification of Redux-related claims brought by plaintiffs who initially opted out of Wyeth's national class action settlement of diet drug litigation and by those claimants who allege primary pulmonary hypertension. This agreement also provides for funding of all defense costs related to all Redux-related claims and provides for Wyeth to fund certain additional insurance coverage to supplement the Company's existing product liability insurance. However, there can be no assurance that uninsured or insufficiently insured Redux-related claims or Redux-related claims for which we are not otherwise indemnified or covered under the AHP indemnity and release agreement will not have a material adverse effect on our future business, results of operations or financial condition or that the potential of any such claims would not adversely affect our ability to obtain sufficient financing to fund operations. We are unable to predict whether the existence of such litigation may adversely affect our business.





Pursuant to agreements we have with Les Laboratoires Servier, from whom Indevus in-licensed rights to Redux, Boehringer Ingelheim Pharmaceuticals, Inc., which assembled Redux, and other parties, we may be required to indemnify such parties for Redux-related liabilities. We are unable to predict whether such indemnification obligations, if they arise, may adversely affect our business.

**Agreements between brand pharmaceutical companies and generic pharmaceutical companies are facing increased government scrutiny in both the U.S.**

We are involved in numerous patent litigations in which generic companies challenge the validity or enforceability of our products' listed patents and/or their applicability of these patents to the generic applicant's products. Likewise, our generics business is also involved in patent litigations in which we challenge the validity or enforceability of innovator companies' listed patents and/or their applicability to our generic products. Therefore settling patent litigations has been and is likely to continue to be part of our business. Parties to such settlement agreements in the U.S., including us, are required by law to file them with the Federal Trade Commission (FTC) and the Antitrust Division of the Department of Justice for review. The FTC has publicly stated that, in its view, some of these settlement agreements violate the antitrust laws and has brought actions against some brand and generic companies that have entered into such agreements. Accordingly, we may receive formal or informal requests from the FTC for information about a particular settlement agreement, and there is a risk that the FTC may commence an action against us alleging violation of the antitrust laws. In addition, some members of Congress are trying to pass legislation that would limit the types of settlement agreements generic manufacturers can enter into with brand companies.

**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.**

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (together, the U.S. Healthcare Legislation), was enacted in the U.S. This legislation has both current and longer-term impacts on us, as discussed below.

The provisions of the U.S. Healthcare Legislation are effective on various dates over the next several years. The principal provisions affecting us provide for the following:

an increase, from 15.1% to 23.1%, in the minimum rebate on branded prescription drugs sold to Medicaid beneficiaries (effective January 1, 2010);

extension of Medicaid prescription drug rebates to drugs dispensed to enrollees in certain Medicaid managed care organizations (effective March 23, 2010);

an increase the additional Medicaid rebates for new formulations ;

the revision of the average manufacturers' price (AMP) definition to remove the physician class of trade;

expansion of the types of institutions eligible for the Section 340B discounts for outpatient drugs provided to hospitals meeting the qualification criteria under Section 340B of the Public Health Service Act of 1944 (effective January 1, 2010);

discounts on branded prescription drug sales to Medicare Part D participants who are in the Medicare coverage gap, also known as the doughnut hole (effective January 1, 2011); and

an annual fee payable to the federal government (which is not deductible for U.S. income tax purposes) based on our prior-calendar-year share relative to other companies of branded prescription drug sales to specified government programs (effective January 1, 2011, with the total fee to be paid each year by the pharmaceutical industry increasing annually through 2018).



A number of the provisions of the U.S. Healthcare Legislation may adversely affect reimbursement for our products. Additionally, 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, and with respect thereto the U.S. Healthcare Legislation could adversely impact our future results of operations.

Over the next few years, implementation guidance relating to the U.S. Healthcare Legislation as well as additional healthcare reform proposals may have a financial impact on the Company. In addition, the U.S. Healthcare Legislation requires that, except in certain circumstances, individuals obtain health insurance beginning in 2014, and it also provides for an expansion of Medicaid coverage in 2014. It is expected that, as a result of these provisions, there will be a substantial increase in the number of Americans with health insurance beginning in 2014, a significant portion of whom will be eligible for Medicaid. We anticipate that this will increase demand for pharmaceutical products overall. However, in view of the many uncertainties, we are unable at this time to determine whether and to what extent sales of our prescription pharmaceutical products in the U.S. will be impacted.

**We may not be able to realize all of the anticipated benefits of our acquisitions of HealthTronics, Penwest and Qualitest.**

The success of our recent acquisition of HealthTronics and our pending acquisitions of Penwest and Qualitest will depend, in large part, on our ability to realize the anticipated benefits and expand our business from integrating aspects of the operations of Endo with aspects of the operations of HealthTronics, Penwest and Qualitest. If we are not able to successfully integrate certain aspects of these companies, the anticipated benefits of the applicable 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 valuations of each of our acquired businesses.**

Accounting for our acquisitions involves complex and subjective valuations of the assets, liabilities, and noncontrolling interests of the acquired entities, 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 valuations and actual results could have a material effect 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.

**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.



**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 us 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 our 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 us. 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 we fail to comply with the privacy regulations, we 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 our business arrangements and practices comply with existing healthcare fraud law. However, a violation could subject us to penalties, fines and/or possible exclusion from Medicare or Medicaid. Such sanctions could significantly reduce our 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 our business and the results of our operations.

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

We regularly monitor developments in statutes and regulations relating to our business. However, we may be required to modify our agreements, operations, marketing and expansion strategies from time to time in response to changes in the statutory and regulatory environment. We carefully structure all of our and HealthTronics agreements, operations, marketing and strategies, although we can provide no assurance that these arrangements will not be challenged successfully.

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

HealthTronics is subject to various 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.

**Our pathology laboratory services unit is heavily regulated, which poses significant compliance risks for the business and places constraints on business opportunities.**

Our pathology laboratory services unit is subject to various federal and state laws and regulations. Among the applicable federal laws and regulations are the Stark Law, Anti-Kickback Statute, False Claims Act, and Clinical Laboratory Improvement Amendments ( CLIA ) and associated regulations and anti-markup regulations, reassignment regulations, and Medicare usual charge regulations. Among the applicable state laws and regulations are account billing statutes and regulations of various forms (including direct billing, anti-markup, and disclosure statutes and regulations), fee-splitting statutes and regulations, anti-kickback statutes and regulations, self-referral statutes and regulations, lab licensure and certification statutes and regulations, and insurance fraud statutes and regulations. If it is determined that any aspect of our pathology laboratory services business model or any specific pathology laboratory services facility or partnership is not in compliance with any of these laws or regulations, this could threaten our ability to carry on aspects of the business model, the business model in its entirety, or activities relating to one or more facilities or partnerships. Noncompliance could also expose the company to federal or state enforcement actions or other proceedings or private lawsuits or other proceedings against the company. Our obligation to operate the pathology laboratory services unit within the strictures of various applicable federal and state laws and regulations constrains our ability to implement new strategies for generating business opportunities. In the future, additional laws and regulations may arise at the federal or state level in the pathology laboratory services field that may create additional uncertainty, negatively impact results for this unit, or jeopardize the functioning of aspects of the business model, the business model in its entirety, or specific facilities or partnerships.

**Penwest is dependent on a limited number of suppliers for the gums used in its TIMERx materials.**

Penwest's TIMERx drug delivery systems are based on a hydrophilic matrix combining a heterodispersed mixture primarily composed of two polysaccharides, xanthan gum and locust bean gum, in the presence of dextrose. These gums are also used in Penwest's Geminex, gastroretentive and SyncroDose drug delivery systems. Penwest purchases these gums from a primary supplier. Penwest has qualified alternate suppliers with respect to such materials, but it can provide no assurance that interruptions in supplies will not occur in the future. TIMERx is the extended-release technology used in Opana ER. Any interruption in TIMERx supply could have a material adverse effect on our sales of Opana ER.

**Failure to complete the proposed acquisition of Qualitest could negatively impact our stock price and future business and financial results.**

There is no assurance that the planned acquisition of Qualitest will occur, and we cannot predict the exact timing of the consummation of the transaction. Consummation of the acquisition is subject to the satisfaction or waiver of various conditions, and we cannot predict whether those conditions will be satisfied or waived. As a result, we cannot assure you that the proposed acquisition will be completed. If the closing conditions for the proposed acquisition set forth in the stock purchase agreement are not satisfied or waived (if permissible under applicable law), or if the transaction is not completed for any other reason, the market price of our common stock may decline. The foregoing risks, or other risks arising in connection with the failure of the acquisition, including the diversion of management attention from conducting the business of the Company and pursuing other opportunities during the pendency of the acquisition process, may have an adverse effect on our business, operations, financial results and stock price.

**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.**

None.

**Item 6. Exhibits.**

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



**SIGNATURES**

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

ENDO PHARMACEUTICALS HOLDINGS INC.

(Registrant)

*/s/* 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: November 2, 2010

---

**Exhibit Index**

Exhibit	
No.	Title
10.14.3*	Third Amendment, effective November 1, 2010, to the Supply and Manufacturing Agreement, dated as of November 23, 1998 and as amended as of December 16, 2009, by and between Endo Pharmaceuticals Inc. and Teikoku Seiyaku Co., Ltd. / Teikoku Pharma USA, Inc.
10.18.5	Sixth Amendment, dated August 9, 2010, to the Amended and Restated Strategic Alliance Agreement, dated as of April 2, 2002, as amended by and between Endo Pharmaceuticals Inc. and Penwest Pharmaceuticals Co. (incorporated herein by reference to Exhibit 10.18.5 of the Current Report on Form 8-K dated August 12, 2010)
10.32.5	Extension Agreement between Endo Pharmaceuticals Inc. and Ventiv Commercial Services, LLC dated as of August 10, 2010 to extend the term of the Sales Representative Services Agreement dated April 1, 2008, as amended
10.32.6	Second Extension Agreement between Endo Pharmaceuticals Inc. and Ventiv Commercial Services, LLC dated as of September 30, 2010 to extend the term of the Sales Representative Services Agreement dated April 1, 2008, as amended (incorporated herein by reference to Exhibit 10.32.5 of the Current Report on Form 8-K dated October 1, 2010).
10.89.1	Credit Facility Amendment dated as of October 25, 2010 among Endo Pharmaceuticals Holdings Inc., the lenders named therein and JPMorgan Chase Bank, N.A., as administrative agent.
10.94	Agreement and Plan of Merger, dated August 9, 2010, by and among Endo Pharmaceuticals Holdings Inc, West Acquisition Corp., and Penwest Pharmaceuticals Co. (incorporated herein by reference to Exhibit 2.1 of the Current Report on Form 8-K dated August 12, 2010).
10.95	Form of Shareholder Tender Agreement, dated August 9, 2010, by and among Endo Pharmaceuticals Holdings Inc, West Acquisition Corp., and Shareholder (incorporated herein by reference to Exhibit 10.93 of the Current Report on Form 8-K dated August 12, 2010).
10.96	Stock Purchase Agreement, dated September 28, 2010, by and among Endo Pharmaceuticals Inc., Endo Pharmaceuticals Holdings Inc., Generics International (US Parent), Inc., and Apax Quartz (Cayman) L.P. (incorporated herein by reference to Exhibit 2.1 of the Current Report on Form 8-K dated September 30, 2010).
10.97	Lease Agreement dated May 19, 2008, by and between HealthTronics, Inc. and HEP- Davis Spring, L.P. (incorporated by reference to Exhibit 10.2 to HealthTronics Current Report on Form 8-K filed with the Securities and Exchange Commission on June 20, 2008).
10.98	Second Amendment to Lease Agreement, dated as of August 20, 2009, between HEP-Davis Spring, L.P. as landlord and HealthTronics, Inc. as tenant (incorporated by reference to Exhibit 10.2 of HealthTronics 10-Q filed with the Securities and Exchange Commission on November 6, 2009).
10.99	Stock Purchase Agreement, dated as of October 10, 2008, by and between HealthTronics, Inc. and Atlantic Urological Associates, P.A (incorporated by reference to Exhibit 10.1 to HealthTronics Current Report on Form 8-K filed with the Securities and Exchange Commission on October 15, 2008).
10.100	Credit Agreement, dated as of December 29, 2009, among HealthTronics, Inc., the lenders party thereto, JPMorgan Chase Bank, National Association, as Administrative Agent, J.P. Morgan Securities, Inc., as Arranger, and Bank of America, N.A., as Syndication Agent (incorporated by reference to Exhibit 10.1 to HealthTronics Current Report on Form 8-K filed with the Securities and Exchange Commission on December 29, 2009).
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

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

- 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 September 30, 2010, filed on November 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.