

ENDO PHARMACEUTICALS HOLDINGS INC

Form 10-Q

July 30, 2009

[Table of Contents](#)

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

Washington, DC 20549

**FORM 10-Q**

(Mark One)

**x** **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE  
ACT OF 1934**  
**FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2009.**

**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)

**(610) 558-9800**

**19317**  
(Zip Code)

(Registrant's Telephone Number, Including Area Code)

**Not applicable**

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

Indicate by check whether the registrant: (1) has filed all reports required to be filed by Sections 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

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

Large accelerated filer ☒

Accelerated filer ☐

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

Smaller reporting company ☐

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

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

Common Stock, \$0.01 par value

Shares outstanding as of July 24, 2009: 117,179,342

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**INDEX**

<u>Forward-Looking Statements</u>	<b>Page</b>
	<b>i</b>
 <b><u>PART I. FINANCIAL INFORMATION</u></b>	
Item 1. <u>Financial Statements</u>	1
<u>Condensed Consolidated Balance Sheets (Unaudited) June 30, 2009 and December 31, 2008</u>	1
<u>Condensed Consolidated Statements of Operations (Unaudited) Three and Six Months Ended June 30, 2009 and 2008</u>	2
<u>Condensed Consolidated Statements of Cash Flows (Unaudited) Six Months Ended June 30, 2009 and 2008</u>	3
<u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>	5
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	49
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	77
Item 4. <u>Controls and Procedures</u>	78
 <b><u>PART II. OTHER INFORMATION</u></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>	81
Item 3. <u>Defaults Upon Senior Securities</u>	81
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	81
Item 5. <u>Other Information</u>	82
Item 6. <u>Exhibits</u>	82
 <b><u>SIGNATURES</u></b>	
	83

**Table of Contents**

**FORWARD LOOKING STATEMENTS**

Statements contained or incorporated by reference in this Quarterly Report on Form 10-Q contain information that includes or is based on forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. These statements, including estimates of future net sales, future expenses, future net income and future earnings per share, contained in the section titled Management's Discussion and Analysis of Financial Condition and Results of Operations, in our Annual Report on Form 10-K for the year ended December 31, 2008, filed with the Securities and Exchange Commission on March 2, 2009, 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, 2008 and Part II, Item 1A of this document 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 herein by reference, including, among others:

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

timing and results of pre-clinical or clinical trials on new products;

our ability to obtain regulatory approval of any of our pipeline products;

competition for the business of our branded and generic products, and in connection with our acquisition of rights to intellectual property assets;

market acceptance of our future products;

government regulation of the pharmaceutical industry;

our dependence on a small number of products;

our dependence on outside manufacturers for the manufacture of 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;

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

significant litigation expenses to defend or assert patent infringement claims;

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

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

**Table of Contents**

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

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

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

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

our ability to successfully integrate Indevus Pharmaceuticals, Inc.;

our ability to successfully execute our strategy;

our operations could be disrupted if our information systems fail or if we are unsuccessful in implementing necessary upgrades; and

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.

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

**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****ENDO PHARMACEUTICALS HOLDINGS INC.****CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)****(In thousands, except share and per share data)**

	<b>June 30, 2009</b>	<b>December 31, 2008</b>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 494,989	\$ 775,693
Restricted cash	178,506	
Marketable securities	850	6,500
Accounts receivable, net	310,754	246,326
Income taxes receivable		1,600
Inventories	98,926	80,656
Prepaid expenses and other current assets	17,594	24,515
Auction-rate Securities Rights, at fair value	24,808	
Deferred income taxes	101,599	48,404
Total current assets	1,228,026	1,183,694
MARKETABLE SECURITIES	241,420	239,204
AUCTION-RATE SECURITIES RIGHTS, at fair value		27,321
PROPERTY AND EQUIPMENT, Net	48,520	44,378
GOODWILL	276,822	181,079
OTHER INTANGIBLES, Net	766,679	205,055
OTHER ASSETS	30,058	28,002
<b>TOTAL ASSETS</b>	<b>\$ 2,591,525</b>	<b>\$ 1,908,733</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 151,956	\$ 160,468
Accrued expenses	303,072	226,005
6.25% convertible notes payable	68,380	
Acquisition-related contingent consideration	149,860	
Income taxes payable	17,789	
Total current liabilities	691,057	386,473
DEFERRED INCOME TAXES	103,447	1,270
ACQUISITION-RELATED CONTINGENT CONSIDERATION	64,090	
CONVERTIBLE SENIOR SUBORDINATED NOTES DUE 2015	251,533	243,150
NON-RECOURSE NOTES PAYABLE	115,017	
OTHER LIABILITIES	78,790	70,729
COMMITMENTS AND CONTINGENCIES (NOTE 10)		
<b>STOCKHOLDERS' EQUITY:</b>		

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

Preferred Stock, \$0.01 par value; 40,000,000 shares authorized; none issued		
Common Stock, \$0.01 par value; 350,000,000 shares authorized; 134,889,283 and 134,302,004 shares issued; 117,172,980 and 116,585,701 outstanding at June 30, 2009 and December 31, 2008, respectively		
	1,349	1,343
Additional paid-in capital	805,301	793,285
Retained earnings	908,021	838,955
Accumulated other comprehensive loss	(2,264)	(1,656)
Treasury stock, 17,716,303 shares at June 30, 2009 and December 31, 2008	(424,816)	(424,816)
Total stockholders' equity	1,287,591	1,207,111
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 2,591,525	\$ 1,908,733

See Notes to Condensed Consolidated Financial Statements.



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

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
<b>REVENUES:</b>				
Net sales	\$ 370,625	\$ 306,161	\$ 704,628	\$ 596,432
Royalty and other revenue	2,483		3,780	
<b>TOTAL REVENUES</b>	<b>373,108</b>	<b>306,161</b>	<b>708,408</b>	<b>596,432</b>
<b>COSTS AND EXPENSES:</b>				
Cost of revenues	95,069	62,993	178,078	119,527
Selling, general and administrative	129,592	126,524	249,598	241,526
Research and development	48,508	26,497	76,922	60,079
Acquisition-related costs	35,023		61,428	
Impairment of other intangible assets		8,083		8,083
<b>OPERATING INCOME</b>	<b>64,916</b>	<b>82,064</b>	<b>142,382</b>	<b>167,217</b>
<b>INTEREST EXPENSE (INCOME), NET</b>	<b>10,416</b>	<b>(428)</b>	<b>18,009</b>	<b>(9,693)</b>
<b>OTHER INCOME, NET</b>	<b>(1,515)</b>	<b>(1,126)</b>	<b>(410)</b>	<b>(844)</b>
<b>INCOME BEFORE INCOME TAX</b>	<b>56,015</b>	<b>83,618</b>	<b>124,783</b>	<b>177,754</b>
<b>INCOME TAX</b>	<b>25,986</b>	<b>26,490</b>	<b>55,717</b>	<b>61,098</b>
<b>NET INCOME</b>	<b>\$ 30,029</b>	<b>\$ 57,128</b>	<b>\$ 69,066</b>	<b>\$ 116,656</b>
<b>NET INCOME PER SHARE:</b>				
Basic	\$ 0.26	\$ 0.46	\$ 0.59	\$ 0.91
Diluted	\$ 0.26	\$ 0.46	\$ 0.59	\$ 0.90
<b>WEIGHTED AVERAGE SHARES:</b>				
Basic	117,158	122,985	116,990	128,561
Diluted	117,350	123,531	117,279	129,078

See Notes to Condensed Consolidated Financial Statements.

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

	<b>Six Months Ended June 30,</b>	
	<b>2009</b>	<b>2008</b>
<b>OPERATING ACTIVITIES:</b>		
Net income	\$ 69,066	\$ 116,656
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	34,647	19,927
Stock-based compensation	7,844	8,958
Amortization of debt issuance costs and premium / discount	9,299	4,196
Selling, general and administrative expenses paid in shares of common stock	126	
Deferred income taxes	(18,521)	(4,257)
Interest earned on marketable securities	(390)	(2,201)
(Gain) loss on disposal of property and equipment	(190)	55
Change in the fair value of acquisition-related contingent consideration	25,930	
Loss on auction-rate securities rights	2,513	
Unrealized gain on trading securities	(4,816)	
Impairment of long-lived assets		11,198
Changes in assets and liabilities which provided (used) cash:		
Accounts receivable	(49,110)	15,631
Inventories	(3,354)	(20,178)
Note receivable		(416)
Prepaid and other assets	12,246	4,214
Accounts payable	(10,655)	(26,259)
Accrued expenses	44,583	9,661
Other liabilities	1,213	(5,292)
Income taxes receivable/payable	20,141	(13,190)
Net cash provided by operating activities	140,572	118,703
<b>INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	(6,012)	(13,385)
Purchases of available-for-sale securities		(134,211)
Proceeds from sales of trading securities	7,050	401,277
Proceeds from the sale of property and equipment		27
Principal payments on note receivable		3,333
License fees		(85,000)
Acquisition, net of cash acquired	(249,546)	(15,000)
Funding of acquisition-related escrow	(175,000)	
Other investments	(1,250)	
Net cash (used in) provided by investing activities	(424,758)	157,041
<b>FINANCING ACTIVITIES:</b>		
Capital lease obligations repayments	(119)	(487)
Tax sharing payments to Endo Pharma LLC		(343)
Tax benefits of stock awards	675	139
Exercise of Endo Pharmaceuticals Holdings Inc. Stock Options	6,536	520

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

Principal payments on 6.25% convertible notes due July 2009	(3,610)	
Net proceeds from issuance of convertible senior subordinated notes due 2015		371,512
Purchase of hedge on convertible senior subordinated notes due 2015	(107,607)	
Sale of common stock warrants		50,371
Purchase of common stock	(374,997)	

Net cash provided by (used in) financing activities	3,482	(60,892)
---	-------	----------

NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(280,704)	214,852
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	775,693	350,325

CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 494,989	\$ 565,177
--	------------	------------

### SUPPLEMENTAL INFORMATION:

Interest paid	\$ 21,021	\$ 32
Income taxes paid	\$ 55,566	\$ 83,700

### SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES

Accrual for purchases of property and equipment	\$ 1,111	\$ 2,688
Settlement of note receivable	\$	\$ (46,667)
Acquisition of license rights	\$	90,657

**Table of Contents**

	Six Months Ended June 30,	
	2009	2008
In connection with the purchase of all of the capital stock of Indevus Pharmaceuticals, Inc., liabilities were assumed as follows:		
Fair value of assets acquired	\$ 1,015,458	\$
Cash paid for the capital stock	(367,221)	
Contingent consideration	(174,350)	
Liabilities assumed	\$ 473,887	\$

See Notes to Condensed Consolidated Financial Statements.

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2009**

**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. (referred to as the Company or we, our, us, or Endo) and its subsidiaries, which are unaudited, include all normal and recurring adjustments considered necessary to present fairly the Company's financial position as of June 30, 2009 and the results of our operations and our cash flows for the periods presented. Operating results for the three-month and six-month periods ended June 30, 2009 are not necessarily indicative of the results that may be expected for the year ending December 31, 2009.

On February 23, 2009, the Company acquired Indevus Pharmaceuticals, Inc., a Delaware corporation (Indevus). Accordingly, as of February 23, 2009, all of the assets acquired and liabilities assumed were recorded at their respective fair values and our consolidated results of operations include Indevus's operating results from February 23, 2009 through June 30, 2009.

The accompanying Condensed Consolidated Balance Sheet as of December 31, 2008 is derived from the Company's audited financial statements at that date and has been recast as a result of our retrospective adoption of FASB Staff Position APB 14-1, *Accounting for Convertible Debt Instruments That May be Settled in Cash upon Conversion (Including Partial Cash Settlement)* (FSP APB 14-1), as codified in the Financial Accounting Standards Board Accounting Standards Codification (FASB ASC) subtopic 470-20, *Debt: Debt with Conversion and Other Options* (ASC 470-20). The accompanying Condensed Consolidated Statements of Operations for the three-month and six-month periods ended June 30, 2008 and the accompanying Condensed Consolidated Statement of Cash Flows for the six-month period ended June 30, 2008 have also been recast as a result of our retrospective adoption of FSP APB 14-1. See Note 2. Recent Accounting Pronouncements and Note 12. Debt, for further details. The Condensed Consolidated Balance Sheet as of December 31, 2008 does not include all of the information and footnotes required by generally accepted accounting principles (referred to as GAAP) for complete financial statements. Since certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted, we suggest that these Condensed Consolidated Financial Statements be read in conjunction with the consolidated financial statements and notes thereto as of and for the year ended December 31, 2008 contained in the Company's Annual Report on Form 10-K. Certain prior period amounts have been reclassified to conform to the current period presentation.

The Company has evaluated subsequent events through July 30, 2009, the date the financial statements were issued.

**NOTE 2. RECENT ACCOUNTING PRONOUNCEMENTS**

*Recently Adopted Accounting Pronouncements*

In September 2006, the Financial Accounting Standards Board (FASB or the Board) issued SFAS No. 157, *Fair Value Measurements* (SFAS 157), as codified in FASB ASC topic 820, *Fair Value Measurements and Disclosures* (ASC 820), which addresses how companies should measure fair value when they are required to use a fair value measure for recognition or disclosure purposes under accounting principles generally accepted in the United States. SFAS 157 is effective for fiscal years beginning after November 15, 2007. In February 2008, the FASB issued FASB Staff Position No. 157-2, *Effective Date of FASB Statement No. 157* (FSP 157-2), as codified in ASC 820. FSP 157-2 delayed the effective date of SFAS 157 for certain non-financial assets and non-financial liabilities to fiscal years beginning after November 15, 2008. SFAS 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined under SFAS 157 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value under SFAS 157 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

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

## **Table of Contents**

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.

On January 1, 2008, the Company adopted SFAS 157 for financial assets and liabilities. The adoption of SFAS 157 for financial assets and liabilities did not have a material impact on the Company's consolidated results of operations and financial condition. On January 1, 2009, the Company adopted SFAS 157 for non-financial assets and non-financial liabilities. The adoption of SFAS 157 for non-financial assets and non-financial liabilities did not have a material impact on the Company's consolidated results of operations and financial condition.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159), as codified in FASB ASC topic 825, *Financial Instruments* (ASC 825), providing companies with an option to report selected financial assets and liabilities at fair value. This Standard's objective is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. Generally accepted accounting principles have required different measurement attributes for different assets and liabilities that can create artificial volatility in earnings. SFAS 159 helps to mitigate this type of accounting-induced volatility by enabling companies to report related assets and liabilities at fair value, which would likely reduce the need for companies to comply with detailed rules for hedge accounting. SFAS 159 also established presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. This Standard requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of the Company's choice to use fair value on its earnings. It also requires entities to display the fair value of those assets and liabilities for which the Company has chosen to use fair value on the face of the balance sheet. SFAS 159 became effective for fiscal years beginning after November 15, 2007. Upon adoption, we chose not to elect the fair value option for our existing financial assets and liabilities. Therefore, adoption of SFAS 159 did not have any impact on our consolidated financial statements. In November 2008, simultaneously with our execution of the agreement with UBS with respect to certain auction rate securities in UBS accounts, we elected the fair value option for the auction-rate securities rights (See Note 3).

On September 12, 2008, the FASB issued FASB Staff Position SFAS 133-1 and FIN 45-4, *Disclosures about Credit Derivatives and Certain Guarantees: An Amendment of FASB Statement No. 133 and FASB Interpretation No. 45; and Clarification of the Effective Date of FASB Statement No. 161* (FSP SFAS 133-1 and FIN 45-4), as codified in FASB ASC topic 815, *Derivatives and Hedging* (ASC 815) and ASC topic 460, *Guarantees* (ASC 460), respectively. FSP SFAS 133-1 and FIN 45-4 requires disclosures by sellers of credit derivatives and amends FASB Interpretation No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness to Others*, to require an additional disclosure about the current status of the payment or performance of a guarantee. FSP SFAS 133-1 and FIN 45-4 became effective for the first interim or annual reporting period that ends after November 15, 2008. We adopted FSP SFAS 133-1 and FIN 45-4 in November 2008. The adoption of FSP SFAS 133-1 and FIN 45-4 did not have a material effect on the Company's consolidated results of operations, financial condition, or required financial statement disclosures.

In October 2008, the FASB issued FASB Staff Position SFAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active* (FSP SFAS 157-3), as codified in ASC 820. FSP SFAS 157-3 clarifies the application of SFAS 157 when determining the fair value of a financial asset when the market for that asset is not currently active. FSP SFAS 157-3 emphasizes that approaches other than the market approach to determining fair value may be appropriate when it is determined that, as a result of market inactivity, other valuation approaches are more representative of fair value. Other valuation approaches can involve significant assumptions regarding future cash flows. FSP SFAS 157-3 clarifies that these assumptions must incorporate adjustments for nonperformance and liquidity risks that market participants would consider in valuing the asset in an inactive market. FSP SFAS 157-3 emphasizes the existing disclosure requirements under SFAS 157 regarding significant unobservable inputs (Level 3 inputs). FSP SFAS 157-3 became effective on October 10, 2008, including with respect to prior periods for which financial statements have not been issued. The Company has adopted FSP SFAS 157-3 beginning with the quarterly period ended September 30, 2008. See Note 3 for a further discussion of fair value.

## **Table of Contents**

On December 11, 2008 the FASB issued FASB Staff Position SFAS 140-4 and FIN 46(R)-8, *Disclosures by Public Entities (Enterprises) about Transfers of Financial Assets and Interests in Variable Interest Entities* (FSP SFAS 140-4 and FIN 46(R)-8), as codified in FASB ASC topic 860, *Transfers and Servicing* (ASC 860). FSP SFAS 140-4 and FIN 46(R)-8 requires additional disclosures by public entities with continuing involvement in transfers of financial assets to special purpose entities and with variable interests in variable interest entities (VIEs), including sponsors that have a variable interest in a VIE. FSP SFAS 140-4 and FIN 46(R)-8 became effective for the first interim or annual reporting period that ends after December 15, 2008. We adopted FSP SFAS 140-4 and FIN 46(R)-8 in December 2008. The adoption of FSP SFAS 140-4 and FIN 46(R)-8 did not have a material effect on the Company's consolidated results of operations, financial condition, or required financial statement disclosures.

In November 2007, the Emerging Issues Task Force of the FASB issued a consensus on Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1), as codified in FASB ASC topic 808, *Collaborative Arrangements* (ASC 808). The scope of EITF 07-1 is limited to collaborative arrangements where no separate legal entity exists and in which the parties are active participants and are exposed to significant risks and rewards that depend on the success of the activity. The Task Force concluded that revenue transactions with third parties and associated costs incurred should be reported in the appropriate line item in each company's financial statements pursuant to the guidance in EITF 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*, as codified in FASB ASC subtopic 605-45, *Revenue Recognition: Principal Agent Considerations* (ASC 605-45). The Task Force also concluded that the equity method of accounting under Accounting Principles Board Opinion 18, *The Equity Method of Accounting for Investments in Common Stock*, as codified primarily in FASB ASC topic 323, *Investments: Equity Method and Joint Ventures* (ASC 323) and topic 325, *Investments: Investments - Other* (ASC 325), should not be applied to arrangements that are not conducted through a separate legal entity. The Task Force also concluded that the income statement classification of payments made between the parties in an arrangement should be based on a consideration of the following factors: the nature and terms of the arrangement; the nature of the entities' operations; and whether the partners' payments are within the scope of existing GAAP. To the extent such costs are not within the scope of other authoritative accounting literature, the income statement characterization for the payments should be based on an analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. The provisions of EITF 07-1, became effective for fiscal years beginning on or after December 15, 2008, and companies are required to apply the provisions through retrospective application to all collaborative arrangements existing at adoption as a change in accounting principle. If it is impracticable to apply the consensus to a specific arrangement, disclosure is required regarding the reason why retrospective application is not practicable and the effect of reclassification on the current period. We have adopted EITF 07-1 as of January 1, 2009. The adoption of EITF 07-1 did not have a material effect on the Company's consolidated results of operations, financial condition or cash flows.

In December 2007, the FASB issued SFAS No. 141(R) *Business Combinations* (SFAS 141(R)), as codified in FASB ASC topic 805, *Business Combinations* (ASC 805) and SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51* (SFAS 160), as codified in FASB ASC topic 810, *Consolidation* (ASC 810). SFAS 141(R) changes how business acquisitions are accounted for and impacts financial statements both on the acquisition date and in subsequent periods. SFAS 160 changes the accounting and reporting for minority interests, which are recharacterized as noncontrolling interests and classified as a component of equity. SFAS 141(R) and SFAS 160 were required to be adopted concurrently and became effective for fiscal years, beginning on or after December 15, 2008. We have adopted SFAS 141(R) and SFAS 160 as of January 1, 2009. The adoption of SFAS 141(R) had a material impact on the accounting for our merger with Indevus in February of 2009. See Note 5 for further discussion. The adoption of SFAS 160 did not have a material effect on the Company's consolidated results of operations, financial condition or cash flows.

In April 2009, the FASB issued FASB Staff Position FAS 141(R)-1, *Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies* (FSP SFAS 141(R)-1), as codified in ASC 805, which amended the provisions related to the initial recognition and measurement, subsequent measurement and disclosure of assets and liabilities arising from contingencies in a business combination under SFAS 141(R). The requirements in SFAS 141 for acquired contingencies were carried forward and require that such contingencies be recognized at fair value on the acquisition date if fair value can be reasonably estimated during the allocation period. Otherwise, companies will typically account for the acquired contingencies in accordance with Statement of Financial Accounting Standards No. 5, *Accounting for Contingencies* (SFAS 5), as codified primarily in FASB ASC topic 450, *Contingencies* (ASC 450). FSP SFAS 141(R)-1 became effective for fiscal years, beginning on or after December 15, 2008. We have adopted FSP SFAS 141(R)-1 as of January 1, 2009. See Note 5 for further discussion.

In April 2008, the FASB issued FASB Staff Position No. 142-3, *Determination of the Useful Life of Intangible Assets* (FSP 142-3) as codified in FASB ASC subtopic 350-30, *Intangibles - Goodwill and Other: General Intangibles Other than Goodwill* (ASC 350-30) and topic 275, *Risks and Uncertainties* (ASC 275), which amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized





## **Table of Contents**

intangible asset under SFAS No. 142, *Goodwill and Other Intangible Assets*, as codified in FASB ASC topic 350, *Intangibles Goodwill and Other* (ASC 350). This pronouncement requires enhanced disclosures concerning a company's treatment of costs incurred to renew or extend the term of a recognized intangible asset. FSP 142-3 became effective for financial statements issued for fiscal years beginning after December 15, 2008. We have adopted FSP 142-3 as of January 1, 2009. The adoption of FSP 142-3 did not have a material impact on our consolidated financial statements.

In May 2008, the FASB issued FASB Staff Position APB 14-1, *Accounting for Convertible Debt Instruments That May be Settled in Cash upon Conversion (Including Partial Cash Settlement)* (FSP APB 14-1), as codified in ASC 470-20. FSP APB 14-1 requires that issuers of convertible debt instruments that may be settled in cash or other assets on conversion to separately account for the liability and equity components of the instrument in a manner that will reflect the entity's nonconvertible debt borrowing rate on the instrument's issuance date when interest cost is recognized in subsequent periods. Our Convertible Notes are within the scope of FSP APB 14-1. Therefore, we 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 FSP APB 14-1 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. We have adopted FSP APB 14-1 as of January 1, 2009. The adoption of FSP APB 14-1 will result in the recognition of approximately \$138.7 million of additional interest expense, on a pre-tax basis, over the life of our Convertible Notes. See Note 12 for further details.

In June 2008, the FASB issued FASB Staff Position EITF 03-6-1, *Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities* (FSP EITF 03-6-1), as codified in FASB ASC topic 260, *Earnings per Share* (ASC 260). FSP EITF 03-6-1 addresses whether instruments granted in share-based payment transactions are participating securities prior to vesting, and therefore need to be included in the computation of earnings per share under the two-class method as described in FASB Statement of Financial Accounting Standards No. 128, *Earnings per Share, as codified in ASC 260*. FSP EITF 03-6-1 is effective for financial statements issued for fiscal years beginning on or after December 15, 2008 and earlier adoption is prohibited. We have adopted FSP EITF 03-6-1 as of January 1, 2009. The adoption of FSP EITF 03-6-1 did not have a material effect on our results of operations or financial position.

In June 2008, the EITF of the FASB ratified the consensus reached in EITF Issue No. 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock* (EITF 07-5), as codified in FASB ASC subtopic 815-40, *Derivatives and Hedging: Contracts in Entity's Own Equity* (ASC 815-40). EITF 07-5 was issued to clarify how to determine whether certain instruments or features are indexed to an entity's own stock under EITF Issue No. 01-6, *The Meaning of Indexed to a Company's Own Stock* (EITF 01-6), also codified in ASC 815-40. The consensus in EITF 07-5 applies to any freestanding financial instrument or embedded feature that has the characteristics of a derivative as defined in FASB Statement No. 133, *Accounting for Derivative Instruments and Hedging Activities* (SFAS 133), as codified in FASB ASC topic 815, *Derivatives and Hedging* (ASC 815). The consensus in EITF 07-5 supersedes EITF 01-6 and became effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. We adopted EITF 07-5 as of January 1, 2009. The adoption of EITF 07-5 did not have a material effect on the Company's consolidated results of operations or financial condition.

In November 2008, the EITF of the FASB ratified the consensus reached in EITF Issue No. 08-6, *Equity Method Accounting Considerations* (EITF 08-6), as codified in ASC 323. The application of the equity method is affected by the accounting for business combinations under SFAS 141(R) and the accounting for consolidated subsidiaries under SFAS 160. Therefore, the objective of EITF 08-6 is to clarify how to account for certain transactions and impairment considerations involving equity method investments. EITF 08-6 became effective for fiscal years beginning on or after December 15, 2008, and interim periods within those fiscal years, consistent with the effective dates of Statement 141(R) and Statement 160. EITF 08-6 is to be applied prospectively. We adopted EITF 08-6 as of January 1, 2009. The adoption of EITF 08-6 did not have a material effect on the Company's consolidated results of operations or financial condition.

In November 2008, the EITF of the FASB ratified the consensus reached in EITF Issue No. 08-7, *Accounting for Defensive Intangible Assets* (EITF 08-7), as codified in the FASB ASC topic 350, subtopic 30 (ASC 350-30). While the guidance in SFAS 141(R) governs initial recognition and measurement of defensive intangible assets, EITF 08-7 was issued to clarify how defensive intangible assets acquired in a business combination or an asset acquisition should be accounted for subsequent to their acquisition. A defensive intangible asset is defined as an intangible asset acquired in a business combination or asset acquisition that an entity does not intend to actively use but intends to prevent others from using. EITF 08-7 requires a defensive intangible asset to be accounted for as a separate unit of accounting and assigned a useful life in accordance with SFAS 142, as codified in ASC 350. EITF 08-7 became effective for intangible assets acquired on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. We adopted EITF 08-7 as of January 1, 2009. The adoption of EITF 08-7 did not have a material effect on the Company's consolidated results of operations or financial condition.

## **Table of Contents**

In April 2009, the FASB issued FSP No. SFAS 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Has Significantly Decreased and Identifying Transactions That Are Not Orderly* (FSP SFAS 157-4), as codified in ASC 820. FSP SFAS 157-4 amends SFAS 157 and provides additional guidance for estimating fair value in accordance with SFAS 157 when the volume and level of activity for the asset and liability have significantly decreased in relation to normal market activity for the asset or liability. FSP SFAS 157-4 also provides guidance on identifying circumstances that indicate a transaction is not orderly. FSP SFAS 157-4 is effective for interim and annual periods ending after June 15, 2009. We adopted FSP SFAS 157-4 beginning with the quarterly period ended June 30, 2009. The adoption of FSP SFAS 157-4 did not have a material effect on the Company's consolidated results of operations or financial condition.

In April 2009, the FASB issued FSP No. SFAS 115-2 and SFAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments* (FSP SFAS 115-2) as codified in FASB ASC topic 320, *Investments—Debt and Equity Securities* (ASC 320). FSP SFAS 115-2 amends SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, as codified in ASC 320 and FSP No. FAS 115-1 and FAS 124-1, *The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments*, as codified in FASB ASC 320. FSP SFAS 115-2 provides additional guidance to make other-than-temporary impairments more operational and to improve the financial statement presentation of such impairments. FSP SFAS 115-2 is effective for interim and annual periods ending after June 15, 2009. We adopted FSP SFAS 115-2 beginning with the quarterly period ended June 30, 2009. The adoption of FSP SFAS 115-2 did not have a material effect on the Company's consolidated results of operations or financial condition.

In April 2009, the FASB issued FSP No. SFAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments* (FSP SFAS 107-1), as codified in ASC 825. FSP SFAS 107-1 amends SFAS No. 107, *Disclosures about Fair Value of Financial Instruments*, and APB Opinion No. 28, *Interim Financial Reporting*, by requiring disclosures with respect to the fair value of financial instruments in interim and annual financial statements. FSP SFAS 107-1 is effective for interim and annual periods ending after June 15, 2009. We adopted FSP SFAS 107-1 beginning with the quarterly period ended June 30, 2009. The adoption of FSP SFAS 107-1 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, Fair Value of Financial Instruments for further discussion.

### *Accounting Pronouncements Issued But Not Yet Adopted*

In June 2009, the FASB issued SFAS No. 167, *Amendments to FASB Interpretation No. 46(R)* (SFAS 167), as codified in ASC 810. SFAS 167 amends FIN 46(R), *Consolidation of Variable Interest Entities (revised December 2003) an interpretation of ARB No. 51* (FIN 46(R)) by replacing the quantitative-based risks and rewards calculation for determining which enterprise, if any, has a controlling financial interest in a variable interest entity with a primarily qualitative approach focused on identifying which enterprise has the power to direct the activities of a variable interest entity that most significantly impact the entity's economic performance and (1) the obligation to absorb losses of the entity or (2) the right to receive benefits from the entity. SFAS 167 requires an additional reconsideration event when determining whether an entity is a variable interest entity when any changes in facts and circumstances occur such that the holders of the equity investment at risk, as a group, lose the power from voting rights or similar rights of those investments to direct the activities of the entity that most significantly impact the entity's economic performance. It also requires ongoing assessments of whether an enterprise is the primary beneficiary of a variable interest entity. SFAS 167 also requires additional disclosures about an enterprise's involvement in variable interest entities. SFAS 167 nullifies FSP SFAS 140-4 and FIN 46(R)-8. However, the content of the enhanced disclosures required by SFAS 167 is generally consistent with that previously required by the FSP. SFAS 167 is effective as of the beginning of each reporting entity's first annual reporting period that begins after November 15, 2009, for interim periods within that first annual reporting period, and for interim and annual reporting periods thereafter. Earlier application is prohibited. The Company is currently evaluating the impact of adopting SFAS 167 on our consolidated results of operations and financial position.

## **NOTE 3. FAIR VALUE OF FINANCIAL INSTRUMENTS**

As of June 30, 2009, 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 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

**Table of Contents**

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. As of June 30, 2009 and December 31, 2008, \$46.9 million and \$356.9 million, respectively, of our money market funds are held in funds that solely invest in U.S. Treasury Bills. 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 as of June 30, 2009 (in thousands):

	June 30, 2009	
	Carrying Amount	Fair Value
<b>Current assets:</b>		
Auction-rate securities	\$ 850	\$ 850
Auction-rate securities rights	24,808	24,808
<b>Long-term assets:</b>		
Auction-rate securities	\$ 237,770	\$ 237,770
Equity securities	3,650	3,650
Equity and cost method investments	28,018	N/A
	\$ 295,096	
<b>Current liabilities:</b>		
Acquisition-related contingent consideration	\$ (149,860)	\$ (149,860)
6.25% Convertible Notes Payable	(68,380)	(68,380)
<b>Long-term liabilities:</b>		
Acquisition-related contingent consideration	(64,090)	(64,090)
1.75% Convertible Senior Subordinated Notes Due 2015	(251,533)	(241,199)
Non-Recourse Notes Payable	(115,017)	(114,205)
Minimum Voltaren® gel royalties due to Novartis AG	(48,281)	(48,281)
	\$ (697,161)	\$ (686,015)

Equity securities consist of publicly traded common stock the value which is based on a quoted market price. These securities are not held to support current operations and are therefore classified as non-current assets. The acquisition-related contingent consideration represents amounts payable to the former shareholders under contingent cash consideration agreements relating to the development referred to as Nebido® (testosterone undecanoate) and octreotide. These amounts are required to be measured at fair value on a recurring basis (see Note 5 for further details). The fair value of our 1.75% Convertible Senior Subordinated Notes is based on an income approach known as the binomial lattice model which incorporated certain inputs and assumptions, including scheduled coupon and principal payments, the conversion feature inherent in the Convertible Notes, the put feature inherent in the Convertible Notes, and a stock price volatility of 36% that was based on historic volatility of the Company's common stock and other factors. The technique is consistent with the methodology used for the adoption of FSP APB 14-1 (see Note 12. Debt). The 6.25% Convertible Notes Payable and 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) for both debt instruments. The 6.25% Convertible Notes Payable due July 15, 2009, were accreted up to their face value at maturity of \$68.3 million and settled in their entirety upon maturity in that amount. Therefore, at June 30, 2009, the carrying value of our 6.25% Convertible Notes approximated fair value. The Non-recourse Notes due in 2024 are being amortized down to their face value at maturity of \$105.0 million. The fair value of our Non-recourse Notes at June 30, 2009 was determined using an income approach (present value technique) consistent with the methodology used as of February 23, 2009. The minimum Voltaren® Gel royalty due to Novartis AG was recorded at fair value at inception during 2008 using an income approach (present value technique) and is being accreted up to the maximum potential future payment of \$60.0 million. The Company is not aware of any events or circumstances that would have a significant adverse effect on the fair value of this Novartis AG liability. We believe the carrying amount of this minimum royalty guarantee at June 30, 2009 represents a reasonable approximation of the costs to terminate or otherwise settle the obligation with Novartis AG. Accordingly, the carrying value approximates fair value as of June 30, 2009. The fair value of equity method and cost method investments is not readily available nor have we estimated the



## **Table of Contents**

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 fair value of our \$20.0 million cost method investment.

As of June 30, 2009, the Company held certain assets and liabilities that are required to be measured at fair value on a recurring basis, including money market funds, available-for-sale securities and trading securities, auction-rate securities rights, and acquisition-related contingent consideration. SFAS 157 (as codified in ASC 820) establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions. The fair value of the Company's money market funds and \$0.9 million of original par value trading auction-rate securities are based on quoted market prices, representing Level 1 inputs under SFAS 157. The fair value of the Company's available-for-sale and the remaining trading securities, auction-rate securities rights and acquisition-related contingent consideration are all based on unobservable inputs as little or no market data exists for these assets and liabilities. Consequently, these inputs fall within Level 3 of the fair value hierarchy under SFAS 157.

### *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. Prior to February 2008, the Company was able to determine the fair value of the auction-rate securities using a market approach valuation technique based on successful auctions of our securities or based on quoted prices in active markets for identical auction-rate securities without any adjustment (Level 1 of the fair value hierarchy).

Since mid-February 2008, the market for auction-rate securities has seen a dramatic decrease in the volume of trades relative to historical levels. At June 30, 2009, (the measurement date), the Company determined that the market for its auction-rate securities was inactive. That determination was made considering that there are very few observable transactions for the auction-rate securities or similar securities, the prices for transactions that have occurred are not current, and the observable prices for those transactions to the extent they exist vary substantially either over time or among market makers, thus reducing the potential usefulness of those observations. In addition, the current lack of liquidity prevents the Company from comparing our securities directly to securities with quoted market prices. Consequently, while we have appropriately considered those observable inputs, ultimately, our auction-rate securities will be classified within Level 3 of the fair value hierarchy described in Note 2 because significant judgments are required to determine fair value at the measurement date.

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

In October 2008, UBS AG (UBS) made an offer (the UBS Offer) of auction-rate securities rights (the Rights) to the Company and other clients of UBS Securities LLC and UBS Financial Services Inc. (collectively, the UBS Entities), pursuant to which the Company is entitled to sell to UBS all auction-rate securities held by the Company as of February 13, 2008 in a UBS account (the Eligible Auction-Rate Securities). The Rights permit the Company to require UBS to purchase the Eligible Auction-Rate Securities for a price equal to original par value plus any accrued but unpaid dividends or interest beginning on June 30, 2010 and ending on July 2, 2012 (the Expiration Date). As of June 30, 2009, we had Eligible Auction-Rate Securities with original par value of \$247.0 million, representing 93% of our total auction-rate securities portfolio at par. The remaining seven percent (7%), or \$18.8 million at par, of our auction-rate securities portfolio are not held in a UBS account and therefore are not subject to the UBS Offer.

The UBS Offer was made pursuant to agreements in principle entered into by the UBS Entities with the Securities and Exchange Commission, the New York Attorney General, the Texas State Securities Board and other state regulatory agencies represented by North American Securities Administrators Association, and a settlement agreement with the Massachusetts Securities Division to settle investigations brought by each of these agencies against the UBS

## **Table of Contents**

Entities relating to the sale and marketing of auction-rate securities. The alleged conduct underlying these investigations suggested that the UBS Entities marketed auction-rate securities as cash alternatives but failed to adequately disclose liquidity risk.

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.

In addition, as part of the UBS Offer, Endo is eligible for no net cost loans, should we desire to borrow money prior to the commencement of the exercise period for the Rights. Under the terms of the UBS Offer, Endo may be eligible for no net cost loans for an amount up to 75% of the market value of the Eligible Auction-Rate Securities at the time of the loan. If and as soon as UBS receives proceeds from a purchase of the Eligible Auction-Rate Securities, the loans will become partially payable in the amount of the proceeds.

Acceptance of the UBS Offer constituted a substantive change in facts and circumstances that altered the Company's view that it intends 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.

Acceptance of the UBS Offer created an enforceable legal right by and between the Company and UBS. The UBS Offer is a legally separate contractual agreement and is non-transferable. The Rights are not readily convertible to cash and do not provide for net settlement. Accordingly, the Rights do not meet the definition of a derivative instrument and are being 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.

Concurrent with the acceptance of the UBS Offer, the Company made a one-time election to transfer the Eligible Auction-Rate Securities from the available-for-sale category to the trading category pursuant to SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, as codified in ASC 323. The Company made the election to transfer the securities into the trading category 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. Changes in the fair value of the Eligible Auction-Rate Securities are now recorded to earnings. During the six-month period ended June 30, 2009, the fair value of these securities increased by \$4.8 million, which was recorded as a gain and included in other income, net in the Condensed Consolidated Statements of Operations.

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

In November 2008, we elected the fair value option under SFAS 159 (as codified in ASC 825) for the Rights. As further described in Note 2, SFAS 159 provides companies with an option to report selected financial assets and liabilities at fair value. As a result of our SFAS 159 election, the fair value of the Rights is re-measured each reporting period with the corresponding changes in fair value reported in earnings. Since the Rights are freestanding financial instruments, they do not affect the separate determination of the fair value of the Eligible Auction-Rate Securities. However, in management's view the Rights act as an economic hedge against further fair value changes in the Eligible Auction-Rate Securities. Accordingly, management has elected the fair value option under SFAS 159, as it believes it is most appropriate to recognize future changes in the fair value of the Rights as those changes occur in order to offset the fair value movements in the Eligible Auction-Rate Securities. As of December 31, 2008 the fair value of our the Rights was \$27.3 million. At June 30, 2009, the fair value of the Rights decreased to \$24.8 million to reflect the fair value measurement of the Rights at that date. The decrease in fair value from December 31, 2008 to June 30, 2009 of \$2.5 million was recognized as a charge to earnings and included in other income, net in the Condensed Consolidated Statements of Operations. Future changes in fair value will also be recognized in earnings in accordance with SFAS 159.

### *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 auction-rate securities. Specifically, the Company used the discount rate adjustment technique described in Appendix B of SFAS 157 (as codified in ASC 820) to determine an indication of fair value.

## **Table of Contents**

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

The Company identifies the times to maturity of the auction-rate securities as the time at which principal is available to the investor. This can occur because the auction-rate security is paying a coupon that is above the required rate of return, and the Company treats the security as being called. It can also occur because the market has returned to normal and the Company treats the auctions as having recommenced. Lastly, and most frequently, the Company treats the principal as being returned as prepayment occurs and at the maturity of the security. The weighted average life used for each security representing time to maturity ranges from 4 to 8 years. The weighted average life measured across the entire auction-rate securities portfolio is approximately seven (7) years.

The Company calculates coupon rates based on estimated relationships between the maximum coupon rate (the coupon rate in event of a failure) and market interest rates. The representative coupon rates on June 30, 2009 ranged from 5.09% to 5.75%. The Company calculates appropriate discount rates for securities that include base interest rates, index spreads over the base rate, and security-specific spreads. These spreads include the possibility of changes in credit risk over time. At June 30, 2009, the spreads over the base rate for our auction-rate securities applied to our auction-rate securities ranged from 195 basis points to 602 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 in the auction-rate securities. We believe it is not unreasonable to assume a 150 basis points adjustment to the required rate of return and a term of either three, four or five years to adjust for this lack of liquidity. The increase in the required rate of return decreases the prices of the securities. However, the assumption of a three, four or five-year term shortens the times to maturity and increases the prices of the securities. The Company has evaluated the impact of applying each term and the reasonableness of the range indicated by the results. The Company chose to use a four-year term to adjust for the lack of liquidity as we believe it is the point within the range that is most representative of fair value. The Company's determination is based in part on the fact that the fair values indicated by the results are reasonable in relation to each other given the nature of the securities and current market conditions.

At June 30, 2009, the fair value of our auction-rate securities, as determined by applying the above described discount rate adjustment technique, was approximately \$238.6 million, representing a 10%, or \$27.2 million discount from their original purchase price or par value, which the Company attributes to liquidity issues rather than credit issues. 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 was increased by approximately \$5.2 million at June 30, 2009, reflecting the change in fair value for the six months ended June 30, 2009. The portion of this increase in fair value related to the Eligible Auction-Rate Securities was \$4.8 million and was recorded in earnings 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, as we currently do not intend to sell these securities, it is not more likely than not that we will be required to sell these securities before the recovery of our amortized cost basis and we currently expect to recover the entire cost basis of these securities. Our assessment was based in large part on the financial condition and near-term prospects of the underlying issuers. Accordingly, we recorded a \$0.3 million increase in shareholders' equity in accumulated other comprehensive loss. Securities not subject to the UBS Offer are analyzed each reporting period for other-than-temporary impairment factors.

### *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 Rights. Specifically, the Company used the discount rate adjustment technique described in Appendix B of SFAS 157 (as codified in ASC 820) to determine an indication of fair value. The Rights provide the Company with the ability to sell the Eligible Auction-Rate Securities at par plus accrued interest and dividends to UBS beginning on June 30, 2010.

The values of the Rights were estimated as the value of a portfolio designed to approximate the cash flows of the UBS Offer. The portfolio consists of a bond issued by UBS that will mature equal to the face value of the Eligible Auction-Rate Securities, a series of payments that will replicate the coupons of the Eligible Auction-Rate Securities, and a short position in the callable Eligible Auction-Rate Securities. If the UBS Offer is in the money on the exercise date, then both the UBS Offer and the replicating portfolio will be worth the difference between the par value plus





**Table of Contents**

accrued interest and dividends of the Eligible Auction-Rate Securities and the market value of the Eligible Auction-Rate Securities. If the UBS Offer is out of the money on the exercise date, then both the replicating portfolio and the UBS Offer 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 Eligible 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, 2009, the fair value of the Rights, as determined by applying the above described discount rate adjustment technique, was approximately \$24.8 million. As described above, 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 Company's financial assets and liabilities measured at fair value on a recurring basis subject to the disclosure requirements of SFAS 157 (as codified in ASC 820) at June 30, 2009, were as follows (in thousands):

		Fair Value Measurements at Reporting Date Using			
		Quoted Prices in			
		Active			
		Markets			
		for	Significant Other	Significant	
		Identical	Observable	Unobservable	
		Assets	Inputs	Inputs	
		(Level 1)	(Level 2)	(Level 3)	Total
Assets:					
Money market funds		\$ 46,949	\$	\$	\$ 46,949
Auction-rate securities		850		237,770	238,620
Auction-rate securities rights				24,808	24,808
Equity securities		3,650			3,650
Total		\$ 51,449	\$	\$ 262,578	\$ 314,027
Liabilities:					
Acquisition-related contingent consideration	current	\$	\$	\$ (149,860)	\$ (149,860)
Acquisition-related contingent consideration	long-term			(64,090)	\$ (64,090)
Total		\$	\$	\$ (213,950)	\$ (213,950)

Auction-rate securities included in Level 1 represent trading securities that were called by the issuer and settled subsequent to June 30, 2009 at amounts equal to our original par value investment. Consequently, these trading securities categorized within Level 1 of the fair value hierarchy are classified as current marketable securities at June 30, 2009.

The following tables present changes to the Company's financial assets and liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) as defined in SFAS 157 (as codified in ASC 820-10) for the three months ended June 30, 2009 (in thousands):

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)		
	Auction-rate Securities	Auction-rate Securities Rights	Total
<b>Assets:</b>			
Balance at March 31, 2009	\$ 227,670	\$ 33,587	\$ 261,257
Amounts sold or redeemed	(400)		(400)

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

Amounts acquired or issued

Transfers in and/or (out) of Level 3	(850)		(850)
Changes in fair value recorded in earnings	10,910	(8,779)	2,131
Unrealized loss included in other comprehensive loss	440		440

Balance at June 30, 2009	\$ 237,770	\$ 24,808	\$ 262,578
--------------------------	------------	-----------	------------

**Table of Contents**

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3) Acquisition-related Contingent Consideration
<b>Liabilities:</b>	
Balance at March 31, 2009	\$ (188,020)
Amounts acquired or issued	
Transfers in and/or (out) of Level 3	
Changes in fair value recorded in earnings	(25,930)
Balance at June 30, 2009	\$ (213,950)

The following tables present changes to the Company's financial assets and liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) as defined in SFAS 157 (as codified in ASC 820) for the six months ended June 30, 2009 (in thousands):

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

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3) Acquisition-related Contingent Consideration
<b>Liabilities:</b>	
Balance at March 31, 2009	\$
Amounts acquired or issued	(188,020)
Transfers in and/or (out) of Level 3	
Changes in fair value recorded in earnings	(25,930)
Balance at June 30, 2009	\$ (213,950)

For a complete discussion of the Company's acquisition-related contingent consideration, including relevant fair value disclosures, see Note 5. Acquisitions.

At June 30, 2009, the fair value of the Company's trading securities was \$221.2 million. The following is a summary of available-for-sale securities held by the Company as of June 30, 2009 and December 31, 2008 (in thousands):

	Amortized Cost	Available-for-sale Gross Unrealized Gains	Gross Unrealized (Losses)	Fair Value
<b>June 30, 2009:</b>				
Money market funds	\$ 46,949	\$	\$	\$ 46,949
<i>Total included in cash and cash equivalents</i>	46,949			46,949

**Table of Contents**

	Amortized Cost	Available-for-sale Gross Unrealized Gains	Gross Unrealized (Losses)	Fair Value
Auction-rate securities	18,800		(1,380)	17,420
Equity securities	5,000		(1,350)	3,650
<i>Long-term marketable securities</i>	23,800		(2,730)	21,070
<i>Total available-for-sale securities</i>	\$ 70,749	\$	\$ (2,730)	\$ 68,019

	Amortized Cost	Available-for-sale Gross Unrealized Gains	Gross Unrealized (Losses)	Fair Value
<b>December 31, 2008:</b>				
Money market funds	\$ 356,867	\$	\$	\$ 356,867
<i>Total included in cash and cash equivalents</i>	356,867			356,867
Auction-rate securities	18,800		(1,729)	17,071
Equity securities	5,000	199		5,199
<i>Long-term available-for-sale securities</i>	23,800	199	(1,729)	22,270
<i>Total available-for-sale securities</i>	\$ 380,667	\$ 199	\$ (1,729)	\$ 379,137

During the six-month period ended June 30, 2009, we sold \$7.1 million of auction-rate securities at par value. During the six-month period ended June 30, 2008, we sold \$113.8 million of original par value variable-rate demand obligations and \$287.0 million of auction-rate securities at par value. There were no realized holding gains and losses resulting from the sales of our auction rate securities and variable rate demand obligations during the six-month period ended June 30, 2009 and 2008. 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 either the Federal Family Education Loan Program, or FFELP, or a combination of FFELP and other monoline insurers such as Ambac Assurance Corp., or AMBAC, and MBIA Insurance Corp, or MBIA. As of July 24, 2009, MBIA was rated Ba3 by Moody's and BB by Standard and Poor's. AMBAC was rated Caa1 by Moody's and BB by Standard and Poor's.

The following tables set forth the fair value of our long-term auction-rate securities by type of security and underlying credit rating as of June 30, 2009 and December 31, 2008 (in thousands):

As of June 30, 2009	Underlying Credit Rating(1)					Total
	AAA	AA	A	Baa	Ba	
<i>Underlying security:</i>						
Student loans	\$ 134,900	\$ 5,062	\$ 66,709	\$ 7,126	\$ 24,823	\$ 238,620
<i>Total auction-rate securities included in long-term marketable securities</i>	\$ 134,900	\$ 5,062	\$ 66,709	\$ 7,126	\$ 24,823	\$ 238,620

As of December 31, 2008	Underlying Credit Rating(1)				Total
	AAA	AA	A		
<i>Underlying security:</i>					
Student loans	\$ 166,885	\$ 35,302	\$ 31,818		\$ 234,005

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

<i>Total auction-rate securities included in long-term marketable securities</i>	\$ 166,885	\$ 35,302	\$ 31,818	\$ 234,005
--	------------	-----------	-----------	------------

(1) Our auction-rate securities maintain split ratings. For purposes of this table, securities are categorized according to their lowest rating. As of June 30, 2009, the yields on our long-term auction-rate securities ranged from 0.51% to 0.98%. These yields represent the predetermined maximum reset rates that occur upon auction failures according to the specific terms within each security's prospectus. As of June 30, 2009, the weighted average yield for our long-term auction-rate securities was 0.79%. Total interest earned on our auction-rate securities during the six-months ended June 30, 2009 and 2008 was \$1.5 million and \$8.8 million, respectively. Further, the issuers have been making interest payments when due.

**Table of Contents**

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.

	June 30, 2009		December 31, 2008	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Debt securities:				
Due in less than 1 year	\$	\$	\$	\$
Due in 1 to 5 years				
Due in 5 to 10 years				
Due after 10 years	18,800	17,420	18,800	17,071
Equity securities	5,000	3,650	5,000	5,199
Total	\$ 23,800	\$ 21,070	\$ 23,800	\$ 22,270

**NOTE 4. INVENTORIES**

Inventories are comprised of the following at June 30, 2009 and December 31, 2008, respectively (in thousands):

	June 30, 2009	December 31, 2008
Raw materials	\$ 12,350	\$ 7,157
Work-in-process	17,876	10,131
Finished goods	68,700	63,368
Total	\$ 98,926	\$ 80,656

**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, par value \$0.001 per share (the Indevus Shares), of Indevus, a Delaware corporation. On that day, the Company accepted for payment in accordance with the terms of the Offer, approximately 60.3 million Indevus Shares representing approximately 76% of the total outstanding Indevus Shares. 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 (the Offer Price), pursuant to the terms of the Agreement and Plan of Merger, dated as of January 5, 2009. Accordingly, the Company paid approximately \$367 million in aggregate initial cash consideration for the Indevus Shares and entered into the Nebido® (TU) 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 Nebido® (TU) Contingent Cash Consideration Agreement. As of the date hereof, Endo has paid the (i) aggregate cash consideration of \$367 million in respect of the Indevus Shares and (ii) cash consideration for unexercised in-the-money options. Endo funded such amounts with existing cash on hand. Indevus common stock ceased trading on NASDAQ at market close on March 23, 2009.

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





## **Table of Contents**

Indevus' approved products include the following:

Sanctura® (trospium chloride) was launched by Indevus in August 2004. Sanctura® is indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency and urinary frequency. We currently co-promote Sanctura® in the U.S. with our marketing partner, Allergan, Inc., however, our right to co-promote expires in September 2009.

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. We currently co-promote Sanctura XR® in the U.S. with our marketing partner, Allergan, Inc., however, our right to co-promote expires in September 2009.

Supprelin® LA was launched by Indevus 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 Indevus' patented Hydro® Polymer Technology, designed to provide the continuous 12-month administration of a controlled dose of histrelin, a GnRH agonist.

Vantas® was launched by Indevus 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 advanced prostate cancer. The product utilizes Indevus' patented Hydro® 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® 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 of Indevus: Vantas® and Supprelin® LA.

Valstar 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 urinary 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, Indevus 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. We continue to work closely with our manufacturing partner to resolve an issue that will likely delay the launch of Valstar™. We are hopeful this matter will be resolved quickly and we hope to re-launch Valstar™ later this year.

Indevus' primary development products include the following:

Testosterone undecanoate (TU) is a long-acting injectable testosterone preparation for the treatment of male hypogonadism that we have historically referred to as Nebido®. On May 6, 2009, we received notice from the FDA that Nebido® is unacceptable as a

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

proprietary name for testosterone undecanoate. Throughout this report, however, when we refer to the contingent cash consideration agreement relating to the product, we will call it the Nebido® (TU) Contingent Cash Consideration Agreement. The Company has submitted a request to the FDA for review of a new proprietary name for this product. Testosterone undecanoate is expected to be the first long-acting testosterone preparation available in the U.S. in the growing market for testosterone replacement therapies. Indevus acquired U.S. rights to testosterone undecanoate from Schering AG, Germany, in July 2005. In June 2008, Indevus 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 testosterone undecanoate intramuscular injection. The FDA has informed us that it is targeting September 2, 2009 as the action date for a decision on this application.

**Table of Contents**

PRO 2000, currently in Phase III clinical trials, is a candidate topical microbicide for the prevention of sexually transmitted infections including infection by the Human Immunodeficiency Virus (HIV), the cause of Acquired Immunodeficiency Syndrome (AIDS). The compound is believed to block the entry of sexually transmitted disease (STD) pathogens into human cells. In addition to its demonstrated activity against HIV infection in laboratory tests and animal models, PRO 2000 has been shown to be active against other STD pathogens such as herpes, chlamydia, and the bacterium that causes gonorrhea. Designed to be applied vaginally prior to sexual intercourse, PRO 2000 promises to offer a discreet safer sex option that can be controlled by women.

Octreotide implant, currently in Phase III clinical trials for the treatment of acromegaly, utilizes Indevus's patented Hydro® 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). Octreotide implant is also approved to treat symptoms associated with metastatic carcinoid tumors and vasoactive intestinal peptide secreting adenomas, which are gastrointestinal tumors. The octreotide implant is also currently in Phase II trials for the treatment of carcinoid syndrome.

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 will market products through four field sales forces and have the capability to develop innovative new therapies using a novel drug delivery technology.

The operating results of Indevus from February 23, 2009 to June 30, 2009 are included in the accompanying Condensed Consolidated Statements of Operations. The Condensed Consolidated Balance Sheet as of June 30, 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 \$541.6 million, which consisted of the following (in thousands):

	<b>Fair Value of Consideration Transferred</b>
Cash	\$ 367,221
Contingent consideration	174,350
<b>Total</b>	<b>\$ 541,571</b>

The contingent consideration relates to the amounts payable under the Nebido® (TU) Contingent Cash Consideration Agreement and the Octreotide Contingent Cash Consideration Agreement. In the event that the Company receives an approval letter from the FDA with respect to the testosterone undecanoate 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 testosterone undecanoate immediately and provides labeling for testosterone undecanoate that does not contain a boxed warning (testosterone undecanoate With Label) or alternatively, (ii) pay an additional \$1.00 per Indevus Share, if such approval letter grants the right to market and sell testosterone undecanoate immediately and provides labeling for testosterone undecanoate that contains a boxed warning (testosterone undecanoate Without Label). In the event that either a testosterone undecanoate With Label approval or a testosterone undecanoate 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 Nebido® (TU) Contingent Cash Consideration Agreement.

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

Endo has deposited \$175.0 million in cash in an escrow account with a paying agent pursuant to the terms of the Nebido® (TU) Contingent Cash Consideration Agreement, which amount is equal to the aggregate amount payable to the former Indevus stockholders if the testosterone undecanoate With Label approval is obtained under the terms of the Nebido® (TU) Contingent Cash Consideration Agreement. This amount is included in our restricted cash balance in the accompanying Condensed Consolidated Balance Sheet and is restricted through December 15,

2009, the date when such

## **Table of Contents**

amount will be released in accordance with the terms of the Nebido® (TU) Contingent Cash Consideration Agreement if not previously paid to former Indevus stockholders under the terms of the Nebido® (TU) Contingent Cash Consideration Agreement.

The range of the undiscounted amounts the Company could pay under the Nebido® (TU) Contingent Cash Consideration Agreement is between \$0 and approximately \$175 million. The fair value of the contractual obligation to pay the testosterone undecanoate contingent consideration recognized on the Acquisition Date was \$134.1 million. We determined the fair value of the obligation to pay the testosterone undecanoate 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 as defined in SFAS 157 (as codified in FASB ASC 820). Under the Nebido® (TU) 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 a testosterone undecanoate With Label approval, (2) obtaining a testosterone undecanoate 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 testosterone undecanoate should the testosterone undecanoate Without Label approval be obtained. The fourth scenario is testosterone undecanoate 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 testosterone undecanoate. 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.

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 \$40.2 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 as defined in SFAS 157 (as codified in FASB ASC 820). 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.

In addition to the potential contingent payments under the Nebido® (TU) 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. (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 Nebido® (TU) 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.

In accordance with SFAS 141(R) (as codified in FASB ASC 805), 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 as defined in SFAS 157 (as codified in FASB ASC 820). The fair value of the Valera Contingent Consideration is estimated using the same assumptions used for the Nebido® (TU) Contingent Cash Consideration Agreement and Octreotide Contingent Cash Consideration Agreement, except that the probabilities associated with the

**Table of Contents**

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.

As of June 30, 2009, the fair value of the acquisition-related contingent consideration increased by \$25.9 million based on changes in management's estimates and other factors that occurred during the three months ended June 30, 2009. The increase in the liability was recorded as a charge to earnings and is included in the acquisition-related costs line item in the Condensed Consolidated Statements of Operations.

As of June 30, 2009, there were no changes to the range of the undiscounted amounts the Company may be required to pay under the Nebido® (TU) Contingent Cash Consideration Agreement and the Octreotide Contingent Consideration Agreement or related to the Valera Contingent Consideration.

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

	February 23, 2009 (As initially reported)	Measurement Period Adjustments	February 23, 2009 (As adjusted)
Cash and cash equivalents	\$ 117,675	\$	\$ 117,675
Accounts receivable	13,725	1,593	15,318
Inventories	15,808	(891)	14,917
Prepaid and other current assets	8,327		8,327
Property, plant and equipment	8,266		8,266
Other intangible assets	586,900	2,000	588,900
Deferred tax assets	159,769	5,624	165,393
Other non-current assets	764	155	919
<b>Total identifiable assets</b>	<b>\$ 911,234</b>	<b>\$ 8,481</b>	<b>\$ 919,715</b>
Accounts payable	\$ (5,081)	\$	\$ (5,081)
Accrued expenses	(27,357)	(1,440)	(28,797)
Convertible notes	(71,682)	(830)	(72,512)
Non-recourse notes	(115,235)		(115,235)
Deferred tax liabilities	(234,599)	1,188	(233,411)
Other non-current liabilities	(18,199)	(652)	(18,851)
<b>Total liabilities assumed</b>	<b>(472,153)</b>	<b>(1,734)</b>	<b>(473,887)</b>
<b>Net identifiable assets acquired</b>	<b>\$ 439,081</b>	<b>\$ 6,747</b>	<b>\$ 445,828</b>
Goodwill	\$ 102,490	\$ (6,747)	\$ 95,743
<b>Net assets acquired</b>	<b>\$ 541,571</b>	<b>\$</b>	<b>\$ 541,571</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 Acquisition Date to estimate the fair value of assets acquired and liabilities assumed. Measurement period adjustments reflect new information obtained about facts and circumstances that existed as of the Acquisition Date. The Company believes that information provides a reasonable basis for estimating the fair values of assets acquired and liabilities assumed but the Company is waiting for additional information necessary to finalize those fair values. Thus, the provisional measurements of fair value set forth above 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 Acquisition Date.

Of the \$588.9 million of acquired intangible assets, \$338.9 million was provisionally assigned to in-process research and development. The remaining \$250.0 million has been provisionally assigned to license rights and is subject to a provisional weighted average useful life of approximately 12 years.

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

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™	\$ 72.0	n/a
Testosterone undecanoate	120.0	n/a



**Table of Contents**

	<b>Valuation (in millions)</b>	<b>Amortization Period (in years)</b>
Octreotide Acromegaly	49.0	n/a
Octreotide Carcinoid Syndrome	9.0	n/a
Pagoclone	35.0	n/a
Pro 2000	29.0	n/a
Supprelin® LA	18.0	n/a
Other	6.9	n/a
<b>Total</b>	<b>\$ 338.9</b>	<b>n/a</b>
<b>License Rights:</b>		
Hydron® Polymer	\$ 31.0	17
Vantas®	21.0	6
Sanctura® Franchise	61.0	14
Supprelin® LA	136.0	10
Other	1.0	4
<b>Total</b>	<b>\$ 250.0</b>	<b>12</b>
<b>Total other intangible assets</b>	<b>\$ 588.9</b>	

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 pursuant to SFAS 157 (as codified in ASC 820). The relief from royalty method is based on a hypothetical royalty stream that would be received if the Company were to out-license the technology. The Hydron® Polymer Technology is currently used in the following products: Vantas®, Supprelin® LA and octreotide. Thus, we derived the hypothetical royalty income from the projected revenues of those drugs. The fair value of the Hydron® Polymer Technology also includes an existing royalty payable by the Company to the Population Council 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 15% 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 \$95.7 million of goodwill is currently assigned to our pharmaceutical products segment, which is our only reportable segment as of June 30, 2009. This assignment is subject to change as this business combination with Indevus could lead to additional reportable segments in the future. 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 \$165.4 million are related primarily to federal net operating loss carryforwards of Indevus and its subsidiaries. The deferred tax liabilities of \$233.4 million are related primarily to the difference between the book basis and tax basis of identifiable intangible assets. To the extent of any change to the provisional fair values of the intangible assets or other items, we would also expect to change the related deferred tax assets and liabilities that have been recorded at the Acquisition Date.

During the three and six months ended June 30, 2009, we expensed \$35.0 million and \$61.4 million of acquisition-related costs, respectively. These costs are included in line item entitled "Acquisition-related costs" in the accompanying Condensed Consolidated Statements of Operations and are comprised of the following items (in thousands):

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

	Acquisition-related Costs	
	Three Months Ended June 30, 2009	February 23, 2009 to June 30, 2009
Investment bank fees, includes Endo and Indevus	\$	\$ 13,030
Accounting and legal	1,073	6,962
Separation costs	6,910	13,879

**Table of Contents**

	Acquisition-related Costs	
	Three Months Ended June 30, 2009	February 23, 2009 to June 30, 2009
Other	1,110	1,627
	9,093	35,498
Changes in fair value of acquisition-related contingent consideration	25,930	25,930
Total	\$ 35,023	\$ 61,428

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

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

Net loss in the above table includes \$10.4 million of acquisition related costs for the three months ended June 30, 2009 and \$17.4 million of acquisition-related costs for the period from February 23, 2009 to June 30, 2009.

The following supplemental pro forma information presents the financial results as if the acquisition of Indevus had occurred January 1, 2009 for the three and six-months ended June 30, 2009 and on January 1, 2008 for the three and six-months ended June 30, 2008. 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 of Indevus been completed on January 1, 2008 or January 1, 2009, nor are they indicative of any future results.

	Three Months Ended June 30, 2008	Six Months Ended June 30, 2009 2008	
<b>Pro forma consolidated results (in thousands, except per share data):</b>			
Revenue	\$ 322,475	\$ 718,708	\$ 627,685
Net income	\$ 29,013	\$ 46,066	\$ 49,927
Basic earnings per share	\$ 0.24	\$ 0.39	\$ 0.39
Diluted earnings per share	\$ 0.23	\$ 0.39	\$ 0.39

These amounts have been calculated after applying the Company's accounting policies and adjusting the results of Indevus to reflect a different revenue recognition model, the additional depreciation and amortization that would have been charged assuming the fair value adjustments to property, plant and equipment, intangible assets, unfavorable leases and current and long-term debt, had been applied on January 1, 2009 or 2008, as applicable, together with the consequential tax effects.

*RxKinetix, Inc.*

On October 12, 2006, the Company acquired all of the outstanding common stock of privately held RxKinetix, Inc. RxKinetix specialized in developing new therapeutics focused on improving the quality of life for patients being treated for cancer. RxKinetix's most advanced product, now named EN3285, was, as of the acquisition date, in clinical Phase II for the prevention of oral mucositis, a painful, debilitating and often dose-limiting side effect that afflicts many patients being treated for cancer with radiation and/or chemotherapy. All of the purchased in-process research and development value from this transaction was assigned to EN3285 since the other products, as of the acquisition date, were very

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

early stage and did not meet the criteria to be recognized as assets.

In December 2007, the Company initiated the first of two phase III clinical trials of EN3285 for the prevention or delay of oral mucositis (OM). Endo had agreed to the trial design with the FDA under the Special Protocol Assessment (SPA) process. In March 2008, the first dosage of EN 3285 was administered to a patient enrolled in the clinical phase III trial, triggering a contingent purchase consideration payment to former shareholders of Indevus in the amount of \$15 million that was made in March 2008. In April 2008, the FDA notified us that they were placing our studies on clinical hold pending the submission to the FDA of additional pre-clinical data. In February 2009, the Company decided to discontinue all development activities related to EN3285.

**Table of Contents****NOTE 6. LICENSE AND COLLABORATION AGREEMENTS*****Commercial Products******Novartis AG***

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

Under the terms of the five-year Voltaren® Gel Agreement, Endo made an upfront cash payment of \$85 million to Novartis AG. Endo has agreed to pay royalties to Novartis AG on annual Net Sales of Voltaren® Gel, subject to certain thresholds as defined in the Voltaren® Gel Agreement. In addition, Endo has agreed to make certain guaranteed minimum annual royalty payments to Novartis AG of \$30 million per year payable in the fourth and fifth 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 Voltaren® Gel or (ii) the guaranteed minimum royalty for such Voltaren® Gel Agreement year. No royalty payments were payable to Novartis during the six months ended June 30, 2009 or 2008. Novartis is also eligible to receive a one-time milestone payment of \$25 million if annual net sales of Voltaren® Gel exceed \$300 million in the U.S. The \$85 million upfront payment and the present value of the guaranteed minimum royalties have been capitalized as an intangible asset in the amount of \$129.0 million, representing the fair value of the exclusive license to market Voltaren® Gel. We are amortizing this intangible asset over its estimated useful life of approximately 5 years.

Endo is solely responsible to commercialize Voltaren® Gel 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 expend a minimum amount of annual advertising and promotional expenses on the commercialization of Voltaren® Gel, subject to certain limitations as provided for under the Voltaren® Gel Agreement. In addition, Endo will be required to perform a minimum number of face-to-face one-on-one discussions with physicians and other healthcare practitioners (referred to as details) for the purpose of promoting Voltaren® Gel within its approved indication during each year of the Voltaren® Gel Agreement, subject to certain provisions under 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 Voltaren® Gel from Novartis. 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 as set forth in the Voltaren® Gel Agreement. Endo has an existing long-term manufacturing and development agreement with Novartis whereby Novartis has agreed to manufacture certain of our commercial products and products in development.

Novartis has the exclusive right, at its sole discretion, to effect a switch of Voltaren® Gel from a prescription product to an over-the-counter (OTC) product in the United States (referred to as an OTC Switch) by filing an amendment or supplement to the Voltaren® Gel 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 may not launch an OTC equivalent product prior to a time specified in the Voltaren® Gel Agreement, and Novartis may not take any action that results in the loss of the prescription product status for Voltaren® Gel 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 Voltaren® Gel 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, provided that, and subject to certain limitations and provisions as set forth in the Voltaren® Gel Agreement. As a condition to the payment of any and all such royalties, net sales of Voltaren® Gel in the United States must have exceeded a certain threshold as defined in the Voltaren® Gel Agreement prior to the launch of the OTC equivalent product by Novartis or its affiliates.

## **Table of Contents**

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 (1) year terms (each referred to as a Renewal Term) beyond the initial term. 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 (6) 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 competitor to Voltaren® Gel. 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 (6)-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 Voltaren® Gel 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 (referred to as the Hind License Agreement) with Hind Healthcare Inc. (referred to as Hind), for the sole and exclusive right to develop, use, market, promote and sell Lidoderm® (lidocaine patch 5%) 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. In March 2002, we extended this license with Hind to cover Lidoderm® in Canada and Mexico. During the six-month periods ended June 30, 2009 and 2008 we recorded \$40.7 million and \$40.5 million for these royalties to Hind, respectively, which were recorded as a reduction to net sales.

### *Penwest Pharmaceuticals Co.*

In September 1997, we entered into a collaboration agreement with Penwest Pharmaceuticals Co. to exclusively co-develop opioid analgesic products for pain management, using Penwest's patent-protected proprietary technology, for commercial sale worldwide. On April 2, 2002, we amended and restated this strategic alliance agreement between the parties (the 2002 Agreement) to provide, among other things, that this collaboration would cover only the opioid analgesic product, oxymorphone ER, now known as Opana® ER (oxymorphone HCl). We had historically shared, on an equal basis, the costs of products developed under this agreement. On March 18, 2003, we received notice from Penwest that it was exercising its right under the agreement to cease funding its share of the development and pre-launch marketing costs of oxymorphone ER due to concerns about their ability to access external capital funding opportunities in the future. Accordingly, we were responsible for funding 100% of these remaining costs until June 22, 2006, the date on which oxymorphone ER received FDA approval. In January 2007, the Company and Penwest entered into an amendment (the 2007 Amendment) to the 2002 Agreement. Under the terms of the 2007 Amendment, Endo and Penwest agreed to restructure the 2002 Agreement to provide that royalties payable to Penwest for U.S. sales of Opana® ER will be calculated based on net sales of the product rather than on operating profit, and to change certain other provisions of the 2002 Agreement. The 2007 Amendment also resolved the parties' ongoing disagreement with regard to sharing of marketing expenses during the period prior to when Opana® ER reaches profitability. The key financial terms of the 2007 Amendment are summarized as follows:

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

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

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

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

In 2003, Penwest opted out of funding development costs for Opana® ER. Under the 2007 Amendment, the parties have agreed that Penwest's share of these unfunded development costs will be fixed at \$28 million and will be recouped by Endo through a temporary 50% reduction in royalties payable to Penwest. As of June 30, 2009, Endo has recouped approximately \$13.8 million of these unfunded development costs.

## **Table of Contents**

Royalties will be reduced by fifty percent (50%) until we recoup our previously recognized unfunded development costs, after which time royalties will be payable on annual net sales based on the royalty rates described above. In September 2008, the \$41 million royalty threshold was met. As a result, we began incurring royalties on the net sales of Opana® ER. Such royalties will be reduced by fifty percent (50%) until we recoup Penwest's share of the unfunded development costs of \$28 million, after which time royalties will be payable on annual net sales based on the royalty rates described above. During the three and six months ended June 30, 2009, we recorded, in costs of sales, royalties on the net sales of Opana® ER of approximately \$4.4 million and \$8.8 million, respectively. No royalties were payable during the six months ended June 30, 2008.

### *Valeant Canada Ltd*

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

### *Vernalis Development Limited*

In July 2004, we entered into a license agreement and a loan agreement with Vernalis Development Limited (referred to as Vernalis), under which Vernalis agreed to license, exclusively to us, rights to market Frova® (frovatriptan succinate) in North America. Launched in the U.S. in June 2002, Frova® is indicated for the acute treatment of migraine headaches in adults. Under the terms of the license agreement, we paid Vernalis an upfront fee of \$30 million and were required to make anniversary payments for the first two years of \$15 million in each of 2005 and 2006 (both \$15 million anniversary payments have been made). Under the loan agreement, we provided Vernalis with a loan of \$50 million in August 2004. We capitalized the \$30 million up-front payment, the present value of the two \$15 million anniversary payments and the difference of \$6.2 million between the face amount of the loan and its present value at inception as an intangible asset representing the fair value of the exclusive license to market Frova®. We are amortizing this intangible asset into cost of revenues over approximately 12.5 years.

Under the terms of the license agreement with Vernalis, we would have been required to make a \$40 million milestone payment upon FDA approval for the short-term prevention of menstrual migraine indication. In September 2007, the FDA issued to the Company and Vernalis, a not approvable letter with respect to our supplemental new drug application (sNDA) for Frova® 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 less than 21 CFR 314.65 for Frova® 2.5 mg tablets. Frova® 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, and range 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®. We withheld 50% of those royalties and used the amount withheld to offset a portion of the unpaid accrued interest under the loan agreement. The term of the license agreement is for the shorter of the time (i) that there are valid claims on the Vernalis patents covering Frova® or there is market exclusivity granted by a regulatory authority, whichever is longer; or (ii) until the date on which a generic version of Frova® is first offered, but in no event longer than 20 years. We can terminate the license agreement under certain circumstances, including upon one years' written notice. In July 2007, Vernalis and Endo entered into Amendment No. 3 (Amendment No. 3) to the license agreement. Under Amendment No. 3, Vernalis granted to Endo, a sole and exclusive (even as against Vernalis) license to make, have made, use, commercialize and have commercialized the product Frova® in Canada, under the Canadian trademark.

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

In February 2008, we entered into a termination agreement with Vernalis to terminate the existing loan agreement between the parties and to settle amounts outstanding thereunder. Concurrent with the termination agreement, we





## **Table of Contents**

entered into Amendment No. 4 to the 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® less than \$85 million. Prior to Amendment, No. 4, royalties were payable by us to Vernalis on all net sales of Frova® in the United States. Once the annual minimum net sales amount is reached, royalty payments will be due only on the portion of annual net sales that exceed the \$85 million threshold. We received a cash payment from Vernalis of \$7 million and acquired an intangible asset representing a future royalty stream on the net sales of Frova® as consideration for the full settlement of the note receivable.

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

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

### *Allergan/Esprit*

In September 2007, Indevus entered into an Amended and Restated License, Commercialization and Supply Agreement with Esprit Pharma, Inc (Esprit), which re-defined the obligations of each party and superseded all previous agreements (the Allergan Agreement). On October 16, 2007, the effective date of the Allergan Agreement, Allergan, Inc. (Allergan) acquired Esprit resulting in Esprit being a wholly-owned subsidiary of Allergan. Upon effectiveness of the Allergan Agreement, Indevus 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 \$112 million, provided there is no product adverse event, as defined in the Allergan Agreement. Commencing January 1, 2010, or earlier in the case of generic competition, 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. Lastly, all third-party royalties paid by the Company as a result of existing licensing, manufacturing and supply agreements associated with sales of Sanctura® and Sanctura XR® will be reimbursed to the Company by Allergan up to six percent (6%) of net sales. Pursuant to the Allergan Agreement, on August 13, 2008, Allergan assumed responsibility to manufacture Sanctura XR® for its use. The Allergan Agreement expires on the later of the twelfth annual anniversary of the launch of Sanctura XR® or the last to expire patent covering Sanctura XR® in the United States. Either party may also terminate the Allergan Agreement in the event of a material breach by the other party. In August 2008, Indevus assigned its rights to receive a fixed percentage of net sales and \$20 million related to a long-term commercialization milestone related to generic competition to the holders of the Non-recourse Notes (see Note 12). The Allergan Agreement superseded all previous agreements with Esprit or its predecessors pertaining to Sanctura® and Sanctura XR®.

In May 2008, together with Madaus AG (referred to as Madaus), Indevus also licensed to Allergan the exclusive right to develop, manufacture, and commercialize Sanctura XR® in Canada. As a result, the Company could receive milestone payments upon achievement of certain sales thresholds. In addition, 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, after which Allergan will have a fully-paid license.

### *Madaus*

In November 1999, Indevus entered into an agreement with Madaus under which Indevus licensed exclusive rights under Madaus' patents and know-how to develop and market certain products, including Sanctura® in the United States. In exchange for these rights, Indevus agreed to pay Madaus potential regulatory and sales milestone payments and royalties on net sales of the licensed products or, if sublicensed by Indevus, a portion of royalties received from its sublicensee on net sales of the licensed product by the sublicensee, in lieu of royalty payments. The agreement expires on the tenth annual anniversary of the launch of Sanctura XR® provided either party may also terminate this agreement in the event of a material breach by the other party. The term of the agreement continues for ten years from the first commercial sale of each licensed product, after which the license is fully paid for that licensed product.

In November 2006, Indevus entered into (i) a License and Supply Agreement and (ii) an amendment to its original license agreement with Madaus (collectively, the Madaus Agreements). Under the Madaus Agreements,



## **Table of Contents**

Indevus agreed to (a) purchase from Madaus all required trospium active pharmaceutical ingredient for production of Sanctura XR<sup>®</sup> through November 2007, (b) license to Madaus 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), (c) pay to Madaus 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, (d) supply Sanctura XR<sup>®</sup> to Madaus for a specified period of time, (e) provide development committee support for a defined period, and (f) provide future know-how to Madaus. In exchange, Madaus (a) waived all rights to manufacture Sanctura XR<sup>®</sup>, (b) agreed to purchase Sanctura XR<sup>®</sup> from Indevus at cost plus a fee based on the number of Sanctura XR<sup>®</sup> capsules sold in the Madaus Territory, and (c) agreed to make payments upon the achievement of certain commercial milestones and royalties based on future sales of Sanctura XR<sup>®</sup> in the Madaus Territory. The Company and Madaus will share the economics of development and commercialization 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 develop and commercialize Sanctura XR<sup>®</sup> in that country. The Company will also pay Madaus a portion of royalties the Company receives for Sanctura<sup>®</sup> and Sanctura XR<sup>®</sup> subject to a minimum of 4% of net sales, which is offsetable against any third party royalties owed by the Company. The term of the Madaus Agreements 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 also terminate this agreement in the event of a material breach by the other party.

### *Supernus*

In March 2003, Indevus entered into a development and license 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 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 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 agreement. The 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) 12 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.

## **Table of Contents**

### *The Population Council*

The Company markets its products utilizing the Hydron® 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® 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 in certain territories received by the Company from the licensing of Vantas® 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® in Europe and in certain other countries outside of Europe. Vantas® 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 approval through the mutual recognition procedure. The Company could receive certain contingent payments from Orion based on approvals and sales thresholds. Additionally, the Company will supply Vantas® 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 15-year term or any subsequent one-year renewal period thereafter with at least six months prior written notice to the other party.

### ***Products in development***

#### *Harvard University*

In December 2008, we entered into a license agreement and a sponsored research agreement with Harvard University (referred to as the Harvard Agreement). Under the terms of the Harvard Agreement, we obtained the exclusive worldwide rights to a new combination pain-drug-delivery technique that targets pain-sensing neurons without affecting motor neurons. Endo is responsible for development and commercialization of any drug candidates discovered under the Harvard Agreement. In December 2008, under the terms of the Harvard Agreement, we made an upfront payment of \$2.0 million and we may pay up to an additional \$16.5 million in clinical, regulatory and approval milestones. In addition, we agreed to provide research funding with respect to these products of approximately \$2.0 million over the three-year life of the sponsored research agreement. Harvard will also receive payments from Endo based on a percentage of Endo's annual net sales of licensed products commercialized under the Harvard Agreement. Endo may terminate the Harvard Agreement upon 60 days' prior written notice without penalty.

#### *Aurigene Discovery Technologies Limited*

In February 2009, we entered into a discovery collaboration agreement with Aurigene Discovery Technologies Limited (referred to as the Aurigene Agreement). The Aurigene Agreement is a three-year collaboration to discover novel drug candidates to treat cancer. Endo has agreed to provide discovery research funding of approximately \$3.0 million over the first three years of the Aurigene Agreement. Endo is responsible for all clinical development and commercialization of drug candidates that advance into human testing. We also may be required to make additional clinical, regulatory and approval milestone payments of up to \$29.8 million and commercial milestone payments of up to an additional \$32.5 million based on cumulative net sales of products commercialized under the Aurigene Agreement. The Aurigene Agreement includes an initial three-year discovery research program, which may be terminated by Endo at our sole discretion upon 60 days' prior written notice without penalty. The Aurigene Agreement will expire in its entirety if Endo does not select any development product candidates by the end of the discovery research program or upon satisfaction and/or expiration of Endo's obligations to make the milestone payments. Subsequent to the initial discovery research program, Endo may terminate the Aurigene Agreement in our sole discretion upon 30 days' prior written notice without penalty.

#### *Grünenthal GMBH*

In February 2009, we entered into a development, license and supply agreement with Grünenthal GMBH (referred to as Grünenthal), granting us the exclusive right in North America to develop and market Grünenthal's investigational drug, axomadol (referred to as the Grünenthal Agreement). Currently in Phase II trials, axomadol is a



## **Table of Contents**

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 up-front and an additional \$20.6 million in June 2009 upon the achievement of a certain milestone as defined in the Grünenthal Agreement. Both the up-front payment and the milestone payment were recognized in research and development expense during the six month period ended June 30, 2009. We could be obligated to pay additional clinical, regulatory and approval milestone payments of up to approximately 22 million euros (approximately \$31 million at June 30, 2009) and possibly development and commercial 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 axomadol product in the United States and Canada. The Grünenthal Agreement will expire in its entirety on the latest to occur 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 axomadol product. 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 90 days' written prior notice to Grünenthal and payment of certain penalties.

### *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 referred to as 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. 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 will be recorded as research and development expense. In addition, Bioniche could potentially receive up to approximately \$110 million royalty in additional payments linked to the achievement of future clinical, regulatory, and commercial milestones related to 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.

### *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 testosterone undecanoate (the BayerSchering Agreement). The Company is responsible for the development and commercialization of testosterone undecanoate 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 testosterone undecanoate. Indevus also agreed to pay to BayerSchering 25% of net sales of testosterone undecanoate to cover both the cost of finished product and royalties. This agreement expires ten years from the first commercial sale of testosterone undecanoate. Either party may also terminate this 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 testosterone undecanoate for a supply price based on net sales of testosterone undecanoate. The supply price is applied against the 25% of net sales owed to BayerSchering pursuant to the BayerSchering Agreement. This agreement expires ten years after the first commercial sale of testosterone undecanoate.

### *Sanofi-Aventis*

In February 1994, Indevus licensed from Rhone-Poulenc Rorer, S.A., now Aventis Pharma S.A. (referred to as Sanofi-Aventis), exclusive, worldwide rights for the manufacture, use and sale of pagoclone 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 pagoclone 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 pagoclone. 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.

## **Table of Contents**

### *Teva Pharmaceutical Industries Ltd.*

In September 2008, Indevus entered into a development, license and commercialization agreement with Teva Pharmaceutical Industries Ltd. (referred to as Teva) for the exclusive, worldwide rights to pagoclone (referred to as the Teva Agreement). The Teva Agreement became effective in November 2008. Under the terms of the Teva Agreement, the Company will conduct, and Teva will reimburse expenses for, a Phase IIb study for stuttering. Teva will be responsible for the conduct of all remaining development and commercialization, including the Phase III program.

In March 2009, Teva converted the Teva Agreement from an equal cost sharing arrangement to a royalty structure whereby Teva will be responsible for all development and commercial costs in the U.S. and the Company will receive royalties on net sales, in addition to milestone payments.

Under the Teva Agreement, the Company could receive up to \$142.5 million in development and sales threshold milestone payments, including an estimated \$11.0 million of contractual payments to be received during the Phase IIb study, of which Indevus has received \$7.5 million as of June 30, 2009.

The term will extend on a country-by-country basis from the effective date to the later of 12 years from first commercial sale or the last valid claim in a country in the territory. Teva may terminate the Teva Agreement (i) by giving notice within a certain time frame from the completion of the Phase IIb study, and (ii) anytime with a specified advance notice, except no such termination will be effective until the completion of any ongoing Phase IIb study. If Teva terminates the Teva Agreement after a product is approved, the Company will pay Teva royalties on its revenues up to an aggregate of certain amounts expended by Teva on development and commercialization. Either party may terminate the Teva Agreement in the event of a material breach by the other party.

### *Medical Research Council*

In July 2005, Indevus entered into the Collaborative Research and Licensing Agreement (the MRC Agreement) with the Medical Research Council (MRC), an agency of the United Kingdom. In exchange for the right to have PRO 2000 included in the MRC's approximately 10,000 person Phase III clinical trial studying the prevention of the transmission of HIV and other sexually-transmitted diseases to be conducted primarily in Africa and India and the right to use the results of this trial, Indevus agreed to grant to the MRC a non-exclusive license to PRO 2000 solely for its use in the Phase III trial and also to supply, at no cost to the MRC, all PRO 2000 and placebo required for the Phase III trial. The MRC will be responsible for all other trial costs. Additionally, Indevus agreed to make PRO 2000 available in developing countries with high need under a license agreement to be negotiated in good faith, or to supply to the MRC PRO 2000 to be distributed in these developing countries at its cost plus a markup pursuant to a supply agreement to be negotiated. The Company will pay the MRC a minimal royalty on sales of PRO 2000 in developed countries. The term of this agreement is ten years from the date of first commercial sale in a developed country.

### *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. (referred to as 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 Valera's 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. Hydron Technologies retained an exclusive, worldwide license to manufacture, market or use products composed of, or produced with the use of, the Hydron® Polymer in certain consumer and oral health fields. Neither party is prohibited from manufacturing, exploiting, using or transferring the rights to any new non-prescription drug product containing the Hydron® Polymer, subject to certain exceptions, for limited exclusivity periods. Subject to certain conditions and exceptions, the Company is obligated to supply certain types of Hydron® Polymers if Hydron Technologies elects to purchase them from the Company. In the event the Company withdraws from the business of manufacturing the Hydron® Polymer, the Company will assign all of its right and interest in the Hydron trademark to Hydron Technologies. The 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.





## **Table of Contents**

### *Orexo AB*

In August 2004, we entered into an agreement with Orexo AB, (referred to as the Orexo Agreement), granting us the exclusive rights to develop and market Orexo AB's patented sublingual muco-adhesive fentanyl product (Rapinyl®) in North America. Rapinyl® is a sub-lingual, fast-dissolving tablet of fentanyl intended for the treatment of breakthrough cancer pain. Rapinyl® is based on Orexo's unique patented technology for sublingual administration. The Orexo Agreement provided for us to make an up-front license fee payment of \$10 million, which we capitalized as an intangible asset representing the fair value of the exclusive right to market products utilizing Orexo's unique patented technology for sublingual administration. We were amortizing this intangible asset over its estimated useful life of 20 years.

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

Pursuant to the terms the Orexo Agreement, we were required to pay a \$0.8 million termination fee to Orexo. In addition, we were required to continue all ongoing clinical trials related to Rapinyl® for a maximum of six months from the delivery of the Orexo Agreement termination notice in July 2008. On October 30, 2008, Endo entered into an early termination agreement effective October 31, 2008 pursuant to which we agreed to cease all involvement in the ongoing clinical trials of Rapinyl® and paid Orexo a lump sum fee equal to \$2.3 million, including the termination fee of \$0.8 million. In exchange, Orexo has released Endo from certain claims under the Orexo Agreement. We are also required to transition the manufacturing process to Orexo or an agreed-upon third party, and supply manufactured product to Orexo or the agreed-upon third party during the transition period for up to a maximum of two years from the date of termination of the agreement. Orexo will pay us 125% of the cost for all manufactured product we provide during the transition period.

### *EpiCept Corp.*

In December 2003, we entered into a license agreement granting us exclusive, worldwide rights to certain patents of EpiCept Corp. as well as exclusive, worldwide commercialization rights to EpiCept's LidoPAIN® BP product. The license agreement provides for Endo to pay EpiCept milestones as well as royalties on the net sales of EpiCept's LidoPAIN® BP product. We made an upfront payment to EpiCept of \$7.5 million which we capitalized as an intangible asset representing the fair value of the exclusive right and the patents. We are amortizing this intangible asset over its useful life of 13 years. EpiCept has also retained an option to co-promote the LidoPAIN® BP product. Milestone payments made by Endo under this agreement, including regulatory milestones and milestones based on sales thresholds, could total up to \$82.5 million. In addition, the agreement contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. This agreement terminates when the last of the underlying patents expires. In January 2009, EpiCept announced that it was discontinuing all drug discovery activities including the development of LidoPAIN® BP. However, the Company intends to maintain the patent rights conveyed by the EpiCept license agreement.

### *Other*

In December 2007, we entered into a license, development and supply agreement with an undisclosed third party collaborative partner for the exclusive clinical development and commercialization rights in Canada and the United States for a certain technology to be utilized in our various product development activities. Under the terms of this agreement the collaborative partner will be responsible for development efforts to conduct pharmaceutical formulation development and will manufacture any such product or products which obtain FDA approval. Endo will be responsible for conducting clinical development activities and for all development costs incurred to obtain regulatory approval. Additional payments of approximately 71.0 million euros (approximately \$99.7 million at June 30, 2009) may become due upon achievement of certain regulatory and commercial milestones. Endo will also make payments to the collaboration partner based on net sales of any product or products commercialized under this agreement.

We have also entered into certain other collaboration agreements with third parties for the development of pain management and other products. These agreements require us to share in the development costs of such products and grant marketing rights to us for such products.

We have also licensed from universities and other companies rights to certain technologies or intellectual property generally in the field of pain management. We are generally required to make upfront payments as well as other payments upon successful completion of regulatory or sales milestones. In addition, these agreements generally require us to pay royalties on sales of the products arising from these agreements. These

agreements generally permit Endo to terminate the agreement with no significant continuing obligation.

**Table of Contents**

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 does not have the ability to exert significant influence over the privately-held company. Pursuant to Financial Accounting Standards Board Interpretation No. 46(R), *Consolidation of Variable Interest Entities (as codified in ASC 810)*, our investment constitutes a variable interest in this privately-held company. We have determined that Endo is not the primary beneficiary and therefore have not consolidated the assets, liabilities, and results of operations of the privately-held company into our Condensed Consolidated Financial Statements. Accordingly, Endo is accounting for this investment under the cost method. As of June 30, 2009, our investment in the privately-held company was \$20 million, representing our maximum exposure to loss.

**NOTE 7. GOODWILL AND OTHER INTANGIBLES**

The changes in the carrying amounts of goodwill were as follows:

	<b>Carrying Amount</b>
Balance at December 31, 2008	\$ 181,079
Acquisition of Indevus (Note 5)	95,743
Balance at June 30, 2009	\$ 276,822

Our other intangible assets consist of the following at June 30, 2009 and December 31, 2008, respectively (in thousands):

	<b>June 30, 2009</b>	<b>December 31, 2008</b>
<b>Indefinite-lived intangibles:</b>		
In process research and development	\$ 276,900	\$
<b>Definite-lived intangibles:</b>		
Licenses	\$ 569,757	\$ 257,757
Less accumulated amortization	(79,978)	(54,452)
Patents		3,200
Less accumulated amortization		(1,450)
	489,779	205,055
<b>Other intangibles, net</b>	<b>\$ 766,679</b>	<b>\$ 205,055</b>

During the first quarter of 2009, net sales of Voltaren® Gel did not meet our original sales forecast. As a result, the Company believed that this could be a potential indicator that the carrying amount of our Voltaren® Gel intangible asset could not be recoverable. As a result, as of March 31, 2009, we compared the carrying amount of our Voltaren® Gel intangible asset to the undiscounted estimated future cash flows of Voltaren® Gel. We concluded that an impairment did not exist since the carrying value of the asset did not exceed the undiscounted estimated future cash flows of Voltaren® Gel. We will continue to monitor any indicators of impairment related to Voltaren® Gel and will perform impairment testing whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable.

Amortization expense for the six month periods ended June 30, 2009 and 2008 was \$27.3 million and \$13.7 million, respectively. As of June 30, 2009, the weighted average amortization period for our definite-lived intangible assets in total was approximately 11 years.

**Table of Contents**

Changes in the gross carrying amount of our other intangible assets for the six-month period ended June 30, 2009, are as follows:

(in thousands)	Gross carrying amount
<i>Balance at December 31, 2008</i>	\$ 260,957
Acquisition of Indevus (Note 5)	588,900
Disposal of patents	(3,200)
 <i>Balance at June 30, 2009</i>	 \$ 846,657

Estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2008 is as follows (in thousands):

2009	\$ 59,756
2010	\$ 63,773
2011	\$ 63,773
2012	\$ 63,773
2013	\$ 51,430

**NOTE 8. COMPREHENSIVE INCOME**

Comprehensive income includes the following components for the three and six months ended June 30, 2009 and 2008 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Net income	\$ 30,029	\$ 57,128	\$ 69,066	\$ 116,656
Other comprehensive income:				
Unrealized gain (loss) on securities, net of tax	583	(14,896)	(608)	(29,950)
Total comprehensive income	\$ 30,612	\$ 42,232	\$ 68,458	\$ 86,706

**NOTE 9. STOCKHOLDERS' EQUITY****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 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 750,000 shares (subject to adjustment for certain transactions). As of June 30, 2009, stock options, restricted stock awards and restricted stock units have been granted under the Stock Incentive Plans.

In May 2009, the Company registered 80,000 shares of Common Stock that may be issued upon the exercise of options granted under the Endo Pharmaceuticals Holdings Inc. Stock Option Agreement, dated June 1, 2009, between the Company and Alan Levin and 43,500 shares of

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

Common Stock that may be issued upon the settlement of restricted stock units granted under the Endo Pharmaceuticals Holdings Inc. Endocentive Stock Award Agreement, dated June 1, 2009, between the Company and Alan Levin, in each case, in connection with Alan Levin's appointment as the Executive Vice President and Chief Financial Officer of the Company, effective on June 1, 2009. The options and restricted stock units were granted to Mr. Levin outside of the Company's 2007 Stock Incentive Plan, but are subject to the terms and conditions of the Company's 2007 Stock Incentive Plan and applicable award agreement. Any shares issued upon the exercise of such options or upon vesting of the restricted stock units will be issued from the Company's treasury shares.

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

The Company accounts for its stock-based compensation plans in accordance with SFAS No. 123(R), *Share-Based Payment* (SFAS 123R), as codified in FASB ASC topic 718 (ASC 718). Under SFAS 123R, all stock-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as an expense in the income statement over the requisite service period.

The Company recognized stock-based compensation expense of \$5.9 million and \$7.8 million, during the three and six months ended June 30, 2009 and \$4.6 million and \$9.0 million during the three and six months ended June 30, 2008, respectively. As of June 30, 2009, the total remaining unrecognized compensation cost related to all non-vested stock-based compensation awards amounted to \$63.3 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 six months ended June 30, 2009 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding, January 1, 2009	4,659,382	\$ 23.95		
Granted	2,129,277	\$ 19.29		
Exercised	(463,305)	\$ 14.10		
Forfeited	(69,455)	\$ 23.00		
Expired	(620,997)	\$ 23.69		

Outstanding, June 30, 2009	5,634,902	\$ 23.03	7.66	\$ 2,596,489
Vested and expected to vest, June 30, 2009	5,187,321	\$ 23.23	7.51	\$ 2,508,881
Exercisable, June 30, 2009	2,137,401	\$ 24.02	5.44	\$ 2,109,955

The total intrinsic value of options exercised during the six months ended each of June 30, 2009 and 2008 was \$3.1 million and \$0.7 million, respectively. The weighted-average grant date fair value of the stock options granted in the six months ended each of June 30, 2009 and 2008 was \$7.46 per option and \$9.55 per option, respectively, determined using the following assumptions:

	2009	2008
Average expected term (years)	5.25	4.91
Risk-free interest rate	2.04%	2.81%
Dividend yield	0.00	0.00
Expected volatility	40%	39%

The weighted average remaining requisite service period of the non-vested stock options was 3.0 years.

**Table of Contents****Restricted Stock Awards**

A summary of our restricted stock awards activity as of June 30, 2009, is presented below:

	Number of Shares	Weighted Average Fair Value Per Share	Aggregate Intrinsic Value
Non-vested, January 1, 2009	5,655	\$ 29.84	
Granted		\$	
Forfeited	(1,131)	\$ 29.84	
Vested	(4,524)	\$ 29.84	\$ 81,070
Non-vested, June 30, 2009		\$	

**Restricted Stock Units**

A summary of our restricted stock units activity as of June 30, 2009, is presented below:

	Number of Shares	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding, January 1, 2009	548,353		
Granted	1,123,443		
Forfeited	(22,941)		
Vested	(118,012)		
Outstanding, June 30, 2009	1,530,843	2.13	\$ 27,432,707
Vested and expected to vest, June 30, 2009	1,293,905	2.11	\$ 23,157,161

The weighted average remaining requisite service period of the non-vested restricted stock units was 3.3 years. The weighted-average grant date fair value of the restricted stock units granted during the six months ended June 30, 2009 was \$19.43 per unit.

**NOTE 10. COMMITMENTS and CONTINGENCIES****Manufacturing, Supply and Other Service Agreements**

We contract with various third party manufacturers and suppliers to provide us with raw materials used in our products and finished goods. Our most significant agreements are with Novartis Consumer Health, Inc., Novartis AG, Teikoku Seiyaku Co., Ltd., Mallinckrodt Inc., Almac Pharma Services and Sharp Corporation. If for any reason we are unable to obtain sufficient quantities of any of the finished goods or raw materials or components required for our products, 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 has agreed to manufacture certain of our commercial products and products in development. We are required to purchase, on an annual basis, a minimum amount of product from Novartis. The purchase price per product is equal to a predetermined amount per unit, subject to periodic adjustments. This agreement had a five-year term, with automatic five-year renewals thereafter. In August 2005, we extended this agreement until 2011. We are required to purchase a minimum of approximately \$20 million per year in each of 2009 and 2010, and approximately \$21 million in 2011. Either party may terminate this agreement on three-years' notice, effective at any time after the initial



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

five-year term. Either party may also terminate this agreement in the event of a material breach by the other party.

Pursuant to the March 2008 Voltaren® Gel license and supply agreement with Novartis AG and Novartis Consumer Health, Inc. (the Voltaren® Gel Agreement) 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 as set forth in the Novartis Agreement.

## **Table of Contents**

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 extending through June 30, 2010, we agreed to spend a minimum of \$20 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.

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

Under the terms of our agreement with Teikoku Seiyaku Co., Ltd (referred to as Teikoku), a Japanese manufacturer, Teikoku manufactures Lidoderm® at its Japanese facility for commercial sale by us in the United States. We also have an option to extend the supply area to other territories. The agreement contains certain provisions requiring Teikoku to qualify an additional manufacturing site, at our request, should we meet certain defined purchasing levels for a defined period of time. On April 24, 2007, we amended this agreement (the Amended Agreement). The material components of the Amended Agreement are as follows:

We agreed to purchase a minimum number of Lidoderm® 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. 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 earlier in accordance with its terms. Either party may terminate the Amended Agreement, upon thirty 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 days written notice. Notwithstanding the foregoing, after December 31, 2021, the Amended Agreement shall be automatically renewed on the first day of January each year unless (i) we and Teikoku agree to terminate the Amended Agreement upon mutual written agreement or (ii) either we or Teikoku terminates the Amended Agreement with 180-day written notice to the other party, which notice shall not in any event be effective prior to July 1, 2022.

### *Mallinckrodt Inc.*

Under the terms of our agreement with Mallinckrodt Inc. (referred to as Mallinckrodt), Mallinckrodt manufactures and supplies to us narcotic active drug substances, in bulk form, and raw materials for inclusion in our controlled substance pharmaceutical products. There is no minimum annual purchase commitment under this agreement. However, we are required to purchase a fixed percentage of our annual requirements of each narcotic active drug substance from Mallinckrodt. The purchase price for these substances is equal to a fixed amount, adjusted on an annual basis. The initial term of this agreement is July 1, 1998 until June 30, 2013, with an automatic renewal provision for unlimited successive one-year periods. Either party may terminate this agreement in the event of a material breach by the other party.

### *Almac Pharma Services*

Under the terms of our agreement with Almac Pharma Services (referred to as Almac), a European manufacturer, Almac manufactures Frova® at its Ireland facility for commercial sale by us in the United States. The agreement with Almac will expire on January 1, 2010, unless earlier terminated in accordance with its terms and can be extended beyond January 1, 2010 upon mutual agreement by the parties. If no agreement as to any extension or termination is reached six months prior to the end of the term, then the agreement will automatically renew for a period of

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

twelve months. Almac has agreed to fix the supply price of Frova<sup>®</sup> for a period of time after which the price will be adjusted at future dates certain based on a price index defined in the agreement, subject to an annual maximum increase.

## **Table of Contents**

### *Sharp Corporation*

Under the terms of our agreement with Sharp Corporation (referred to as 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 the parties. Endo has the right to terminate the Sharp agreement at any time upon ninety days' written notice.

### *Ventiv Commercial Services, LLC*

On May 15, 2008, we entered into a services agreement (referred to as the Ventiv Agreement) with Ventiv Commercial Services, LLC (referred to as Ventiv). Under the terms of the Ventiv Agreement, Ventiv will provide 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 will promote primarily Voltaren® Gel and will be required to perform a minimum number of face-to-face one-on-one discussions with physicians and other 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.

Under the terms of the Ventiv Agreement, we incurred a one-time implementation fee that we recognized in selling, general, and administrative expense in the second quarter of 2008. In addition, we are required to pay Ventiv a monthly fixed fee during the term of the Ventiv Agreement based on a pre-approved budget. Included in the fixed monthly fee are certain costs such as the Ventiv sales representative and district manager salaries, Ventiv Field Force travel, and office and other routine expenses, as well as a fixed management fee. If the Ventiv Agreement is terminated prior to the completion of the first twelve months of Detailing (as defined in the Ventiv Agreement), Endo is obligated to pay Ventiv the remaining unpaid portion of the fixed management fee. Ventiv will also be eligible to earn a performance-based bonus equal to the fixed management fee during each year of the Ventiv Agreement. This performance-based bonus is payable upon the achievement of certain conditions, including the number of Voltaren® Gel tubes sold and the number of Details achieved.

The Ventiv Agreement is effective April 1, 2008 and will expire on June 30, 2010. Among other standard and customary termination rights granted under the Ventiv Agreement, we may terminate the Ventiv Agreement at our sole discretion at any time upon 120 days' written prior notice to Ventiv, at which time we may be required to pay Ventiv a termination fee of up to \$1 million. In January 2009, we agreed to certain changes to the Ventiv Agreement, including modification to the termination rights such that Endo is now permitted to terminate the Ventiv Agreement at our sole discretion at any time upon thirty days' prior written notice. The Ventiv Agreement can also be terminated by either party upon reasonable written notice, if either party has committed a material breach that has not been remedied within thirty days from the giving of written notice.

In May 2009, we entered into an Amendment to the Ventiv Agreement (the Ventiv Amendment), to amend certain provisions in the Ventiv Agreement including a reduction in the Ventiv Field Force from 275 to 80 sales representatives effective June 1, 2009. The Company will pay Ventiv a partial termination fee in connection with the Ventiv Amendment.

### *Catalent Pharma Solutions, Inc.*

In September 2007, Indevus entered into a Manufacturing and Supply Agreement (the Catalent Agreement) with Catalent Pharma Solutions, Inc. (now Catalent Pharma Solutions, LLC) (Catalent), to manufacture Sanctura XR® bulk capsules and to package them in bottles for sale and blister packages to be used as samples in the United States. As described in Note 6, in August 2008, Allergan assumed responsibility to manufacture Sanctura XR® for its own use. As a result, Allergan entered into a separate agreement to manufacture and package Sanctura XR®, and Indevus entered into a new agreement to manufacture Sanctura XR® bulk capsules. The Catalent Agreement terminates in September 2012, subject to earlier termination by either party in the event of a material breach by the other party. The Company may terminate this agreement at any time if regulatory actions prohibit or materially restrict the manufacture, sale or use of the product in the United States. The Company supplies Catalent with the active pharmaceutical ingredient used to manufacture the Sanctura XR® capsules sold to Madaus.

### *BayerSchering Pharma AG*

The BayerSchering Agreement contains certain minimum purchase requirements that would commence after the second year of sales of testosterone undecanoate following approval of the product. Such minimums will be a percentage of purchases the Company would make in the second year of sales. After the second year of sales, the Company will be able to determine such minimum purchase requirements.

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 testosterone undecanoate for a supply price based on net sales of testosterone undecanoate. The

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

supply price is applied against the 25% of net sales owed to BayerSchering pursuant to the BayerSchering Agreement. This agreement expires ten years from the first commercial sale of testosterone undecanoate.

## **Table of Contents**

### *General*

In addition to the manufacturing and supply agreements described above, we have agreements with (1) UPS Supply Chain Solutions, Inc. (f/d/b/a Livingston Healthcare Services, Inc.) for customer service support, warehouse and distribution services and certain financial functions that expires in 2010, (2) Kunitz and Associates Inc. for assistance with adverse event reporting, and (3) DecisionLine Clinical Research Corporation for certain 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 Notes 5 and 6 for a complete description of future milestone and royalty commitments pursuant to our acquisitions, license and collaboration agreements.

### **Employment Agreements**

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

### **Research Contracts**

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

### **Legal Proceedings**

While we cannot predict the outcome of our ongoing legal proceedings, we believe that the claims against us are without merit, and we intend to vigorously defend our position. An adverse outcome in any of these proceedings could have a material adverse effect on our current and future financial position, results of operations and cash flows.

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

In September 1997, Indevus announced a market withdrawal of its first commercial prescription product, the anti-obesity medication Redux (dexfenfluramine hydrochloride capsules C-IV), which had been launched by its licensee, American Home Products Corporation, now Wyeth, in June 1996. 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. 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 the Company's existing product liability insurance. The Company believes its total insurance coverage, including the additional insurance coverage funded by Wyeth, is sufficient to address the potential remaining Redux product liability exposure. However, there can be no assurance Redux claims will not exceed the amount of insurance coverage available to the Company and Wyeth's indemnification obligations under the AHP Indemnity and Release Agreement. If such insurance coverage and Wyeth indemnification is not sufficient to satisfy Redux-related claims, the payment of amounts to satisfy such claims may have a material adverse effect on the Company's business, results of operations or financial condition. Prior to the effectiveness of the AHP Indemnity and Release Agreement, Redux-related defense costs of Indevus were paid by, or subject to reimbursement from, Indevus's product liability insurers. To date, there have been no Redux-related product liability settlements or judgments paid by Indevus or their insurers.

As of June 30, 2009, the Company had an outstanding insurance claim of approximately \$3.0 million, relating to payments made by the Company to the group of law firms defending the Company in the Redux-related product liability litigation, for services rendered by such law firms through May 30, 2001. The full amount of the Company's current outstanding insurance claim is made pursuant to the Company's product liability policy issued to Indevus by



## **Table of Contents**

Reliance Insurance Company (Reliance). In October 2001, the Commonwealth Court of Pennsylvania granted an Order of Liquidation to the Insurance Commissioner of Pennsylvania to begin liquidation proceedings against Reliance. It is uncertain when, if ever, the Company will collect any of its remaining \$3.0 million of claims. If the Company incurs additional product liability defense and other costs subject to claims on the Reliance product liability policy up to the \$5.0 million limit of the policy, the Company will have to pay such costs without expectation of reimbursement and will incur charges to operations for all or a portion of such payments.

### *Indevus Tender Offer*

On January 9, 2009, a purported stockholder of Indevus filed a complaint seeking certification of a class action lawsuit in the Court of Chancery of the State of Delaware, docketed as *Gober v. Endo Pharmaceuticals, et al.*, C.A. No. 4276 (Del. Ch.) (the Gober Action) against Endo, BTB Purchaser Inc., a Delaware Corporation (referred to as Purchaser) a direct, wholly-owned subsidiary of Endo, Indevus and each of Indevus' s directors. The Gober Action purports to be brought individually and on behalf of all public stockholders of Indevus. The Gober Action alleges that Indevus' s director defendants breached their fiduciary duties to Indevus' s stockholders in connection with the Offer and that each of the defendants aided and abetted such alleged breach of Indevus' s director defendants' fiduciary duties. Based on these allegations, the Gober Action seeks, among other relief, declaring the action to be a class action, injunctive relief enjoining preliminarily and permanently the Offer, rescinding, to the extent already implemented, the Offer or any of the terms thereof or awarding rescissory damages, directing that the defendants account to plaintiff and other members of the purported class for all damages caused by them and account for all profits and any special benefits obtained as a result of breaches of their fiduciary duties to the purported stockholder and other members of the purported class, awarding plaintiff the costs of the Gober Action including a reasonable allowance for the expenses of plaintiffs' attorneys and experts and granting plaintiff and other members of the purported class such further relief as the court deems just and proper.

On January 12, 2009, a purported stockholder of Indevus filed a complaint seeking certification of a class action lawsuit in the Superior Court of the Commonwealth of Massachusetts, docketed as *Schroeder [sic] v. Endo Pharmaceuticals, et al.*, 09-0126 (the Schroeder Action) against Endo, Purchaser, Indevus and each of Indevus' s directors. The Schroeder Action purports to be brought individually and on behalf of all public stockholders of Indevus. The Schroeder Action alleges that Indevus' s director defendants breached their fiduciary duties to Indevus' s stockholders in connection with the Offer and that each of the defendants aided and abetted such alleged breach of Indevus' s director defendants' fiduciary duties. Based on these allegations, the Schroeder Action seeks, among other relief, declaring the action to be a class action, injunctive relief enjoining preliminarily and permanently the Offer, rescinding, to the extent already implemented, the Offer or any of the terms thereof or awarding rescissory damages, directing that the defendants account to plaintiff and other members of the purported class for all damages caused by them and account for all profits and any special benefits obtained as a result of breaches of their fiduciary duties to the purported stockholder and other members of the purported class, awarding plaintiff the costs of the Schroeder Action including a reasonable allowance for the expenses of plaintiffs' attorneys and experts and granting plaintiff and other members of the purported class such further relief as the court deems just and proper.

On January 13, 2009, a purported stockholder of Indevus filed a complaint seeking certification of a class action lawsuit in the Superior Court of the Commonwealth of Massachusetts, docketed as *Wexler v. Indevus Pharmaceuticals, et al.*, 09-0166 (the Wexler Action) against Endo, Purchaser, Indevus and each of Indevus' s directors. The Wexler Action purports to be brought individually and on behalf of all public stockholders of Indevus. The Wexler Action alleges that Indevus' s director defendants breached their fiduciary duties to Indevus' s stockholders in connection with the Offer and the Merger and that each of the defendants aided and abetted such alleged breach of Indevus' s director defendants' fiduciary duties. Based on these allegations, the Wexler Action seeks, among other relief, declaring the action to be a class action, declaring that the Merger Agreement was entered into in breach of the defendants' fiduciary duties and is therefore unlawful and unenforceable, injunctive relief enjoining the Offer and the Merger, directing the individual defendants to exercise their fiduciary duties to obtain a transaction which is in the best interests of Indevus' s stockholders, rescinding, to the extent already implemented, the Offer and the Merger or any of the terms thereof, awarding plaintiff the costs and disbursements of the Wexler Action including reasonable attorneys' and experts' fees and granting such other and further relief as the court deems just and proper.

On January 20, 2009, a purported stockholder of Indevus filed a complaint seeking certification of a class action lawsuit in the Court of Chancery of the State of Delaware, docketed as *Mishket v. Cooper, et al.*, C.A. No. 4299 (referred to as the Mishket Action) against Endo, Purchaser and each of Indevus' s directors as defendants and Indevus as a nominal defendant. The Mishket Action purports to be brought individually and on behalf of all public stockholders of Indevus. The Mishket Action alleges that Indevus' s director defendants breached their fiduciary duties to Indevus' s stockholders in connection with the Offer and that each of the defendants aided and abetted such alleged breach of Indevus' s director defendants' fiduciary duties. Based on these allegations, the Mishket Action seeks, among other



## **Table of Contents**

relief, declaring the action to be a class action, injunctive relief enjoining preliminarily and permanently the Offer, rescinding, to the extent already implemented, the Offer or any of the terms thereof or awarding rescissory damages, directing that the defendants account to plaintiff and other members of the purported class for all damages caused by them and account for all profits and any special benefits obtained as a result of breaches of their fiduciary duties to the purported stockholder and other members of the purported class, awarding plaintiff the costs of the Mishket Action including a reasonable allowance for the expenses of plaintiffs' attorneys and experts and granting plaintiff and other members of the purported class such further relief as the court deems just and proper.

On January 30, 2009, a purported stockholder of Indevus filed a complaint seeking certification of a class action lawsuit in the Court of Chancery of the State of Delaware, docketed as *Hell v. Indevus Pharmaceuticals, et al.*, C.A. No. 4327 (referred to as the Hell Action) against Endo, Purchaser, Indevus and each of Indevus's directors. The Hell Action purports to be brought individually and on behalf of all public stockholders of Indevus. The Hell Action alleges that Indevus's director defendants breached their fiduciary duties to Indevus's stockholders in connection with the Offer and that Endo and Merger Sub aided and abetted such alleged breach by the Indevus director defendants. The Hell Action also alleges that the Indevus Schedule 14D-9 Solicitation Statement fails to disclose material information about the Offer, that the defendant directors did not protect against purported conflicts of interest and that the terms of the Merger Agreement prevent stockholders of Indevus from receiving appropriate consideration for their Indevus shares. Based on these allegations, the Hell Action seeks, among other relief, declaring the action to be a class action on, enjoining, preliminarily and permanently, the Offer, rescinding the Offer or granting damages to the extent the Offer has been consummated, directing that the defendants account for all damages, profits and special benefits obtained as a result of their purportedly unlawful conduct, awarding plaintiff the costs and disbursements of the Hell Action including reasonable attorneys' and experts fees and granting such other and further relief as the court deems just and proper.

On February 4, 2009, the parties to the Gober Action, Mishket Action, Wexler Action, and Schroeder Action executed a Memorandum of Understanding (the Memorandum of Understanding), setting forth the terms and conditions for settlement of each of the actions. The Memorandum of Understanding does not include the plaintiff in the Hell Action. The parties agreed that, after arm's length discussions between and among the parties, Indevus will provide additional supplemental disclosures to its Schedule 14D-9 and that the Company Termination Fee, as defined in the Merger Agreement, will be reduced by 10% (from \$20,000,000 to \$18,000,000). In exchange, following confirmatory discovery, the parties will attempt in good faith to agree to a stipulation of settlement and, upon court approval in the Gober Action of that stipulation, the Plaintiffs will dismiss each of the other above-referenced actions with prejudice, and the Defendants will be released from any claims arising out of the Proposed Transaction. The Defendants have agreed not to oppose any fee application by Plaintiffs' counsel that does not exceed \$700,000 in the aggregate.

On July 2, 2009, the Schroeder Action was voluntarily dismissed with prejudice as to Plaintiff Schroeder.

Endo and Purchaser have denied, and continue to deny, that either of them has committed or aided and abetted in the commission of any violation of law of any kind or engaged in any of the wrongful acts alleged in the above-referenced actions. Endo and Purchaser each expressly maintains that it has diligently and scrupulously complied with its legal duties, and has executed the Memorandum of Understanding solely to eliminate the burden and expense of further litigation.

### *Department of Health and Human Services Subpoena*

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

### *Pricing Litigation*

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

The federal court cases have been or are in the process of being consolidated in the United States District Court for the District of Massachusetts under the Multidistrict Litigation Rules as *In re: Pharmaceutical Industry Average Wholesale Price Litigation, MDL 1456*. The following previously reported cases are pending in MDL 1456 and have been consolidated into one consolidated complaint: *City of New York v. Abbott Laboratories, Inc., et al.*; *County of Albany v. Abbott Laboratories, Inc., et al.*; *County of Allegany v. Abbott Laboratories, Inc., et al.*; *County of*

*Broome v.*

## **Table of Contents**

*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.

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.*

A case has been filed in the Third Judicial District Court of Salt Lake County Utah by the State of Utah against EPI and nine other pharmaceutical companies, containing allegations similar to the allegations contained in the case filed by the State of Alabama: *State of Utah v. Actavis US, Inc., et al.*, Civ. Action No. 070913719. That case was removed to federal court, transferred to the MDL, and then remanded to the court in which it was originally filed.

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

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

The Company intends to contest all of these cases vigorously 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 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 (oxycodone hydrochloride extended-release tablets CII). IMPAX stated in its letter that the FDA requested IMPAX to provide notification to us and Penwest of any Paragraph IV certifications submitted with its ANDA, as required under section 355(j) of the Federal Food, Drug and Cosmetics Act, or the FDCA Act. Accordingly, IMPAX's letter included notification that it had filed Paragraph IV certifications with respect to Penwest's U.S. Patent Nos. 7,276,250, 5,958,456 and 5,662,933, which cover the formulation of Opana® ER. These patents are listed in the FDA's Orange Book and expire in 2022, 2013 and 2013, respectively. The Company's Opana® ER product has new dosage form exclusivity that prevents final

approval of any ANDA by the FDA until the exclusivity

## **Table of Contents**

expires on June 22, 2009. In addition, because IMPAX's application referred to patents owned by Penwest and contained a Paragraph IV certification under section 355(j) of the FDCA Act, we believe IMPAX's notice triggered the 45-day period under the FDCA Act in which we and Penwest could file a patent infringement action and trigger the automatic 30-month stay of approval. Subsequently, on January 25, 2008, the Company and our partner Penwest filed a lawsuit against IMPAX in the United States District Court for the District of Delaware in connection with IMPAX's ANDA. The lawsuit alleges infringement of certain Orange Book-listed U.S. patents that cover the Opana® ER formulation. In response, Impax filed an answer and counterclaims, asserting claims for declaratory judgment that the patents listed in the Orange Book are invalid, not infringed and/or unenforceable. Additionally, the lawsuit previously filed by the Company and Penwest on November 15, 2007 against IMPAX remains pending. We cannot predict the outcome of this litigation.

On June 16, 2008, the Company received a notice from IMPAX that it had filed an amendment to its ANDA containing Paragraph IV certifications for the 7.5 mg, 15 mg and 30 mg strengths of oxymorphone hydrochloride extended release tablets. The notice covers Penwest's U.S. Patent Nos. 7,276,250, 5,958,456 and 5,662,933. Subsequently, on July 25, 2008, the Company and our partner Penwest filed a lawsuit against IMPAX in the United States District Court for the District of Delaware in connection with IMPAX's amended ANDA. The lawsuit alleges infringement of certain Orange Book-listed U.S. patents that cover the Opana® ER formulation. In response, Impax filed an answer and counterclaims, asserting claims for declaratory judgment that the patents listed in the Orange Book are invalid, not infringed and/or unenforceable. Additionally, the lawsuits previously filed by the Company and Penwest against IMPAX remain pending.

All three of these pending suits against IMPAX were transferred to the United States District Court for the District of New Jersey. We cannot predict the outcome of this litigation. We intend, and we have been advised by Penwest that they too intend, to pursue all available legal and regulatory avenues in defense of Opana® ER, including enforcement of our intellectual property rights and approved labeling.

In February 2008, we along with our partner Penwest, received a notice from Actavis South Atlantic LLC (Actavis), advising of the filing by Actavis of an ANDA containing a Paragraph IV certification under 21 U.S.C. Section 355(j) for a generic version of Opana® ER (oxymorphone hydrochloride extended-release tablets CII). The Actavis Paragraph IV certification notice refers to Penwest's U.S. Patent Nos. 5,128,143, 5,662,933, 5,958,456 and 7,276,250, which cover the formulation of Opana® ER. These patents are listed in the FDA's Orange Book and expire or expired in 2008, 2013, 2013 and 2023, respectively. In addition to these patents, Opana® ER has a new dosage form (NDA) exclusivity that prevents final approval of any ANDA by the FDA until the exclusivity expires on June 22, 2009. Subsequently, on March 28, 2008, we and Penwest filed a lawsuit against Actavis in the U.S. District Court for the District of New Jersey in connection with Actavis's ANDA. The lawsuit alleges infringement of an Orange Book-listed U.S. patent that covers the Opana® ER formulation. On May 5, 2008, Actavis filed an answer and counterclaims, asserting claims for declaratory judgment that the patents listed in the Orange Book are invalid, not infringed and/or unenforceable, as well as a claim of unfair competition against Endo and Penwest.

On or around June 2, 2008, the Company received a notice from Actavis that it had filed an amendment to its ANDA containing Paragraph IV certifications for the 7.5 mg and 15 mg dosage strengths of oxymorphone hydrochloride extended release tablets. On or around July 2, 2008, the Company received a notice from Actavis that it had filed an amendment to its ANDA containing Paragraph IV certifications for the 30 mg dosage strength. Both notices cover Penwest's U.S. Patent Nos. 5,128,143, 7,276,250, 5,958,456 and 5,662,933. On July 11, 2008, the Company and Penwest, filed suit against Actavis in the United States District Court for the District of New Jersey. The lawsuit alleges infringement of an Orange Book-listed U.S. patent that covers the Opana® ER formulation. On August 14, 2008, Actavis filed an answer and counterclaims, asserting claims for declaratory judgment that the patents listed in the Orange Book are invalid, not infringed and/or unenforceable, as well as a claim of unfair competition against Endo and Penwest.

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

On July 14, 2008, the Company received a notice from Sandoz, Inc. (Sandoz), advising of the filing by Sandoz of an ANDA containing a Paragraph IV certification under 21 U.S.C. Section 355(j) with respect to oxymorphone hydrochloride extended-release oral tablets in 5 mg, 10 mg, 20 mg and 40 mg dosage strengths. The Sandoz Paragraph IV certification notice refers to Penwest's U.S. Patent Nos. 5,662,933, 5,958,456 and 7,276,250, which cover the formulation of Opana® ER. These patents are listed in the FDA's Orange Book and expire in 2013, 2013 and 2023, respectively. In addition to these patents, Opana® ER has a new dosage form (NDA) exclusivity that prevents final



## **Table of Contents**

approval of any ANDA by the FDA until the exclusivity expires on June 22, 2009. Subsequently, on August 22, 2008, the Company and our partner Penwest filed a lawsuit against Sandoz in the United States District Court for the District of Delaware in connection with Sandoz's ANDA. The lawsuit alleges infringement of an Orange Book-listed U.S. patent that covers the Opana® ER formulation. In response, Sandoz filed an answer and counterclaims, asserting claims for declaratory judgment that the patents listed in the Orange Book are invalid, not infringed and/or unenforceable.

On November 20, 2008, the Company received a notice from Sandoz that it had filed an amendment to its ANDA containing Paragraph IV certifications for the 7.5 mg, 15 mg and 30 mg dosage strengths of oxymorphone hydrochloride extended release tablets. The notice covers Penwest's U.S. Patent Nos. 5,128,143, 7,276,250, 5,958,456 and 5,662,933. On December 30, 2008, the Company and Penwest, filed suit against Sandoz in the United States District Court for the District of New Jersey. The lawsuit alleges infringement of an Orange Book-listed U.S. patent that covers the Opana® ER formulation. In response, Sandoz filed an answer and counterclaims, asserting claims for declaratory judgment that the patents listed in the Orange Book are invalid, not infringed and/or unenforceable.

Both of these pending suits against Sandoz were transferred to the United States District Court for the District of New Jersey. We cannot predict the outcome of this litigation. We intend, and we have been advised by Penwest that they too intend, to pursue all available legal and regulatory avenues in defense of Opana® ER, including enforcement of our intellectual property rights and approved labeling.

On September 12, 2008, the Company received a notice from Barr Laboratories, Inc. (Barr), advising of the filing by Barr of an ANDA containing a Paragraph IV certification under 21 U.S.C. Section 355(j) with respect to oxymorphone hydrochloride extended-release oral tablets in a 40 mg dosage strength. On September 15, 2008, the Company received a notice from Barr that it had filed an ANDA containing a Paragraph IV certification under 21 U.S.C. Section 355(j) with respect to oxymorphone hydrochloride extended-release oral tablets in 5 mg, 10 mg, and 20 mg dosage strengths. Both notices refer to Penwest's U.S. Patent Nos. 5,662,933, 5,958,456 and 7,276,250, which cover the formulation of Opana® ER. These patents are listed in the FDA's Orange Book and expire in 2013, 2013 and 2023, respectively. In addition to these patents, Opana® ER has a new dosage form (NDA) exclusivity that prevents final approval of any ANDA by the FDA until the exclusivity expires on June 22, 2009. Subsequently, on October 20, 2008, the Company and our partner Penwest filed a lawsuit against Barr in the United States District Court for the District of Delaware in connection with Barr's ANDA. The lawsuit alleges infringement of certain Orange Book-listed U.S. patents that cover the Opana® ER formulation. In response, Barr filed an answer and counterclaims, asserting claims for declaratory judgment that the patents listed in the Orange Book are invalid, not infringed and/or unenforceable. This suit was transferred to the United States District Court for the District of New Jersey. On June 2, 2009, the Company received a notice from Barr that it had filed an ANDA containing a Paragraph IV certification under 21 U.S.C. Section 355(j) with respect to oxymorphone hydrochloride extended-release oral tablets in 7.5 mg, 15 mg, and 30 mg dosage strengths. This notice also refers to Penwest's U.S. Patent Nos. 5,662,933, 5,958,456 and 7,276,250, which cover the formulation of Opana® ER. On July 2, 2009, the Company and our partner Penwest filed a lawsuit against Barr in the United States District Court for the District of New Jersey in connection with Barr's ANDA. We cannot predict the outcome of this litigation. We intend, and we have been advised by Penwest that they too intend, to pursue all available legal and regulatory avenues in defense of Opana® ER, including enforcement of our intellectual property rights and approved labeling.

### *Paragraph IV Certifications on Sanctura XR®*

On June 2, 2009, the Company 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 the Company's Orange Book listed patent (7,410,978) is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Watson's generic product. This patent expires February 1, 2025. The Company's Sanctura XR® product has new dosage form exclusivity that prevents final approval of any ANDA by the FDA until the exclusivity expires on August 3, 2010.

Because Watson's application referred to patents owned by Endo and licensed to Allergan, and contained a Paragraph IV certification under section 355(j) of the FDCA Act, we believe Watson's notice triggered the 45-day period under the FDCA Act in which we and Allergan could file a patent infringement action and trigger the automatic 30-month stay of approval. Subsequently, on July 13, 2009, the Company and our partners Allergan and Supernus filed a lawsuit against Watson in the United States District Court for the District of Delaware in connection with Watson's ANDA. The lawsuit alleges infringement of Orange Book-listed U.S. patent 7,410,978 that covers the Sanctura XR® formulation. We intend to contest this case vigorously. We cannot predict the timing or outcome of this litigation.

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

On July 25, 2008, the LecTec Corporation filed a complaint in the United States District Court for the Eastern District of Texas against the Company and several other pharmaceutical companies alleging that each of the defendants sells products that infringe one or more claims of patents owned by LecTec. The Company's product Lidoderin® is





**Table of Contents**

identified in the complaint. The complaint alleges that Lidoderm® infringes U.S. Patents 5,536,263 and 5,741,510. On September 30, 2008, the Company filed an answer denying infringement and alleging that the patents are invalid. On February 10, 2009, the plaintiff filed a motion for preliminary injunction against the Company. The Company intends to contest this case vigorously. However, we cannot predict the timing or outcome of this litigation.

*Other Legal Proceedings*

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

**11. NET INCOME PER SHARE**

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

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
<b>Numerator:</b>				
Net income available to common stockholders	\$ 30,029	\$ 57,128	\$ 69,066	\$ 116,656
<b>Denominator:</b>				
For basic per share data    weighted average shares	117,158	122,985	116,990	128,561
Effect of dilutive stock options	192	546	289	517
For diluted per share data    weighted average shares	117,350	123,531	117,279	129,078
Basic net income per share	\$ 0.26	\$ 0.46	\$ 0.59	\$ 0.91
Diluted net income per share	\$ 0.26	\$ 0.46	\$ 0.59	\$ 0.90

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

The 1.75% Convertible Senior Subordinated Notes due April 15, 2015 (Convertible Notes) 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 the Convertible Notes based on the average market price of our common 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, SFAS No. 128, *Earnings Per Share* as codified by ASC 260, requires us to analyze separately the impact of the convertible note hedge and warrant agreements on diluted EPS. As a result, the purchases of the convertible note hedges are excluded because their impact will always be anti-dilutive. The treasury stock method will be applied when the warrant is in-the-money with the proceeds from the exercise of the warrant used to repurchase shares based on the average stock price in the calculation of diluted weighted average shares. Until the warrants are in-the-money, they have no impact on the diluted weighted average share calculation. The total number of shares that could potentially be included under the warrants is 1.3 million.

The following reconciliation shows the shares excluded from the calculation of diluted earnings per share as the inclusion of such shares would be anti-dilutive for the three and six months ended June 30, 2009 and 2008 (in thousands):

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

	Six Months Ended June 30,	
	2009	2008
Weighted average shares excluded:		
1.75% Convertible senior subordinated notes due 2015 and warrants(1)	14,294	14,294
Employee stock-based awards	4,585	3,211
	18,879	17,505

## **Table of Contents**

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

## **12. DEBT**

### *Convertible Senior Subordinated Notes Due 2015*

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

We received proceeds of approximately \$370.7 million from the issuance, net of the initial purchaser's discount and certain other costs of the offering. Interest is payable semi-annually in arrears on each April 15 and October 15. 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 Convertible Notes. It is our current intention to settle the principal amount of any conversion consideration in cash.

In addition to entering into the convertible note hedge transaction and the warrant transaction, we entered into a privately-negotiated accelerated share repurchase agreement with the same counterparty. We used approximately \$57 million representing a portion of the net proceeds from the Convertible Notes offering to pay the cost of the convertible note hedge transaction, taking into account the proceeds from the warrant transaction, and used the balance of the net proceeds or approximately \$314 million, together with approximately \$11 million of cash on hand, to repurchase a variable number of shares of our common stock pursuant to the accelerated share repurchase agreement entered into as part of our broader share repurchase program. Pursuant to the accelerated share repurchase agreement, the counterparty delivered 11.9 million shares of our common stock to the Company on the day that the Convertible Note offering closed, April 15, 2008. On August 14, 2008, Endo received approximately 1.4 million additional shares of our common stock based on the volume-weighted average price of our common stock during a specified averaging period set forth by the accelerated share repurchase agreement. The common stock acquired through the accelerated share repurchase agreement has been included in treasury stock in our Condensed Consolidated Balance Sheets as of June 30, 2009 and December 31, 2008.

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

### *Adoption of FSP APB 14-1*

As discussed in Note 2, on January 1, 2009 we adopted FSP APB 14-1 (as codified in ASC 470-20). FSP APB 14-1 requires that issuers of convertible debt instruments that may be settled in cash or other assets on conversion to separately account for the liability and equity components of the instrument in a manner that will reflect the entity's nonconvertible debt borrowing rate on the instrument's issuance date when interest cost is recognized in subsequent periods.

As a result of our adoption of FSP APB 14-1, we separated the debt portion of our Convertible Notes from the equity portion at their fair value retrospective to the date of issuance and we are amortizing the resulting discount into interest expense over the life of the Convertible Notes.

In order to determine the fair value of the debt portion and equity portion of our Convertible Notes in accordance with SFAS 157, we first attempted to use a market approach by identifying prices and other relevant information generated by market transactions at or near the issuance date of our Convertible Notes, that involved comparable companies issuing nonconvertible debt with similar embedded features (other than the conversion feature). We were unable to identify any such transactions. As a result, the Company determined that an expected present value technique, or income approach that maximizes the use of observable market inputs is the preferred approach to measure the fair value of the debt and equity components of our Convertible Notes. Specifically, the Company used an income approach known as the binomial lattice model.



**Table of Contents**

To calculate the fair value of the debt and equity components of our Convertible Notes, the Company constructed a binomial lattice to model future changes in the equity value of the Company, and a convertible bond lattice for the Convertible Notes, which incorporated certain inputs and assumptions, including scheduled coupon and principal payments, the conversion feature inherent in the Convertible Notes, the put feature inherent in the Convertible Notes, and a stock price volatility of 36% that was based on historic volatility of the Company's common stock and other factors.

An implied credit spread of 6.12% was calculated based on the results of the convertible bond lattice described above. The fair value of the debt component was then calculated by discounting the coupon and principal payments of the Convertible Notes with a risk free interest rate of 2.97% and the implied credit spread of 6.12%, which collectively represent the Company's estimated nonconvertible debt borrowing rate of 9.09%. As a result of this analysis, the fair value of the debt component of our Convertible Notes was determined to be \$237.3 million on the date of issuance.

The provisions of FSP APB 14-1 are to be applied retrospectively to all periods presented upon adoption. As a result of our adoption of FSP APB 14-1, we recorded a retrospective adjustment to our Condensed Consolidated Balance Sheet as of April 15, 2008 to separate the debt and equity components of our Convertible Notes. This adjustment resulted in a reclassification out of Convertible Senior Subordinated Notes Due 2015 into Additional Paid-In Capital of \$142.2 million, which represents the fair value of the equity component of our Convertible Notes on the date of issuance.

In addition, we were required to reclassify the portion of the initial purchaser's discount and certain other costs of the offering that were attributable to the equity component of our Convertible Notes. The initial purchaser's discount and certain other costs of the offering were originally recorded as a contra-liability account applied to the face amount of the Convertible Notes and were being amortized to interest expense utilizing the effective interest method. Upon adoption of FSP APB 14-1, we recorded an adjustment out of the contra-liability account and into Additional Paid-In Capital of \$3.3 million, which represents the portion of the original purchaser's discount and certain other costs of the offering that are relate to the equity component of our Convertible Notes.

The adoption of FSP APB 14-1 resulted in the recognition of an additional \$10.4 million of interest expense and a reduction to our income tax expense of \$4.0 million for the year ended December 31, 2008. Accordingly, we recorded a \$6.4 million adjustment to beginning retained earnings in our June 30, 2009 Condensed Consolidated Balance Sheet.

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

	<b>June 30, 2009</b>
Principal amount of Convertible Notes	\$ 379,500
Unamortized discount related to the debt component <sup>(1)</sup>	(127,967)
<b>Net carrying amount of the debt component</b>	<b>\$ 251,533</b>
Carrying amount of the equity component	\$ 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 in accordance with FSP APB 14-1. This discount will be amortized to interest expense over the term of the Convertible Notes.

We recognized \$11.7 million of interest expense related to our Convertible Notes for the six months ended June 30, 2009, \$3.3 million of which related to the contractual interest payments and \$8.4 million of which related to the amortization of the debt discount and certain other costs of the offering. During the six months ended June 30, 2008, we recognized \$4.7 million of interest expense related to our Convertible Notes, \$1.4 million of which related to the contractual interest payments and \$3.3 million of which related to the amortization of the debt discount and certain other costs of the offering.

As a result of applying FSP APB 14-1 retrospectively to all periods presented, we recognized the following incremental effects on individual line items on the Condensed Consolidated Balance Sheet (in thousands):

	December 31, 2008		
	Incremental		
	Before the Impact of FSP APB 14-1	Impact of Adoption of FSP APB 14-1	As Adjusted
Deferred income taxes asset/(liability) (non-current)	\$ 47,898	\$ (49,168)	\$ (1,270)
Convertible senior subordinated notes due 2015	371,695	(128,545)	243,150
Additional paid-in capital	707,503	85,782	793,285
Retained earnings	\$ 845,360	\$ (6,405)	\$ 838,955

## **Table of Contents**

### *Convertible Notes Due July 2009*

As a result of our acquisition of Indevus, 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 the remaining \$68.3 million in outstanding principal to satisfy the Notes in their entirety.

### *Non-recourse Notes*

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

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

Principal and interest on the Non-recourse Notes will be paid from the royalties from Allergan. Payments may also be made from the interest reserve account (described below) and certain other accounts established in accordance with the Indenture. In connection with the issuance of the Non-recourse Notes, a \$10.0 million interest reserve account was established to fund potential interest payment shortfalls. Approximately \$3.5 million of the interest reserve account remains and is classified as restricted cash in the Company's condensed consolidated balance sheet as of June 30, 2009. Royalty Sub will receive directly all royalties payable to the Company until the Non-recourse Notes have been repaid in full.

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.

**Table of Contents**

thereunder, including assuming all rights to future royalty payments from Allergan. Based on current expectations, it is reasonably possible that we may reach the maximum number of times we can fund the capital account to satisfy an interest payment shortfall as early as November 2010.

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

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

**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, 2008 (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**

We are a specialty pharmaceutical company engaged in the research, development, manufacturing, sale and marketing of branded and generic prescription pharmaceuticals used primarily to treat and manage pain, overactive bladder, prostate cancer and the early onset of puberty in children, or central precocious puberty.

We have a portfolio of branded products that includes established brand names such as Lidoderm®, Opana® ER and Opana®, Percocet®, Frova®, Voltaren® Gel, Sanctura XR®, Sanctura®, Vantas®, Delatestryl®, and Supprelin® LA. Branded products comprised approximately 89% of our revenues in the first six months of 2009, with 52% of our revenues coming from Lidoderm®. Our non-branded generic portfolio, which accounted for 10% of revenues in the first six months of 2009, 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 and endocrinology. Indevus's approved products include Sanctura® and Sanctura XR® for overactive bladder (OAB), which is co-promoted with Allergan, Inc. (Allergan), Vantas® for advanced prostate cancer, Supprelin® LA for central precocious puberty (CPP), Delatestryl® for the treatment of hypogonadism and Valstar® for bladder cancer. Indevus also has a core urology and endocrinology portfolio containing multiple compounds in development including testosterone undecanoate for hypogonadism (formerly known as Nebido®), PRO 2000 for the prevention of infection by HIV and other sexually-transmitted pathogens, and the octreotide implant for acromegaly and carcinoid syndrome.

Through a dedicated sales force of approximately 870 sales representatives in the United States, and through a contract field force of approximately 80 sales representatives, we market our branded pharmaceutical products to high-prescribing physicians in pain management, neurology, surgery, anesthesiology, oncology, urology, endocrinology and primary care. Our sales force also targets retail pharmacies and other



healthcare professionals throughout the United States.

## **Table of Contents**

### ***Business Environment***

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) continues to provide an effective prescription drug benefit under the Medicare program (known as Medicare Part D). Uncertainty exists surrounding the new administration and Congress and the impact any government decisions or programs will have on the pharmaceutical industry. Various measures have been discussed and/or passed in both the U.S. House of Representatives and U.S. Senate that would impose additional pricing pressures on our products, including proposals to legalize the importation of prescription drugs and either allow, or require, the Secretary of Health and Human Services to negotiate drug prices within Medicare Part D directly with pharmaceutical manufacturers. Additionally, various proposals have been introduced that would increase the rebates we pay on sales to Medicaid patients or impose additional rebates on sales to patients who receive their medicines through Medicare Part D or other government programs. Further, proposals to expand coverage to the uninsured could include some form of price rebates or tax on the pharmaceutical industry. In addition, many U.S. states are facing substantial budget difficulties due to the downturn in the economy and are expected to seek aggressive cuts or other offsets in healthcare spending. We expect pricing pressures at the federal and state levels to become more severe, which could have a material adverse effect on our consolidated results of operations.

The Food and Drug Administration (FDA) held a public advisory committee meeting in June 2009 to discuss acetaminophen use in both over-the-counter (OTC) and prescription (Rx) products, the potential for liver injury, and potential interventions to reduce the incidence of liver injury. The panel's recommendations followed the release in May 2009 of an 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®. 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 consolidated results of operations and cash flows.

### ***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, par value \$0.001 per share (the Indevus Shares), of Indevus, a Delaware corporation. On that day, the Company accepted for payment in accordance with the terms of the Offer, approximately 60.3 million Indevus Shares representing approximately 76% of the total outstanding Indevus Shares. 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 (the Offer Price), pursuant to the terms of the Agreement and Plan of Merger, dated as of January 5, 2009. Accordingly, the Company paid approximately \$367 million in aggregate initial cash consideration for the Indevus Shares and entered into the Nebido® (TU) 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 Nebido® (TU) Contingent Cash Consideration Agreement. As of the date hereof, Endo has paid the (i) aggregate cash consideration of \$367 million in respect of the Indevus Shares and (ii) cash consideration for unexercised in-the-money options. Endo funded such amounts with existing cash on hand. Indevus common stock ceased trading on NASDAQ at market close on March 23, 2009.

## **Table of Contents**

### ***Pipeline Developments***

On January 29, 2009, the Company announced that by mutual agreement it concluded its research collaboration with Alexza Pharmaceuticals, Inc. to develop an inhaled fentanyl product for the treatment of breakthrough pain using Alexza's Staccato® inhalation technology. The product, Staccato® fentanyl (AZ-003/EN-3294), has completed Phase I clinical testing and was returned to Alexza. In 2007, Endo licensed exclusive rights to develop and commercialize AZ-003 in North America.

In February 2009, we entered into a discovery collaboration agreement with Aurigene Discovery Technologies Limited (referred to as the Aurigene Agreement). The Aurigene Agreement is a three-year collaboration to discover novel drug candidates to treat cancer.

In February 2009, we entered into a development, license and supply agreement with Grünenthal GMBH, (referred to as 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.

In March 2009, the FDA accepted for review the complete response submission to the new drug application for testosterone undecanoate intramuscular injection, an investigational testosterone preparation for the treatment of male hypogonadism. The FDA is targeting September 2, 2009 as the action date for a decision on this application. In May 2009, we received notice from the FDA that Nebido® is unacceptable as a proprietary name for testosterone undecanoate. The Company has submitted a request to the FDA for review of a new proprietary name for this product.

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 referred to as 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. 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 million in July 2009, which will be recorded as research and development expense. In addition, Bioniche could potentially receive up to approximately \$110 million in additional payments linked to the achievement of future clinical, regulatory, and commercial milestones related to 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.

### ***Branded Business Activity***

In February 2009, The Company, and Penwest Pharmaceuticals (Penwest) settled litigation with Actavis South Atlantic LLC (Actavis) regarding the production and sale of generic formulations of Opana® ER (oxymorphone hydrochloride) Extended Release Tablets CII. Endo and Penwest have agreed to dismiss their suit with prejudice and Actavis has agreed to dismiss its counterclaims with prejudice. Under the terms of the settlement, Endo and Penwest have agreed to grant Actavis a license to the patents to sell a generic version of Opana® ER on or after July 15, 2011, and earlier under certain circumstances and have agreed not to sue Actavis under such patents.

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

### ***Changes in Directors & Officers and Other Related Matters***

In February 2009, the Company announced the appointment of William P. Montague to the Company's board of directors. Mr. Montague, 62, retired in July last year as chief executive officer and a director of Mark IV Industries. Mark IV Industries is a diversified global manufacturer of highly-engineered systems and components for the transportation, industrial and automotive markets. He joined Mark IV Industries in April 1972, became chief financial officer in 1986 and was named president in 1996. Mr. Montague is also a director of Gibraltar Industries, Inc., a NASDAQ-listed company that is a leading manufacturer, processor and distributor of products for the building, industrial, and vehicular markets. Mr. Montague serves as a member of the audit committee of Endo's board.



**Table of Contents**

In March 2009, the Company announced the appointment of Nancy J. Hutson, Ph.D., to the Company's board of directors. Dr. Hutson retired from Pfizer, Inc. in 2006 after spending 25 years in various research and leadership positions with that company, serving most recently as senior vice president, Pfizer Global Research and Development and director of Pfizer's pharmaceutical R&D site, known as Groton/New London Laboratories. Dr. Hutson currently is a director of Cubist Pharmaceuticals, Inc. and Inspire Pharmaceuticals, Inc. and serves on the board of Planned Parenthood of Connecticut. Dr. Hutson serves as a member of the compensation committee of Endo's board.

On May 5, 2009, the Company's Board of Directors appointed Alan G. Levin to be the Company's Executive Vice President and Chief Financial Officer. From June 2008 until May 2009, Mr. Levin, 47, was the executive vice president and chief financial officer of Moksha8 Pharmaceuticals, Inc., a privately held, specialty pharmaceuticals company focused in Latin America and other emerging markets. From 1987 until 2007, Mr. Levin worked at Pfizer Inc. where he served in a variety of executive positions, including treasurer, senior vice president of finance and strategic management for the company's research and development organization and most recently senior vice president and chief financial officer. Mr. Levin began his career in public accounting and received a bachelor's degree from Princeton University and a master's from New York University's Stern School of Business.

**RESULTS OF OPERATIONS**

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

**Revenues**

Revenues for the three and six months ended June 30, 2009 increased 22% to \$373.1 million and 19% to \$708.4 million, respectively from the comparable 2008 periods. This increase in revenues is primarily driven by increased net sales of Opana® ER and Opana® and Voltaren® Gel, a topical drug added to our portfolio in March 2008. Also, included in the three and six months ended June 30, 2009 are the net sales of our newly acquired products, included in other brands, from our acquisition of Indevus. For the three months ended June 30, 2009, increased sales volume contributed 17% of the total growth in revenues of 22%, while sales of Indevus products contributed 5% of the total growth in revenues. For the six months ended June 30, 2009, increased sales volume contributed 14% of the total growth in revenues of 19%, while price increases and the sale of Indevus products contributed the remaining 1% and 4% of the total growth in revenues, respectively.

The following table displays our revenues by product category and as a percentage of total revenues for the three and six months ended June 30, 2009 and 2008 (dollars in thousands):

	Three Months Ended				Six Months Ended			
	June 30,		June 30,		June 30,		June 30,	
	2009	2008	2009	2008	2009	2008	2009	2008
	\$	%	\$	%	\$	%	\$	%
Lidoderm®	\$ 195,472	52	\$ 185,050	60	\$ 367,108	52	\$ 365,574	61
Opana® ER and Opana®	55,219	15	46,392	15	107,984	15	86,675	15
Percocet®	32,014	9	33,382	11	65,704	9	65,182	11
Voltaren® Gel	25,534	7	997	*	37,853	5	997	*
Frova®	15,187	4	12,886	4	27,479	4	26,941	4
Other brands	16,915	4	3,467	1	25,823	4	5,283	1
Total brands	340,341	91	282,174	92	631,951	89	550,652	92
Total generics	30,284	8	23,987	8	72,677	10	45,780	8
Total royalty and other revenues	2,483	1			3,780	1		
Total revenues	\$ 373,108	100	\$ 306,161	100	\$ 708,408	100	\$ 596,432	100

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

\*- Denotes an amount less than 1% of total revenues

*Lidoderm*<sup>®</sup>. Net sales of *Lidoderm*<sup>®</sup> for the three months ended June 30, 2009 increased by \$10.4 million, or 6%, from the comparable 2008 period. Net sales of *Lidoderm*<sup>®</sup> for the six months ended June 30, 2009 increased by \$1.5 million, or 0.4%, from the comparable 2008 period. During the second quarter of 2009, *Lidoderm*<sup>®</sup> net sales increased from the same period in 2008 primarily as a result of wholesaler purchasing patterns, which resulted in an inventory workdown in the first quarter and a subsequent restocking of inventory in the second quarter. As expected, we recognize that the growth of this product has slowed as it matures and competition in the topical pain market increases.

**Table of Contents**

**Opana® ER and Opana®.** Net sales of Opana® ER and Opana® for the three months ended June 30, 2009 increased by \$8.8 million, or 19% from the comparable 2008 period. Net sales of Opana® ER and Opana® for the six months ended June 30, 2009 increased by \$21.3 million, or 25% from the comparable 2008 period. The growth in net sales is primarily attributable to continued prescription and market share growth of the products, as we continue to drive our promotional efforts through physician targeting. In addition, our strategy to aggressively contract with managed care organizations has resulted in increases in volume as we have broadened our access for the brand.

**Percocet®.** Net sales of Percocet® for the three months ended June 30, 2009 decreased by \$1.4 million, or 4% from the comparable 2008 period. Net sales of Percocet® for the six months ended June 30, 2009 increased by \$0.5 million, or 1% from the comparable 2008 period.

**Voltaren® Gel.** Net sales of Voltaren® Gel for the three months ended June 30, 2009 were \$25.5 million and net sales for the six months ended June 30, 2009 were \$37.9 million compared to \$1.0 million for the six months ended June 30, 2008. The Company launched Voltaren® Gel in March 2008. We believe the growth of Voltaren® Gel since its launch is driven by the product's proven clinical effectiveness combined with our continued promotional activities aimed at increasing product awareness in the target audience. We believe we are establishing a stronger position in the osteoarthritis market with Voltaren® Gel.

**Other brands.** Net sales of our other branded products for the three months ended June 30, 2009 increased by \$13.5 million from the comparable 2008 period. Net sales of our other branded products for the six months ended June 30, 2009 increased by \$20.5 million from the comparable 2008 period. This increase is primarily driven by the acquisition of Indevus, which contributed approximately \$20.7 million of net sales during the period from February 23, 2009 through June 30, 2009.

**Generics.** Net sales of our generic products for the three months ended June 30, 2009 increased by \$6.3 million, or 26% from the comparable 2008 period. Net sales of our generic products for the six months ended June 30, 2009 increased by \$26.9 million, or 59% from the comparable 2008 period. The increase was primarily due to a shortage of other competing generic opioids in the market. The supply of these generic products has largely returned to normal levels and consequently our net sales of generic products for the six months ended June 30, 2009 may not be indicative of future results.

**Royalty and other revenues.** Royalty and other revenues for the three and six months ended June 30, 2009 was \$2.5 million and \$3.8 million, respectively. These amounts consist primarily of royalties earned from Allergan on net sales of Sanctura® and Sanctura XR® in the United States.

**Gross Margin, Costs and Expenses**

The following table sets forth costs and expenses for the three and six months ended June 30, 2009 and 2008:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2009		2008		2009		2008	
	\$	% of Revenues	\$	% of Revenues	\$	% of Revenues	\$	% of Revenues
Cost of revenues	\$ 95,069	25%	\$ 62,993	21%	\$ 178,078	25%	\$ 119,527	20%
Selling, general and administrative	129,592	35	126,524	41	249,598	35	241,526	41
Research and development	48,508	13	26,497	9	76,922	11	60,079	10
Acquisition related costs	35,023	9			61,428	9		
Impairment of long-lived assets			8,083	3			8,083	1
Total costs and expenses*	\$ 308,192	83%	\$ 224,097	73%	\$ 566,026	80%	\$ 429,215	72%

\* Total percentages may not sum due to rounding.

**Cost of Revenues and Gross Margin.** Cost of revenues for the three months ended June 30, 2009 increased by \$32.1 million or 51%, to \$95.1 million from \$63.0 million in the comparable 2008 period. Cost of revenues for the six months ended June 30, 2009 increased by \$58.6 million or 49%, to \$178.1 million from \$119.5 million in the comparable 2008 period. Gross profit margins for the three months ended June 30, 2009 and 2008 were 75% and 79%, respectively. Gross profit margins for the six months ended June 30, 2009 and 2008 were 75% and 80%,

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

respectively. The reduction in gross profit margins is primarily due to the increased amortization expense in 2009 and the royalty recorded on sales of Opana® ER. During the first quarter of 2009, as a result of our acquisition of Indevus, we recorded amortizable intangible assets totaling \$312.0 million.



**Table of Contents**

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses for the three months ended June 30, 2009 increased to \$129.6 million from \$126.5 million in the comparable 2008 period. Selling, general and administrative expenses for the six months ended June 30, 2009 increased to \$249.6 million from \$241.5 million in the comparable 2008 period. The increase is primarily attributable to our acquisition of Indevus during the first quarter of 2009 partially offset by expense efficiency measures taken in 2009.

**Research and Development Expenses.** Research and development expenses for the three months ended June 30, 2009 increased to \$48.5 million from \$26.5 million in the comparable 2008 period. Research and development expenses for the six months ended June 30, 2009 increased to \$76.9 million from \$60.1 million in the comparable 2008 period. The increase in research and development expenses for the three and six months ended June 30, 2009 when compared to the same periods in 2008 is primarily attributable to upfront and milestone payments to Grünenthal related to axomadol, of which \$20.6 million was expensed during the three months ended June 30, 2009 and \$30.0 million was expensed during the six months ended June 30, 2009. We expect research and development expenses to increase in the future as a result of the recent investments in our pipeline, the acquisition of Indevus and our collaborative agreements with Grünenthal, Aurigene, Harvard University and Bioniche.

**Acquisition-Related Costs.** As a result of our acquisition of Indevus in the first quarter of 2009, we incurred acquisition-related costs attributable to transaction fees, professional service fees, employee retention and separation arrangements and other costs related to the acquisition. During the three months ended June 30, 2009, we recorded \$25.9 million of expense, related to changes in the fair value of acquisition-related contingent consideration which is included in acquisition-related costs. Acquisition-related costs for the three and six months ended June 30, 2009 were \$35.0 million and \$61.4 million, respectively.

**Impairment of Other Intangible Assets**

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

**Interest Expense (Income), net**

The components of interest expense (income), net for the three and six months ended June 30, 2009 and 2008 are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Interest expense	\$ 11,471	\$ 5,471	\$ 20,204	\$ 5,741
Interest income	(1,055)	(5,899)	(2,195)	(15,434)
Interest expense (income), net	\$ 10,416	\$ (428)	\$ 18,009	\$ (9,693)

Interest expense for the three months ended June 30, 2009 increased to \$11.5 million from \$5.5 million in the comparable 2008 period. For the six months ended June 30, 2009, interest expense increased to \$20.2 million from \$5.7 million in the comparable 2008 period. This change is primarily due to interest expense recognized on the 16% Non-recourse Notes and the 6.25% convertible notes assumed from Indevus. Interest income decreased to \$1.1 million for the three months ended June 30, 2009 compared to \$5.9 million in the comparable 2008 period. Interest income decreased to \$2.2 million for the six month period ended June 30, 2009 compared to \$15.4 million in the comparable 2008 period. 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. During 2008, as a result of uncertainties in the global credit markets, the auction-rate securities market became illiquid and since that time, yields on these securities have decreased significantly.

**Other Income, net**

The components of other income, net for the three and six months ended June 30, 2009 and 2008, are as follows (in thousands):

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Unrealized gain on trading securities	\$ (10,910)	\$	\$ (4,816)	\$
Loss on auction-rate securities rights	8,779		2,513	
Other expense (income)	616	(1,126)	1,893	(844)
Other income, net	\$ (1,515)	\$ (1,126)	\$ (410)	\$ (844)

## **Table of Contents**

During the fourth quarter of 2008, upon accepting the UBS Offer of auction-rate securities rights, the Company made a one-time election to transfer Eligible Auction-rate Securities out of the available-for-sale category and into the trading category. As such, the change in the fair value of these securities is now charged to earnings. During the three months ended June 30, 2009, the value of our trading auction-rate securities increased by \$10.9 million. During the six months ended June 30, 2009, the value of our trading auction-rate securities increased by \$4.8 million. The increases in fair value were partially offset by losses recorded as a result of decreases in the fair value of our auction-rate securities rights. During the three and six months ended June 30, 2009, decreases in the fair value of our auction-rate securities rights were \$8.8 million and \$2.5 million, respectively.

### ***Income Tax***

Income tax for the three months ended June 30, 2009 decreased to \$26.0 million from \$26.5 million in the comparable period. For the six months ended June 30, 2009, income tax decreased to \$55.7 million from \$61.1 million. This decrease is due to the decrease in income before income tax for the three and six months ended June 30, 2009, partially offset by the increase in our effective income tax rate to 46.4% for the three months ended June 30, 2009 from 31.7% in the comparable 2008 period and the increase in our effective income tax rate to 44.7% for the six months ended June 30, 2009 from 34.4% in the comparable 2008 period. The increase in the effective income tax rate is due to the non-deductible charges to earnings for the increase in the fair value of the Indevus acquisition-related contingent consideration, certain non-deductible Indevus acquisition-related costs, the absence of certain unrecognized tax benefits that reversed in 2008 and a reduction in tax exempt interest for the period, partially offset by an R&D credit that was not available in the comparable 2008 period due to the expiration of the R&D credit until its retroactive reinstatement in the fourth quarter of 2008.

### ***2009 Outlook***

We estimate that our 2009 net sales will be between \$1.390 billion and \$1.440 billion. Diluted earnings per share are projected to be between \$1.26 and \$1.34. Our estimate is based on the continued growth of our branded product portfolio, primarily driven by prescription demand for Opana® ER, Opana® and Voltaren® Gel, our recent acquisition of Indevus and growth in our generic portfolio. Cost of revenues as a percentage of net sales is expected to increase when compared to 2008. This increase is expected due to continued expansion of our contracting with managed care organizations, a full year of amortization expense on the Voltaren® Gel intangible asset, additional amortization expense related to the acquisition of Indevus and the impact of a full year of royalties on the 2009 net sales of Opana® ER. Selling, general and administrative expenses are expected to increase as we continue to promote our key on-market products, including those acquired as part of our acquisition of Indevus. Research and development expenses are expected to increase as we invest in pipeline development programs, both branded and generic. The increase in operating expenses is expected to be partially offset by the continued rationalization of our cost infrastructure. There can be no assurance that the Company will achieve these results.

## **LIQUIDITY AND CAPITAL RESOURCES**

Our principal source of liquidity is cash generated from operations. Our principal liquidity requirements are for working capital for operations, acquisitions, licenses, milestone payments, capital expenditures and debt service payments. Cash, cash equivalents and current marketable securities were approximately \$495.8 million at June 30, 2009 compared to \$782.2 million at December 31, 2008. The Company continues to maintain a sufficient level of working capital, which was approximately \$537.0 million at June 30, 2009, decreasing from \$797.2 million at December 31, 2008.

In 2009, we expect cash generated from operations together with our cash and cash equivalents to be sufficient to cover cash needs for working capital and general corporate purposes, the payment of contractual obligations, including scheduled interest payments on our Convertible Notes, principal and interest payments on Indevus debt assumed by the Company, \$68.3 million of which became due in July 2009 and was satisfied in full by the company, and any regulatory and/or sales milestones that may become due. We expect that sales of our currently marketed products to allow us to continue to generate positive cash flow from operations. In February 2009, we deposited \$175 million in an escrow account until December 15, 2009 to fund potential payments under the Nebido® (TU) Contingent Cash Consideration Agreement, which amount is not included in the cash, cash equivalents and current marketable securities total above.

**Table of Contents**

Beyond 2009, 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, the potential payments of approximately \$124 million in contingent cash consideration payments related to our acquisition of Indevus, the payment of contractual obligations, including scheduled interest payments on our convertible notes, principal and interest payments on the remaining \$105.0 million face non-recourse notes, certain minimum royalties due to Novartis and the regulatory or sales milestones that may become due, the settlement of outstanding litigation described under Note 10. Commitments and Contingencies-Legal Proceedings included in Part 1 Item I of this Report, and/or the purchase, redemption or retirement of our Convertible Notes, including a principal payment of \$379.5 million at maturity in 2015. Based on current expectations, it is reasonably possible that we may reach the maximum number of times we can fund the capital account to satisfy an interest payment shortfall on our Non-recourse Notes as early as November 2010.

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.

Pursuant to our previously announced \$750 million share repurchase plan, we may, from time to time, seek to repurchase shares of our common stock 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 the amount of cash generated from operations, cash requirements for investment in the Company's business, repayment of outstanding debt, current stock price, market conditions and other factors. The share repurchase program may be suspended, modified or discontinued at any time and is set to expire in April 2010. As of June 30, 2009, the approximate amount of shares that may be purchased under the share repurchase plan is \$325.2 million.

We may also elect to incur additional debt or issue equity or convertible securities to finance ongoing operations, acquisitions or to meet our other liquidity needs. Any issuances of equity securities or convertible securities could have a dilutive effect on the ownership interest of our current shareholders and may adversely impact earnings per share in future periods. An acquisition may be accretive or dilutive and by its nature, involve numerous risks and uncertainties.

**Marketable Securities.** Beginning in 2008 and continuing into 2009, the securities and credit markets have experienced severe volatility and disturbance, increasing risk with respect to certain of our financial assets. At June 30, 2009, \$238.6 million of our marketable securities portfolio was invested in auction-rate debt securities with ratings varying from Ba to AAA. Despite recent downgrades in certain of our auction-rate securities, the Company believes that our exposure to loss is mitigated as a result of the auction-rate securities rights agreement with UBS (described in more detail below) which management views as an economic hedge against potential credit risk losses. 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. 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 either the Federal Family Education Loan Program, or FFELP, or a combination of FFELP and other monoline insurers such as Ambac Assurance Corp., or AMBAC, and MBIA Insurance Corp, or MBIA. As of July 24, 2009, MBIA was rated Ba3 by Moody's and BB by Standard and Poor's. AMBAC was rated Caa1 by Moody's and BB by Standard and Poor's.

The following tables set forth the fair value of our long-term auction-rate securities by type of security and underlying credit rating as of June 30, 2009 and December 31, 2008 (in thousands):

As of June 30, 2009	Underlying Credit Rating(1)					Total
	AAA	AA	A	Baa	Ba	
<i>Underlying security:</i>						
Student loans	\$ 134,900	\$ 5,062	\$ 66,709	\$ 7,126	\$ 24,823	\$ 238,620
<i>Total auction-rate securities included in long-term marketable securities</i>	\$ 134,900	\$ 5,062	\$ 66,709	\$ 7,126	\$ 24,823	\$ 238,620



**Table of Contents**

As of December 31, 2008

	Underlying Credit Rating(1)			
	AAA	AA	A	Total
<i>Underlying security:</i>				
Student loans	\$ 166,885	\$ 35,302	\$ 31,818	\$ 234,005
<i>Total auction-rate securities included in long-term marketable securities</i>	\$ 166,885	\$ 35,302	\$ 31,818	\$ 234,005

(1) Our auction-rate securities maintain split ratings. For purposes of this table, securities are categorized according to their lowest rating.  
*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. Prior to February 2008, the Company was able to determine the fair value of the auction-rate securities using a market approach valuation technique based on successful auctions of our securities or based on quoted prices in active markets for identical auction-rate securities without any adjustment (Level 1 of the fair value hierarchy).

Since mid-February 2008, the market for auction-rate securities has seen a dramatic decrease in the volume of trades relative to historical levels. At June 30, 2009, (the measurement date), the Company determined that the market for its auction-rate securities was inactive. That determination was made considering that there are very few observable transactions for the auction-rate securities or similar securities, the prices for transactions that have occurred are not current, and the observable prices for those transactions to the extent they exist vary substantially either over time or among market makers, thus reducing the potential usefulness of those observations. In addition, the current lack of liquidity prevents the Company from comparing our securities directly to securities with quoted market prices. Consequently, while we have appropriately considered those observable inputs, ultimately, our auction-rate securities will be classified within Level 3 of the fair value hierarchy because significant judgments are required to determine fair value at the measurement date.

*Overview of Auction-Rate Securities Rights*

In October 2008, UBS AG (UBS) made an offer (the UBS Offer) of auction-rate securities rights (the Rights) to the Company and other clients of UBS Securities LLC and UBS Financial Services Inc. (collectively, the UBS Entities), pursuant to which the Company is entitled to sell to UBS all auction-rate securities held by the Company as of February 13, 2008 in a UBS account (the Eligible Auction-Rate Securities). The Rights permit the Company to require UBS to purchase the Eligible Auction-Rate Securities for a price equal to original par value plus any accrued but unpaid dividends or interest beginning on June 30, 2010 and ending on July 2, 2012 (the Expiration Date). As of June 30, 2009, we had Eligible Auction-Rate Securities with original par value of \$247.0 million, representing 93% of our total auction-rate securities portfolio at par. The remaining seven percent (7%), or \$18.8 million at par, of our auction-rate securities portfolio are not held in a UBS account and therefore are not subject to the UBS Offer.

## **Table of Contents**

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

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.

In addition, as part of the UBS Offer, Endo is eligible for no net cost loans, should we desire to borrow money prior to the commencement of the exercise period for the Rights. Under the terms of the UBS Offer, Endo may be eligible for no net cost loans for an amount up to 75% of the market value of the Eligible Auction-Rate Securities at the time of the loan. If and as soon as UBS receives proceeds from a purchase of the Eligible Auction-Rate Securities, the loans will become partially payable in the amount of the proceeds.

Acceptance of the UBS Offer constituted a substantive change in facts and circumstances that altered the Company's view that it intends 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.

Acceptance of the UBS Offer created an enforceable legal right by and between the Company and UBS. The UBS Offer is a legally separate contractual agreement and is non-transferable. The Rights are not readily convertible to cash and do not provide for net settlement. Accordingly, the Rights do not meet the definition of a derivative instrument and are being 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.

Concurrent with the acceptance of the UBS Offer, the Company made a one-time election to transfer the Eligible Auction-Rate Securities from the available-for-sale category to the trading category pursuant to SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, as codified in ASC 323. The Company made the election to transfer the securities into the trading category 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. Changes in the fair value of the Eligible Auction-Rate Securities are now recorded to earnings. During the six-month period ended June 30, 2009, the fair value of these securities increased by \$4.8 million, which was recorded as a gain and included in other income, net in the Condensed Consolidated Statements of Operations.

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

In November 2008, we elected the fair value option under SFAS 159 (as codified in ASC 825) for the Rights. SFAS 159 provides companies with an option to report selected financial assets and liabilities at fair value. As a result of our SFAS 159 election, the fair value of the Rights is re-measured each reporting period with the corresponding changes in fair value reported in earnings. Since the Rights are freestanding financial instruments, they do not affect the separate determination of the fair value of the Eligible Auction-Rate Securities. However, in management's view the Rights act as an economic hedge against further fair value changes in the Eligible Auction-Rate Securities. Accordingly, management has elected the fair value option under SFAS 159, as it believes it is most appropriate to recognize future changes in the fair value of the Rights as those changes occur in order to offset the fair value movements in the Eligible Auction-Rate Securities. As of December 31, 2008 the fair value of our the Rights was \$27.3 million. At June 30, 2009, the fair value of the Rights decreased to \$24.8 million to reflect the fair value measurement of the Rights at that date. The decrease in fair value from December 31, 2008 to June 30, 2009 of \$2.5 million was recognized as a charge to earnings and included in other income, net in the Condensed Consolidated Statements of Operations. Future changes in fair value will also be recognized in earnings in accordance with SFAS 159.

## **Table of Contents**

### *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 auction-rate securities. Specifically, the Company used the discount rate adjustment technique described in Appendix B of SFAS 157 (as codified in ASC 820) to determine an indication of fair value.

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

The Company identifies the times to maturity of the auction-rate securities as the time at which principal is available to the investor. This can occur because the auction-rate security is paying a coupon that is above the required rate of return, and the Company treats the security as being called. It can also occur because the market has returned to normal and the Company treats the auctions as having recommenced. Lastly, and most frequently, the Company treats the principal as being returned as prepayment occurs and at the maturity of the security. The weighted average life used for each security representing time to maturity ranges from 4 to 8 years. The weighted average life measured across the entire auction-rate securities portfolio is approximately seven (7) years.

The Company calculates coupon rates based on estimated relationships between the maximum coupon rate (the coupon rate in event of a failure) and market interest rates. The representative coupon rates on June 30, 2009 ranged from 5.09% to 5.75%. The Company calculates appropriate discount rates for securities that include base interest rates, index spreads over the base rate, and security-specific spreads. These spreads include the possibility of changes in credit risk over time. At June 30, 2009, the spreads over the base rate for our auction-rate securities applied to our auction-rate securities ranged from 195 basis points to 602 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 in the auction-rate securities. We believe it is not unreasonable to assume a 150 basis points adjustment to the required rate of return and a term of either three, four or five years to adjust for this lack of liquidity. The increase in the required rate of return decreases the prices of the securities. However, the assumption of a three, four or five-year term shortens the times to maturity and increases the prices of the securities. The Company has evaluated the impact of applying each term and the reasonableness of the range indicated by the results. The Company chose to use a four-year term to adjust for the lack of liquidity as we believe it is the point within the range that is most representative of fair value. The Company's determination is based in part on the fact that the fair values indicated by the results are reasonable in relation to each other given the nature of the securities and current market conditions.

At June 30, 2009, the fair value of our auction-rate securities, as determined by applying the above described discount rate adjustment technique, was approximately \$238.6 million, representing a 10%, or \$27.2 million discount from their original purchase price or par value, which the Company attributes to liquidity issues rather than credit issues. Had the Company chosen to apply a three or five year term with respect to the liquidity adjustment, the resultant discount to the original purchase price or par value would have been \$21.3 million and \$32.7 million, respectively. We believe we have appropriately reflected our best estimate of the assumptions that market participants would use in pricing the assets in a current transaction to sell the asset at the measurement date. Accordingly, the carrying value of our auction-rate securities was increased by approximately \$5.2 million at June 30, 2009, reflecting the change in fair value for the six months ended June 30, 2009. The portion of this increase in fair value related to the Eligible Auction-Rate Securities was \$4.8 million and was recorded in earnings 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, as we currently do not intend to sell these securities, it is not more likely than not that we will be required to sell these securities before the recovery of our amortized cost basis and we currently expect to recover the entire cost basis of these securities. Our assessment was based in large part on the financial condition and near-term prospects of the underlying issuers. Accordingly, we recorded a \$0.3 million increase in shareholders' equity in accumulated other comprehensive loss. Securities not subject to the UBS Offer are analyzed each reporting period for other-than-temporary impairment factors.

### *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 Rights. Specifically, the Company used the discount rate adjustment technique described in Appendix B of SFAS 157 (as codified in ASC 820) to determine an indication of fair value. The Rights provide the Company with the ability to sell the Eligible Auction-Rate Securities at par plus accrued interest and dividends to UBS beginning on June 30, 2010.





## **Table of Contents**

The values of the Rights were estimated as the value of a portfolio designed to approximate the cash flows of the UBS Offer. The portfolio consists of a bond issued by UBS that will mature equal to the face value of the Eligible Auction-Rate Securities, a series of payments that will replicate the coupons of the Eligible Auction-Rate Securities, and a short position in the callable Eligible Auction-Rate Securities. If the UBS Offer is in the money on the exercise date, then both the UBS Offer and the replicating portfolio will be worth the difference between the par value plus accrued interest and dividends of the Eligible Auction-Rate Securities and the market value of the Eligible Auction-Rate Securities. If the UBS Offer is out of the money on the exercise date, then both the replicating portfolio and the UBS Offer 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 Eligible 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, 2009, the fair value of the Rights, as determined by applying the above described discount rate adjustment technique, was approximately \$24.8 million. As described above, 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. Had the Company chosen to apply a three or five year term with respect to the liquidity adjustment for the auction-rate securities, the resultant value of the Rights at June 30, 2009 would have been \$19.2 million and \$30.0, respectively. 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.

During the six-month period ended June 30, 2009, we sold \$7.1 million of auction-rate securities at par value. During the six-month period ended June 30, 2008, we sold \$113.8 million of original par value variable-rate demand obligations and \$287.0 million of auction-rate securities at par value. There were no realized holding gains and losses resulting from the sales of our auction rate securities and variable rate demand obligations during the six-month period ended June 30, 2009 and 2008. The cost of securities sold is based on the specific identification method.

As of June 30, 2009, the yields on our long-term auction-rate securities ranged from 0.51% to 0.98%. These yields represent the predetermined maximum reset rates that occur upon auction failures according to the specific terms within each security's prospectus. As of June 30, 2009, the weighted average yield for our long-term auction-rate securities was 0.79%. Total interest earned on our auction-rate securities during the six-months ended June 30, 2009 and 2008 was \$1.5 million and \$8.8 million, respectively. Further, the issuers have been making interest payments when due.

Given the inactivity in the auction-rate securities market, the Company cannot predict when future auctions related to our existing auction-rate securities portfolio will be successful. As a result of the current illiquidity in the auction-rate securities markets and the long-term remaining duration of the underlying securities, we have classified these investments as long-term marketable securities in the Condensed Consolidated Balance Sheets at June 30, 2009 and December 31, 2008. The Eligible Auction-rate Securities subject to the Rights, are eligible for redemption beginning June 30, 2010. As a result, we have classified the Rights as a current asset in the Condensed Consolidated Balance Sheet at June 30, 2009. Auction-rate securities classified as long-term at June 30, 2009 and December 31, 2008 were \$237.7 million and \$234.0 million, respectively. Since February 2008, when we began to experience failed auctions, and through July 24, 2009, we have sold, without a loss, \$91.4 million of our original par value auction-rate securities, either through successful auctions or mandatory tenders by the issuers. Of this \$91.4 million of original par value auction-rate securities, \$0.9 million was classified as current marketable securities at June 30, 2009.

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.

If uncertainties in the credit and capital markets continue, these 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, our financial condition and cash flows. 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.

**Table of Contents**

**Working Capital.** Working capital decreased to \$537.0 million as of June 30, 2009 from \$797.2 million as of December 31, 2008. The components of our working capital as of June 30, 2009 and December 31, 2008 are below:

	June 30, 2009	December 31, 2008
Total current assets	\$ 1,228,026	\$ 1,183,694
Less: Total current liabilities	691,057	386,473
<b>Working capital</b>	<b>\$ 536,969</b>	<b>\$ 797,221</b>

Working capital decreased primarily as a result of our first quarter acquisition of Indevus and the payment of the initial upfront cash consideration of \$367 million, which was partially offset by cash generated from operations for the six months ended June 30, 2009. Total current assets in the table above include \$178.5 million of restricted cash.

The following table summarizes our statement of cash flows and liquidity as of June 30, 2009 and 2008 (dollars in thousands):

	Six Months Ended June 30, 2009	2008
Net cash flow provided by (used in):		
Operating activities	\$ 140,572	\$ 118,703
Investing activities	(424,758)	157,041
Financing activities	3,482	(60,892)
Net (decrease) increase in cash and cash equivalents	(280,704)	214,852
Cash and cash equivalents, beginning of period	775,693	350,325
Cash and cash equivalents, end of period	\$ 494,989	\$ 565,177
Current ratio	1.78:1	2.9:1
Days sales outstanding	48	44

**Net Cash Provided by Operating Activities.** Net cash provided by operating activities was \$140.6 million for the six months ended June 30, 2009 compared to \$118.7 million for the six months ended June 30, 2008. Significant components of our operating cash flows for the six months ended June 30, 2009 and 2008 are as follows:

	Six Months Ended June 30, 2009	2008
<b>Cash Flow Data-Operating Activities:</b>		
Net income	\$ 69,066	\$ 116,656
Depreciation and amortization	34,647	19,927
Stock-based compensation	7,844	8,958
Change in fair value of contingent consideration	25,930	
Impairment of long-lived assets		11,198
Interest earned on available-for-sale securities	(390)	(2,201)
Loss on auction-rate securities rights	2,513	
Unrealized loss on trading securities	(4,816)	
Changes in assets and liabilities which (used) provided cash:	15,064	(35,829)
Other, net	(9,286)	(6)

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

Net cash provided by operating activities	\$ 140,572	\$ 118,703
---	------------	------------

The primary drivers of the increase in cash flow provided by operating activities when compared to the prior year were the positive impact of changes in operating assets and liabilities as a result of our increases in net sales when compared to the prior period.

***Net Cash Used In Investing Activities.*** Net cash used in investing activities was \$424.8 million for the six months ended June 30, 2009 compared to net cash provided by investing activities of \$157.0 million during the same period of 2008. During the six months ended June 30, 2009, the Company completed its acquisition of Indevus and paid initial upfront cash consideration, net of cash acquired of \$249.6 million. The Company also deposited \$175.0 million in cash in an escrow account with a paying agent through December 15, 2009, pursuant to the terms of the Nebido® (TU) Contingent Cash Consideration Agreement, which amount is equal to the aggregate amount payable to the former Indevus stockholders if the testosterone undecanoate approval is obtained and is not subject to a boxed warning label

## **Table of Contents**

by the FDA. In addition, the Company sold \$7.1 million of trading auction-rate securities at par value, which was offset by the purchases of property and equipment of \$6.0 million and an additional investment of \$1.3 million in Life Sciences Opportunities Fund (Institutional) II, L.P. During the six months ended June 30, 2008, the Company collected \$3.3 million in principal payments from Vernalis on our note receivable and sold \$401.3 million of available-for-sale securities, which was partially offset by purchases of available-for-sale securities of \$134.2 million. Also during the six months ended June 30, 2008, we made an \$85 million upfront payment to Novartis AG to obtain the exclusive U.S. marketing rights for the prescription medicine Voltaren® Gel, and paid \$13.4 million for capital expenditures. During 2008, the first dosage of EN 3285 was administered to a patient enrolled in a clinical phase III trial. Accordingly, we paid \$15 million in additional contingent purchase price consideration to the former stockholders of RxKinetics in March 2008.

***Net Cash Provided by Financing Activities.*** Net cash provided by financing activities was \$3.5 million for the six months ended June 30, 2009 compared to net cash used in financing activities of \$60.9 million during the six months ended June 30, 2008. In connection with the April 2008 issuance of our 1.75% Convertible Senior Subordinated Notes, we received proceeds of approximately \$371.5 million, net of the original purchaser's discount. Concurrently with the issuance of the Convertible Notes, we entered into a privately negotiated convertible note hedge transaction with affiliates of the initial purchasers. The cost of the call option was approximately \$107.6 million. In addition, we sold warrants to affiliates of certain of the initial purchasers whereby they have the option to purchase up to approximately 13.0 million shares of our common stock at an initial strike price of \$40.00 per share. We received approximately \$50.4 million in cash proceeds from the sale of these warrants. In addition to entering into the convertible note hedge transaction and the warrant transaction, we entered into a privately-negotiated accelerated share repurchase agreement with the same counterparty, as part of our broader share repurchase program. We used approximately \$57 million representing a portion of the net proceeds from the Convertible Notes offering to pay the cost of the convertible note hedge transaction, taking into account the proceeds from the warrant transaction, and used the balance of the net proceeds of approximately \$314 million, together with approximately \$11 million of cash on hand, to repurchase a variable number of shares of our common stock pursuant to the accelerated share repurchase agreement entered into as part of our broader share repurchase program. Pursuant to the accelerated share repurchase agreement, the counterparty delivered 11.9 million shares of our common stock to the Company on the day that the Convertible Note offering closed, April 15, 2008. In addition to the accelerated share repurchase, beginning in April 2008 we made open market purchases of our common stock as part of our broader share repurchase program. During the six months ended June 30, 2008, we purchased approximately 2.0 million shares on the open market for a total purchase price of approximately \$50.0 million.

***Research and Development.*** Over the past few years, we have incurred significant expenditures relating to the conduct of 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 expect to spend significant funds on our share of the cost of these programs, including the costs of research, pre-clinical 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., Almac Pharma Services, Sharp Corporation, Ventiv Commercial Services, LLC, Catalent Pharma Solutions, Inc., and BayerSchering Pharma AG. If for any reason we are unable to obtain sufficient quantities of any of the finished goods or raw materials or components required for our products, it could have a material adverse effect on our business, financial condition, results of operations and cash flows. For a complete description of commitments under manufacturing, supply and other service agreements, see Note 10 of the Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

## **Table of Contents**

**Legal Proceedings.** We are subject to various patent, product liability, government investigations and other legal proceedings in the ordinary course of business. Contingent accruals are recorded when we determine that a loss related to a litigation matter is both probable and reasonably estimable. Due to the fact that legal proceedings and other contingencies are inherently unpredictable, our assessments involve significant judgments regarding future events. For a complete description of legal proceedings, see Note 10 of the Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

**Acquisitions.** On February 23, 2009 (the Acquisition Date), the Company completed its initial tender offer (the Offer) for all outstanding shares of common stock, par value \$0.001 per share (the Indevus Shares), of Indevus, a Delaware corporation. On that day, the Company accepted for payment in accordance with the terms of the Offer, approximately 60.3 million Indevus Shares representing approximately 76% of the total outstanding Indevus Shares. 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 (the Offer Price), pursuant to the terms of the Agreement and Plan of Merger, dated as of January 5, 2009. Accordingly, the Company paid approximately \$367 million in aggregate initial cash consideration for the Indevus Shares and entered into the Nebido® (TU) 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 Nebido® (TU) Contingent Cash Consideration Agreement. As of the date hereof, Endo has paid the (i) aggregate cash consideration of \$367 million in respect of the Indevus Shares and (ii) cash consideration for unexercised in-the-money options. Endo funded such amounts with existing cash on hand. Indevus common stock ceased trading on NASDAQ at market close on March 23, 2009.

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

Indevus' s approved products include the following:

Sanctura® (trospium chloride) was launched by Indevus in August 2004. Sanctura® is indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency and urinary frequency. We currently co-promote Sanctura® in the U.S. with our marketing partner, Allergan, Inc., however, our right to co-promote expires in September 2009.

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. We currently co-promote Sanctura XR® in the U.S. with our marketing partner, Allergan, Inc., however, our right to co-promote expires in September 2009.

Supprelin® LA was launched by Indevus 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 Indevus' s patented Hydro® Polymer Technology, designed to provide the continuous 12-month administration of a controlled dose of histrelin, a GnRH agonist.

Vantas® was launched by Indevus 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 advanced prostate cancer. The product utilizes Indevus' s patented Hydro® 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® 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.

**Table of Contents**

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 of Indevus: Vantas® and Supprelin® LA.

Valstar 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 urinary 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, Indevus 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. We continue to work closely with our manufacturing partner to resolve an issue that will likely delay the launch of Valstar™. We are hopeful this matter will be resolved quickly and we hope to re-launch Valstar™ later this year.

Indevus's primary development products include the following:

Testosterone undecanoate (TU) is a long-acting injectable testosterone preparation for the treatment of male hypogonadism that we have historically referred to as Nebido®. On May 6, 2009, we received notice from the FDA that Nebido® is unacceptable as a proprietary name for testosterone undecanoate. Throughout this report, however, when we refer to the contingent cash consideration agreement relating to the product, we will call it the Nebido® (TU) Contingent Cash Consideration Agreement. The Company has submitted a request to the FDA for review of a new proprietary name for this product. Testosterone undecanoate is expected to be the first long-acting testosterone preparation available in the U.S. in the growing market for testosterone replacement therapies. Indevus acquired U.S. rights to testosterone undecanoate from Schering AG, Germany, in July 2005. In June 2008, Indevus 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 testosterone undecanoate intramuscular injection. The FDA has informed us that it is targeting September 2, 2009 as the action date for a decision on this application.

PRO 2000, currently in Phase III clinical trials, is a candidate topical microbicide for the prevention of sexually transmitted infections including infection by the Human Immunodeficiency Virus (HIV), the cause of Acquired Immunodeficiency Syndrome (AIDS). The compound is believed to block the entry of sexually transmitted disease (STD) pathogens into human cells. In addition to its demonstrated activity against HIV infection in laboratory tests and animal models, PRO 2000 has been shown to be active against other STD pathogens such as herpes, chlamydia, and the bacterium that causes gonorrhea. Designed to be applied vaginally prior to sexual intercourse, PRO 2000 promises to offer a discreet safer sex option that can be controlled by women.

Octreotide implant, currently in Phase III clinical trials for the treatment of acromegaly, utilizes Indevus's 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). Octreotide implant is also approved to treat symptoms associated with metastatic carcinoid tumors and vasoactive intestinal peptide secreting adenomas, which are gastrointestinal tumors. 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 primary development products acquired from Indevus.

Product	Indication	Development Phase	Anticipated
			Year of Completion
Testosterone undecanoate	Hypogonadism (Testosterone Deficiency)	NDA filed	2009
Pro 2000	Prevention of HIV and sexually-transmitted diseases	Phase III	2011



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

Octreotide implant	Acromegaly	Phase III	2011
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 filing an NDA with 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.

**Table of Contents**

The total estimated cost to complete our core development product listed above is estimated to be approximately \$60 million to \$80 million in total. We have not included compounds in development for which we do not expect to incur significant research and development costs. Estimating costs and time to complete development of a compound is difficult due to the uncertainties of the development process and the requirements of the FDA which could necessitate additional and unexpected clinical trials or other development, testing and analysis. Results of any testing could result in a decision to alter or terminate development of a compound, in which case estimated future costs could change substantially. Certain compounds could benefit from subsidies, grants or government or agency-sponsored studies that could reduce our development costs. In the event we were to enter into a licensing or other collaborative agreement with a corporate partner involving sharing, funding or assumption by such corporate partner of development costs, the estimated development costs to be incurred by us could be substantially less than the estimate above. Additionally, research and development costs are extremely difficult to estimate for early-stage compounds due to the fact that there is generally less comprehensive data available for such compounds to determine the development activities that would be required prior to the filing of an NDA. Actual costs to complete development of any of our products may differ significantly from the estimate noted above. We are currently considering strategic partners for future development and commercialization of PRO 2000.

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 will market products through four field sales forces and have the capability to develop innovative new therapies using a novel drug delivery technology.

The operating results of Indevus from February 23, 2009 to June 30, 2009 are included in the accompanying Condensed Consolidated Statements of Operations. The Condensed Consolidated Balance Sheet as of June 30, 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 \$541.6 million, which consisted of the following (in thousands):

	<b>Fair Value of Consideration Transferred</b>
Cash	\$ 367,221
Contingent consideration	174,350
<b>Total</b>	<b>\$ 541,571</b>

The contingent consideration relates to the amounts payable under the Nebido® (TU) Contingent Cash Consideration Agreement and the Octreotide Contingent Cash Consideration Agreement. In the event that the Company receives an approval letter from the FDA with respect to the testosterone undecanoate 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 testosterone undecanoate immediately and provides labeling for testosterone undecanoate that does not contain a boxed warning (testosterone undecanoate With Label) or alternatively, (ii) pay an additional \$1.00 per Indevus Share, if such approval letter grants the right to market and sell testosterone undecanoate immediately and provides labeling for testosterone undecanoate that contains a boxed warning (testosterone undecanoate Without Label). In the event that either a testosterone undecanoate With Label approval or a testosterone undecanoate 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 Nebido® (TU) Contingent Cash Consideration Agreement.

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

Endo has deposited \$175.0 million in cash in an escrow account with a paying agent pursuant to the terms of the Nebido® (TU) Contingent Cash Consideration Agreement, which amount is equal to the aggregate amount payable to the former Indevus stockholders if the testosterone undecanoate With Label approval is obtained under the terms of the



## **Table of Contents**

Nebido® (TU) Contingent Cash Consideration Agreement. This amount is included in our restricted cash balance in the accompanying Condensed Consolidated Balance Sheet and is restricted through December 15, 2009, the date when such amount will be released in accordance with the terms of the Nebido® (TU) Contingent Cash Consideration Agreement if not previously paid to former Indevus stockholders under the terms of the Nebido® (TU) Contingent Cash Consideration Agreement.

The range of the undiscounted amounts the Company could pay under the Nebido® (TU) Contingent Cash Consideration Agreement is between \$0 and approximately \$175 million. The fair value of the contractual obligation to pay the testosterone undecanoate contingent consideration recognized on the Acquisition Date was \$134.1 million. We determined the fair value of the obligation to pay the testosterone undecanoate 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 as defined in SFAS 157 (as codified in FASB ASC 820). Under the Nebido® (TU) 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 a testosterone undecanoate With Label approval, (2) obtaining a testosterone undecanoate 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 testosterone undecanoate should the testosterone undecanoate Without Label approval be obtained. The fourth scenario is testosterone undecanoate 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 testosterone undecanoate. 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.

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 \$40.2 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 as defined in SFAS 157 (as codified in FASB ASC 820). 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.

In addition to the potential contingent payments under the Nebido® (TU) 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. (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 Nebido® (TU) 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.

In accordance with SFAS 141(R) (as codified in FASB ASC 805), 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 as defined in SFAS 157 (as codified in FASB ASC 820). The fair value of the Valera Contingent

**Table of Contents**

Consideration is estimated using the same assumptions used for the Nebido® (TU) 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.

As of June 30, 2009, the fair value of the acquisition-related contingent consideration increased by \$25.9 million based on changes in management's estimates and other factors that occurred during the three months ended June 30, 2009. The increase in the liability was recorded as a charge to earnings and is included in the acquisition-related costs line item in the Condensed Consolidated Statements of Operations.

As of June 30, 2009, there were no changes to the range of the undiscounted amounts the Company may be required to pay under the Nebido® (TU) Contingent Cash Consideration Agreement and the Octreotide Contingent Consideration Agreement or related to the Valera Contingent Consideration.

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

	February 23, 2009 (As initially reported)	Measurement Period Adjustments	February 23, 2009 (As adjusted)
Cash and cash equivalents	\$ 117,675	\$	\$ 117,675
Accounts receivable	13,725	1,593	15,318
Inventories	15,808	(891)	14,917
Prepaid and other current assets	8,327		8,327
Property, plant and equipment	8,266		8,266
Other intangible assets	586,900	2,000	588,900
Deferred tax assets	159,769	5,624	165,393
Other non-current assets	764	155	919
<b>Total identifiable assets</b>	<b>\$ 911,234</b>	<b>\$ 8,481</b>	<b>\$ 919,715</b>
Accounts payable	\$ (5,081)	\$	\$ (5,081)
Accrued expenses	(27,357)	(1,440)	(28,797)
Convertible notes	(71,682)	(830)	(72,512)
Non-recourse notes	(115,235)		(115,235)
Deferred tax liabilities	(234,599)	1,188	(233,411)
Other non-current liabilities	(18,199)	(652)	(18,851)
<b>Total liabilities assumed</b>	<b>(472,153)</b>	<b>(1,734)</b>	<b>(473,887)</b>
<b>Net identifiable assets acquired</b>	<b>\$ 439,081</b>	<b>\$ 6,747</b>	<b>\$ 445,828</b>
Goodwill	\$ 102,490	\$ (6,747)	\$ 95,743
<b>Net assets acquired</b>	<b>\$ 541,571</b>	<b>\$</b>	<b>\$ 541,571</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 Acquisition Date to estimate the fair value of assets acquired and liabilities assumed. Measurement period adjustments reflect new information obtained about facts and circumstances that existed as of the Acquisition Date. The Company believes that information provides a reasonable basis for estimating the fair values of assets acquired and liabilities assumed but the Company is waiting for additional information necessary to finalize those fair values. Thus, the provisional measurements of fair value set forth above 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 Acquisition Date.

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

Of the \$588.9 million of acquired intangible assets, \$338.9 million was provisionally assigned to in-process research and development. The remaining \$250.0 million has been provisionally assigned to license rights and is subject to a provisional weighted average useful life of approximately 12 years.

**Table of Contents**

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™	\$ 72.0	n/a
Testosterone undecanoate	120.0	n/a
Octreotide Acromegaly	49.0	n/a
Octreotide Carcinoid Syndrome	9.0	n/a
Pagoclone	35.0	n/a
Pro 2000	29.0	n/a
Supprelin® LA	18.0	n/a
Other	6.9	n/a
Total	\$ 338.9	n/a
<b>License Rights:</b>		
Hydron® Polymer	\$ 31.0	17
Vantas®	21.0	6
Sanctura® Franchise	61.0	14
Supprelin® LA	136.0	10
Other	1.0	4
Total	\$ 250.0	12
Total other intangible assets	\$ 588.9	

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 pursuant to SFAS 157 (as codified in ASC 820). The relief from royalty method is based on a hypothetical royalty stream that would be received if the Company were to out-license the technology. The Hydron® Polymer Technology is currently used in the following products: Vantas®, Supprelin® LA and octreotide. Thus, we derived the hypothetical royalty income from the projected revenues of those drugs. The fair value of the Hydron® Polymer Technology also includes an existing royalty payable by the Company to the Population Council 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 15% 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 \$95.7 million of goodwill is currently assigned to our pharmaceutical products segment, which is our only reportable segment as of June 30, 2009. This assignment is subject to change as this business combination with Indevus could lead to additional reportable segments in the future. 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 \$165.4 million are related primarily to federal net operating loss carryforwards of Indevus and its subsidiaries. The deferred tax liabilities of \$233.4 million are related primarily to the difference between the book basis and tax basis of identifiable intangible assets. To the extent of any change to the provisional fair values of the intangible assets or other items, we would also expect to change the related deferred tax assets and liabilities that have been recorded at the Acquisition Date.





**Table of Contents**

During the three and six months ended June 30, 2009, we expensed \$35.0 million and \$61.4 million of acquisition-related costs, respectively. These costs are included in line item entitled Acquisition-related costs in the accompanying Condensed Consolidated Statements of Operations and are comprised of the following items (in thousands):

	Acquisition-related Costs	
	Three Months Ended June 30, 2009	February 23, 2009 to June 30, 2009
Investment bank fees, includes Endo and Indevus	\$	\$ 13,030
Accounting and legal	1,073	6,962
Separation costs	6,910	13,879
Other	1,110	1,627
	9,093	35,498
Changes in fair value of acquisition-related contingent consideration	25,930	25,930
<b>Total</b>	<b>\$ 35,023</b>	<b>\$ 61,428</b>

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

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

Net loss in the above table includes \$10.4 million of acquisition related costs for the three months ended June 30, 2009 and \$17.4 million of acquisition-related costs for the period from February 23, 2009 to June 30, 2009.

The following supplemental pro forma information presents the financial results as if the acquisition of Indevus had occurred January 1, 2009 for the three and six-months ended June 30, 2009 and on January 1, 2008 for the three and six-months ended June 30, 2008. 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 of Indevus been completed on January 1, 2008 or January 1, 2009, nor are they indicative of any future results.

Pro forma consolidated results (in thousands, except per share data):	Three Months Ended June 30, 2008	Six Months Ended June 30, 2009	2008
Revenue	\$ 322,475	\$ 718,708	\$ 627,685
Net income	\$ 29,013	\$ 46,066	\$ 49,927
Basic earnings per share	\$ 0.24	\$ 0.39	\$ 0.39
Diluted earnings per share	\$ 0.23	\$ 0.39	\$ 0.39

These amounts have been calculated after applying the Company's accounting policies and adjusting the results of Indevus to reflect a different revenue recognition model, the additional depreciation and amortization that would have been charged assuming the fair value adjustments to property, plant and equipment, intangible assets, unfavorable leases and current and long-term debt, had been applied on January 1, 2009 or 2008, as applicable, together with the consequential tax effects.

## Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - 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 and, are not reflected in the expected cash requirements for Contractual Obligations table below. In addition, under certain arrangements, we may be required to make royalty payments based on a percentage of

## Table of Contents

future sales of the products in the event regulatory approval for marketing is obtained. From a business perspective, we view these payments favorably as they signify that the products are moving successfully through the development phase toward commercialization. For a complete description of our contingent payments involving our license and collaboration agreements, see Note 6, and Note 10 of the Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

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.

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

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

**Convertible Senior Subordinated Notes due 2015.** As discussed in Note 12 to the Condensed Consolidated Financial Statements in Part I, Item 1 of this Report, in April 2008, we issued \$379.5 million in aggregate principal amount of 1.75% Convertible Senior Subordinated Notes due April 15, 2015 (the Convertible Notes) in a private offering for resale to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended.

We received proceeds of approximately \$370.7 million from the issuance, net of the initial purchaser's discount and certain other costs of the offering. Interest is payable semi-annually in arrears on each April 15 and October 15. 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 Convertible Notes. It is our current intention to settle the principal amount of any conversion consideration in cash.

**Non-recourse Notes.** As discussed in Note 12 to the Condensed Consolidated Financial Statements in Part I, Item 1 of this Report, on August 26, 2008, 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 provisionally recorded these notes at their fair value of approximately \$115.2 million. The Company will amortize these notes to their face value of \$105.0 million at maturity in 2024.

In connection with the issuance of the Non-recourse Notes, Indevus and Royalty Sub entered into a Purchase and Sale Agreement pursuant to which Indevus sold to Royalty Sub its rights to receive royalty payments from Allergan arising under the Allergan Agreement (as described in Note 6 of the Condensed Consolidated Financial Statements in Part I, Item 1 of this Report) for sales in the U.S. of Sanctura® 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.



**Table of Contents**

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. Approximately \$3.5 million of the interest reserve account remains and is classified as restricted cash in the Company's condensed consolidated balance sheet as of June 30, 2009. Royalty Sub will receive directly all royalties payable to the Company until the Non-recourse Notes have been repaid in full.

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

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

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

**Expected Cash Requirements for Contractual Obligations.** The following table presents our expected cash requirements for contractual obligations for each of the following years subsequent to December 31, 2008 (in thousands):

Contractual Obligations	Total	2009	Payment Due by Period				Thereafter
			2010	2011	2012	2013	
Operating Lease Obligations	\$ 40,305	\$ 9,779	\$ 7,625	\$ 5,044	\$ 4,284	\$ 4,318	\$ 9,255
Convertible Senior Subordinated Notes	379,500						379,500
Interest payments on Convertible Senior Subordinated Notes	41,783	6,641	6,641	6,641	6,641	6,641	8,578
Convertible Notes	71,925	71,925					
Interest on Convertible Notes	1,311	1,311					
Non-recourse Notes	105,000						105,000
Interest on Non-recourse Notes	261,800	12,600	16,800	16,800	16,800	16,800	182,000
Minimum Purchase Commitments to Novartis	61,000	20,000	20,000	21,000			
Minimum Royalty Obligation Due to Hind	1,500	500	500	500			
Minimum Purchase Commitments to Teikoku(1)	128,000	32,000	32,000	32,000	32,000		
Limited Partnership Commitment(2)	2,000	2,000					
Minimum Voltaren® Royalty Obligations Due to Novartis AG (3)	60,000			15,000	30,000	15,000	
Minimum advertising and promotion spend(4)	25,625	15,625	10,000				
Other Commitments(5)	5,661	2,305	1,525	1,739	92		



**Table of Contents**

Contractual Obligations	Total	2009	Payment Due by Period				
			2010	2011	2012	2013	Thereafter
Shire Minimum Payments(6)	2,875		1,375	1,500			
Total	\$ 1,188,285	\$ 174,686	\$ 96,466	\$ 100,224	\$ 89,817	\$ 42,759	\$ 684,333

- (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) On December 12, 2003, we entered into a subscription agreement to invest up to \$10 million into Life Sciences Opportunities Fund (Institutional) II, L.P., a Delaware limited partnership formed to carry out investments in life science companies. During the year ended December 31, 2007, we invested \$5.3 million in this partnership, bringing our cumulative cash investment to \$8.0 million as of December 31, 2008 leaving a commitment balance of \$2.0 million. In February 2009, we invested an additional \$1.25 million in this partnership. We are accounting for this investment utilizing the equity method.
- (3) Under the terms of the five-year Voltaren® Gel Agreement, Endo made an up-front cash payment of \$85 million to Novartis AG. Endo has agreed to pay royalties to Novartis AG on annual net sales of the licensed product, subject to certain thresholds all as defined in the 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 and (ii) the guaranteed minimum royalty for such Agreement year.
- (4) 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 to be determined based on a percentage of net sales of the licensed product.
- (5) Included in this balance is our fixed obligation payable to Ventiv during the first twelve months of detailing under the Ventiv Agreement, as well as ongoing funding for research related to an agreement with Harvard University and Aurigene Discovery Technologies Limited.
- (6) 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 by Indevus 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 remaining payments to be made to Shire consist of \$1.4 million payable in January 2010 and \$1.5 million payable in January 2011.

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.

On January 1, 2007, we adopted FIN 48 and recorded a \$7.7 million non-current liability representing the Company's unrecognized tax benefits with respect to our uncertain tax positions. As of June 30, 2009, our liability for unrecognized tax benefits amounted to \$27.7 million (including interest and penalties). Due to the nature and timing of

## **Table of Contents**

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 FIN 48 liability has been excluded from the above contractual obligations table. It is expected that the amount of unrecognized tax benefits will change during the next twelve months; however, the Company does not anticipate any adjustments that would lead to a material impact on our results of operations, cash flows, or financial position.

**Fluctuations.** Our quarterly results have fluctuated in the past, and may continue to fluctuate. These fluctuations may be to the timing of new product launches, purchasing patterns of our customers, market acceptance of our products, the impact of competitive products and pricing, impairment of intangible assets, separation benefits, business combination transaction costs, upfront, milestone and certain other payments made or accrued pursuant to licensing agreements and changes in the fair value of financial instruments and contingent assets and liabilities recorded as part of a business combination. Further, a substantial portion of our net sales are through three wholesale drug distributors who in turn supply our products to pharmacies, hospitals and physicians. Accordingly, we are potentially subject to a concentration of credit risk with respect to our trade receivables.

**Growth Opportunities.** We continue to evaluate growth opportunities including strategic investments, licensing arrangements, acquisitions of businesses, product rights or technologies, and strategic alliances and promotional arrangements which could require significant capital resources. We intend to continue to focus our business development activities on further diversifying our revenue base through product licensing and company acquisitions, as well as other opportunities to enhance stockholder value. Through execution of our business strategy we intend to focus on developing new products through both an internal and a virtual research and development organization with greater scientific and clinical capabilities; expanding the Company's product line by acquiring new products and technologies in existing therapeutic and complementary areas; increasing revenues and earnings through sales and marketing programs for our innovative product offerings and effectively using the Company's resources; and providing additional resources to support our generics business.

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

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

**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, 2008, filed with the Securities and Exchange Commission on March 2, 2009.

## **RECENT ACCOUNTING PRONOUNCEMENTS**

### *Recently Adopted Accounting Pronouncements*

In September 2006, the Financial Accounting Standards Board (FASB or the Board) issued SFAS No.157, *Fair Value Measurements* (SFAS 157), as codified in FASB ASC topic 820, *Fair Value Measurements and Disclosures* (ASC 820), which addresses how companies should measure fair value when they are required to use a fair value measure for recognition or disclosure purposes under accounting principles generally accepted in the United States. SFAS 157 is effective for fiscal years beginning after November 15, 2007. In February 2008, the FASB issued FASB Staff Position No. 157-2, *Effective Date of FASB Statement No. 157* (FSP 157-2), as codified in ASC 820. FSP 157-2 delayed the effective date of SFAS 157 for certain non-financial assets and non-financial liabilities to fiscal years beginning after November 15, 2008. SFAS 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined under SFAS 157 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value under SFAS 157 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

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





## **Table of Contents**

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.

On January 1, 2008, the Company adopted SFAS 157 for financial assets and liabilities. The adoption of SFAS 157 for financial assets and liabilities did not have a material impact on the Company's consolidated results of operations and financial condition. On January 1, 2009, the Company adopted SFAS 157 for non-financial assets and non-financial liabilities. The adoption of SFAS 157 for non-financial assets and non-financial liabilities did not have a material impact on the Company's consolidated results of operations and financial condition.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159), as codified in FASB ASC topic 825, *Financial Instruments* (ASC 825), providing companies with an option to report selected financial assets and liabilities at fair value. This Standard's objective is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. Generally accepted accounting principles have required different measurement attributes for different assets and liabilities that can create artificial volatility in earnings. SFAS 159 helps to mitigate this type of accounting-induced volatility by enabling companies to report related assets and liabilities at fair value, which would likely reduce the need for companies to comply with detailed rules for hedge accounting. SFAS 159 also established presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. This Standard requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of the Company's choice to use fair value on its earnings. It also requires entities to display the fair value of those assets and liabilities for which the Company has chosen to use fair value on the face of the balance sheet. SFAS 159 became effective for fiscal years beginning after November 15, 2007. Upon adoption, we chose not to elect the fair value option for our existing financial assets and liabilities. Therefore, adoption of SFAS 159 did not have any impact on our consolidated financial statements. In November 2008, simultaneously with our execution of the agreement with UBS with respect to certain auction rate securities in UBS accounts, we elected the fair value option for the auction-rate securities rights (See Note 3 of the Condensed Consolidated Financial Statements in Part I, Item 1 of this Report).

On September 12, 2008, the FASB issued FASB Staff Position SFAS 133-1 and FIN 45-4, *Disclosures about Credit Derivatives and Certain Guarantees: An Amendment of FASB Statement No. 133 and FASB Interpretation No. 45; and Clarification of the Effective Date of FASB Statement No. 161* (FSP SFAS 133-1 and FIN 45-4), as codified in FASB ASC topic 815, *Derivatives and Hedging* (ASC 815) and ASC topic 460, *Guarantees* (ASC 460), respectively. FSP SFAS 133-1 and FIN 45-4 requires disclosures by sellers of credit derivatives and amends FASB Interpretation No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness to Others*, to require an additional disclosure about the current status of the payment or performance of a guarantee. FSP SFAS 133-1 and FIN 45-4 became effective for the first interim or annual reporting period that ends after November 15, 2008. We adopted FSP SFAS 133-1 and FIN 45-4 in November 2008. The adoption of FSP SFAS 133-1 and FIN 45-4 did not have a material effect on the Company's consolidated results of operations, financial condition, or required financial statement disclosures.

In October 2008, the FASB issued FASB Staff Position SFAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active* (FSP SFAS 157-3), as codified in ASC 820. FSP SFAS 157-3 clarifies the application of SFAS 157 when determining the fair value of a financial asset when the market for that asset is not currently active. FSP SFAS 157-3 emphasizes that approaches other than the market approach to determining fair value may be appropriate when it is determined that, as a result of market inactivity, other valuation approaches are more representative of fair value. Other valuation approaches can involve significant assumptions regarding future cash flows. FSP SFAS 157-3 clarifies that these assumptions must incorporate adjustments for nonperformance and liquidity risks that market participants would consider in valuing the asset in an inactive market. FSP SFAS 157-3 emphasizes the existing disclosure requirements under SFAS 157 regarding significant unobservable inputs (Level 3 inputs). FSP SFAS 157-3 became effective on October 10, 2008, including with respect to prior periods for which financial statements have not been issued. The Company has adopted FSP SFAS 157-3 beginning with the quarterly period ended September 30, 2008. See Note 3 of the Condensed Consolidated Financial Statements in Part I, Item 1 of this Report for a further discussion of fair value.

## **Table of Contents**

On December 11, 2008 the FASB issued FASB Staff Position SFAS 140-4 and FIN 46(R)-8, *Disclosures by Public Entities (Enterprises) about Transfers of Financial Assets and Interests in Variable Interest Entities* (FSP SFAS 140-4 and FIN 46(R)-8), as codified in FASB ASC topic 860, *Transfers and Servicing* (ASC 860). FSP SFAS 140-4 and FIN 46(R)-8 requires additional disclosures by public entities with continuing involvement in transfers of financial assets to special purpose entities and with variable interests in variable interest entities (VIEs), including sponsors that have a variable interest in a VIE. FSP SFAS 140-4 and FIN 46(R)-8 became effective for the first interim or annual reporting period that ends after December 15, 2008. We adopted FSP SFAS 140-4 and FIN 46(R)-8 in December 2008. The adoption of FSP SFAS 140-4 and FIN 46(R)-8 did not have a material effect on the Company's consolidated results of operations, financial condition, or required financial statement disclosures.

In November 2007, the Emerging Issues Task Force of the FASB issued a consensus on Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1), as codified in FASB ASC topic 808, *Collaborative Arrangements* (ASC 808). The scope of EITF 07-1 is limited to collaborative arrangements where no separate legal entity exists and in which the parties are active participants and are exposed to significant risks and rewards that depend on the success of the activity. The Task Force concluded that revenue transactions with third parties and associated costs incurred should be reported in the appropriate line item in each company's financial statements pursuant to the guidance in EITF 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*, as codified in FASB ASC subtopic 605-45, *Revenue Recognition: Principal Agent Considerations* (ASC 605-45). The Task Force also concluded that the equity method of accounting under Accounting Principles Board Opinion 18, *The Equity Method of Accounting for Investments in Common Stock*, as codified primarily in FASB ASC topic 323, *Investments: Equity Method and Joint Ventures* (ASC 323) and topic 325, *Investments: Investments - Other* (ASC 325), should not be applied to arrangements that are not conducted through a separate legal entity. The Task Force also concluded that the income statement classification of payments made between the parties in an arrangement should be based on a consideration of the following factors: the nature and terms of the arrangement; the nature of the entities' operations; and whether the partners' payments are within the scope of existing GAAP. To the extent such costs are not within the scope of other authoritative accounting literature, the income statement characterization for the payments should be based on an analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. The provisions of EITF 07-1, became effective for fiscal years beginning on or after December 15, 2008, and companies are required to apply the provisions through retrospective application to all collaborative arrangements existing at adoption as a change in accounting principle. If it is impracticable to apply the consensus to a specific arrangement, disclosure is required regarding the reason why retrospective application is not practicable and the effect of reclassification on the current period. We have adopted EITF 07-1 as of January 1, 2009. The adoption of EITF 07-1 did not have a material effect on the Company's consolidated results of operations, financial condition or cash flows.

In December 2007, the FASB issued SFAS No. 141(R) *Business Combinations* (SFAS 141(R)), as codified in FASB ASC topic 805, *Business Combinations* (ASC 805) and SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51* (SFAS 160), as codified in FASB ASC topic 810, *Consolidation* (ASC 810). SFAS 141(R) changes how business acquisitions are accounted for and impacts financial statements both on the acquisition date and in subsequent periods. SFAS 160 changes the accounting and reporting for minority interests, which are recharacterized as noncontrolling interests and classified as a component of equity. SFAS 141(R) and SFAS 160 were required to be adopted concurrently and became effective for fiscal years, beginning on or after December 15, 2008. We have adopted SFAS 141(R) and SFAS 160 as of January 1, 2009. The adoption of SFAS 141(R) had a material impact on the accounting for our merger with Indevus in February of 2009. See Note 5 of the Condensed Consolidated Financial Statements in Part I, Item 1 of this Report for further discussion. The adoption of SFAS 160 did not have a material effect on the Company's consolidated results of operations, financial condition or cash flows.

In April 2009, the FASB issued FASB Staff Position FAS 141(R)-1, *Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies* (FSP SFAS 141(R)-1), as codified in ASC 805, which amended the provisions related to the initial recognition and measurement, subsequent measurement and disclosure of assets and liabilities arising from contingencies in a business combination under SFAS 141(R). The requirements in SFAS 141 for acquired contingencies were carried forward and require that such contingencies be recognized at fair value on the acquisition date if fair value can be reasonably estimated during the allocation period. Otherwise, companies will typically account for the acquired contingencies in accordance with Statement of Financial Accounting Standards No. 5, *Accounting for Contingencies* (SFAS 5), as codified primarily in FASB ASC topic 450, *Contingencies* (ASC 450). FSP SFAS 141(R)-1 became effective for fiscal years, beginning on or after December 15, 2008. We have adopted FSP SFAS 141(R)-1 as of January 1, 2009. See Note 5 of the Condensed Consolidated Financial Statements in Part I, Item 1 of this Report for further discussion.

In April 2008, the FASB issued FASB Staff Position No. 142-3, *Determination of the Useful Life of Intangible Assets* (FSP 142-3) as codified in FASB ASC subtopic 350-30, *Intangibles - Goodwill and Other: General Intangibles Other than Goodwill* (ASC 350-30) and topic 275, *Risks and Uncertainties* (ASC 275), which amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized



## **Table of Contents**

intangible asset under SFAS No. 142, *Goodwill and Other Intangible Assets*, as codified in FASB ASC topic 350, *Intangibles Goodwill and Other* (ASC 350). This pronouncement requires enhanced disclosures concerning a company's treatment of costs incurred to renew or extend the term of a recognized intangible asset. FSP 142-3 became effective for financial statements issued for fiscal years beginning after December 15, 2008. We have adopted FSP 142-3 as of January 1, 2009. The adoption of FSP 142-3 did not have a material impact on our consolidated financial statements.

In May 2008, the FASB issued FASB Staff Position APB 14-1, *Accounting for Convertible Debt Instruments That May be Settled in Cash upon Conversion (Including Partial Cash Settlement)* (FSP APB 14-1), as codified in ASC 470-20. FSP APB 14-1 requires that issuers of convertible debt instruments that may be settled in cash or other assets on conversion to separately account for the liability and equity components of the instrument in a manner that will reflect the entity's nonconvertible debt borrowing rate on the instrument's issuance date when interest cost is recognized in subsequent periods. Our Convertible Notes are within the scope of FSP APB 14-1. Therefore, we 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 FSP APB 14-1 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. We have adopted FSP APB 14-1 as of January 1, 2009. The adoption of FSP APB 14-1 will result in the recognition of approximately \$138.7 million of additional interest expense, on a pre-tax basis, over the life of our Convertible Notes. See Note 12 of the Condensed Consolidated Financial Statements in Part I, Item 1 of this Report for further details.

In June 2008, the FASB issued FASB Staff Position EITF 03-6-1, *Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities* (FSP EITF 03-6-1), as codified in FASB ASC topic 260, *Earnings per Share* (ASC 260). FSP EITF 03-6-1 addresses whether instruments granted in share-based payment transactions are participating securities prior to vesting, and therefore need to be included in the computation of earnings per share under the two-class method as described in FASB Statement of Financial Accounting Standards No. 128, *Earnings per Share*, as codified in ASC 260. FSP EITF 03-6-1 is effective for financial statements issued for fiscal years beginning on or after December 15, 2008 and earlier adoption is prohibited. We have adopted FSP EITF 03-6-1 as of January 1, 2009. The adoption of FSP EITF 03-6-1 did not have a material effect on our results of operations or financial position.

In June 2008, the EITF of the FASB ratified the consensus reached in EITF Issue No. 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock* (EITF 07-5), as codified in FASB ASC subtopic 815-40, *Derivatives and Hedging: Contracts in Entity's Own Equity* (ASC 815-40). EITF 07-5 was issued to clarify how to determine whether certain instruments or features are indexed to an entity's own stock under EITF Issue No. 01-6, *The Meaning of Indexed to a Company's Own Stock* (EITF 01-6), also codified in ASC 815-40. The consensus in EITF 07-5 applies to any freestanding financial instrument or embedded feature that has the characteristics of a derivative as defined in FASB Statement No. 133, *Accounting for Derivative Instruments and Hedging Activities* (SFAS 133), as codified in FASB ASC topic 815, *Derivatives and Hedging* (ASC 815). The consensus in EITF 07-5 supersedes EITF 01-6 and became effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. We adopted EITF 07-5 as of January 1, 2009. The adoption of EITF 07-5 did not have a material effect on the Company's consolidated results of operations or financial condition.

In November 2008, the EITF of the FASB ratified the consensus reached in EITF Issue No. 08-6, *Equity Method Accounting Considerations* (EITF 08-6), as codified in ASC 323. The application of the equity method is affected by the accounting for business combinations under SFAS 141(R) and the accounting for consolidated subsidiaries under SFAS 160. Therefore, the objective of EITF 08-6 is to clarify how to account for certain transactions and impairment considerations involving equity method investments. EITF 08-6 became effective for fiscal years beginning on or after December 15, 2008, and interim periods within those fiscal years, consistent with the effective dates of Statement 141(R) and Statement 160. EITF 08-6 is to be applied prospectively. We adopted EITF 08-6 as of January 1, 2009. The adoption of EITF 08-6 did not have a material effect on the Company's consolidated results of operations or financial condition.

In November 2008, the EITF of the FASB ratified the consensus reached in EITF Issue No. 08-7, *Accounting for Defensive Intangible Assets* (EITF 08-7), as codified in the FASB ASC topic 350, subtopic 30 (ASC 350-30). While the guidance in SFAS 141(R) governs initial recognition and measurement of defensive intangible assets, EITF 08-7 was issued to clarify how defensive intangible assets acquired in a business combination or an asset acquisition should be accounted for subsequent to their acquisition. A defensive intangible asset is defined as an intangible asset acquired in a business combination or asset acquisition that an entity does not intend to actively use but intends to prevent others from using. EITF 08-7 requires a defensive intangible asset to be accounted for as a separate unit of accounting and assigned a useful life in accordance with SFAS 142, as codified in ASC 350. EITF 08-7 became effective for intangible assets acquired on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. We adopted EITF 08-7 as of January 1, 2009. The adoption of EITF 08-7 did not have a material effect on the Company's consolidated results of operations or financial condition.



## **Table of Contents**

In April 2009, the FASB issued FSP No. SFAS 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Has Significantly Decreased and Identifying Transactions That Are Not Orderly* (FSP SFAS 157-4), as codified in ASC 820. FSP SFAS 157-4 amends SFAS 157 and provides additional guidance for estimating fair value in accordance with SFAS 157 when the volume and level of activity for the asset and liability have significantly decreased in relation to normal market activity for the asset or liability. FSP SFAS 157-4 also provides guidance on identifying circumstances that indicate a transaction is not orderly. FSP SFAS 157-4 is effective for interim and annual periods ending after June 15, 2009. We adopted FSP SFAS 157-4 beginning with the quarterly period ended June 30, 2009. The adoption of FSP SFAS 157-4 did not have a material effect on the Company's consolidated results of operations or financial condition.

In April 2009, the FASB issued FSP No. SFAS 115-2 and SFAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments* (FSP SFAS 115-2) as codified in FASB ASC topic 320, *Investments—Debt and Equity Securities* (ASC 320). FSP SFAS 115-2 amends SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, as codified in ASC 320 and FSP No. FAS 115-1 and FAS 124-1, *The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments*, as codified in FASB ASC 320. FSP SFAS 115-2 provides additional guidance to make other-than-temporary impairments more operational and to improve the financial statement presentation of such impairments. FSP SFAS 115-2 is effective for interim and annual periods ending after June 15, 2009. We adopted FSP SFAS 115-2 beginning with the quarterly period ended June 30, 2009. The adoption of FSP SFAS 115-2 did not have a material effect on the Company's consolidated results of operations or financial condition.

In April 2009, the FASB issued FSP No. SFAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments* (FSP SFAS 107-1), as codified in ASC 825. FSP SFAS 107-1 amends SFAS No. 107, *Disclosures about Fair Value of Financial Instruments*, and APB Opinion No. 28, *Interim Financial Reporting*, by requiring disclosures with respect to the fair value of financial instruments in interim and annual financial statements. FSP SFAS 107-1 is effective for interim and annual periods ending after June 15, 2009. We adopted FSP SFAS 107-1 beginning with the quarterly period ended June 30, 2009. The adoption of FSP SFAS 107-1 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 of the Condensed Consolidated Financial Statements in Part I, Item 1 of this Report for further discussion.

### *Accounting Pronouncements Issued But Not Yet Adopted*

In June 2009, the FASB issued SFAS No. 167, *Amendments to FASB Interpretation No. 46(R)* (SFAS 167), as codified in ASC 810. SFAS 167 amends FIN 46(R), *Consolidation of Variable Interest Entities (revised December 2003) – an interpretation of ARB No. 51 (FIN 46(R))* by replacing the quantitative-based risks and rewards calculation for determining which enterprise, if any, has a controlling financial interest in a variable interest entity with a primarily qualitative approach focused on identifying which enterprise has the power to direct the activities of a variable interest entity that most significantly impact the entity's economic performance and (1) the obligation to absorb losses of the entity or (2) the right to receive benefits from the entity. SFAS 167 requires an additional reconsideration event when determining whether an entity is a variable interest entity when any changes in facts and circumstances occur such that the holders of the equity investment at risk, as a group, lose the power from voting rights or similar rights of those investments to direct the activities of the entity that most significantly impact the entity's economic performance. It also requires ongoing assessments of whether an enterprise is the primary beneficiary of a variable interest entity. SFAS 167 also requires additional disclosures about an enterprise's involvement in variable interest entities. SFAS 167 nullifies FSP SFAS 140-4 and FIN 46(R)-8. However, the content of the enhanced disclosures required by SFAS 167 is generally consistent with that previously required by the FSP. SFAS 167 is effective as of the beginning of each reporting entity's first annual reporting period that begins after November 15, 2009, for interim periods within that first annual reporting period, and for interim and annual reporting periods thereafter. Earlier application is prohibited. The Company is currently evaluating the impact of adopting SFAS 167 on our consolidated results of operations and financial position.

### **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, 2008, filed with the Securities and Exchange Commission on March 2, 2009. Our exposures to market risk have not changed materially since December 31, 2008.

## **Table of Contents**

### **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 the end of the period covered by this report. 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 the end of the period covered by this report.

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

There were no changes in the Company's internal control over financial reporting during the second quarter of 2009 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting. Notwithstanding the foregoing, we recently announced the appointment of Alan G. Levin as the Company's Executive Vice President and Chief Financial Officer.

## **PART II**

### **OTHER INFORMATION**

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

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

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

The risk factors listed below are included for the purposes of updating 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, 2008 filed with the SEC on March 2, 2009. Other than these new risk factors resulting from our acquisition of Indevus, there have been no material changes from the risk factors disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2008.

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

The Food and Drug Administration (FDA) held a public advisory committee meeting in June 2009 to discuss acetaminophen use in both over-the-counter (OTC) and prescription (Rx) products, the potential for liver injury, and potential interventions to reduce the incidence of liver injury. The panel's recommendations followed the release in May 2009 of an 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®. 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 consolidated results of operations and cash flows.

### ***We are dependent upon the ability of Allergan to perform its obligations with respect to sales of Sanctura® and Sanctura XR®.***

Two of our products Sanctura® and Sanctura XR® are treatments for overactive bladder, which we co-promote with our marketing partner, Allergan. Under the terms of our agreement with Allergan, Allergan is responsible for all U.S. marketing and sales activities relating to Sanctura® and Sanctura XR®, and Allergan is obligated to pay royalties





## **Table of Contents**

based on net sales of Sanctura® and Sanctura XR®. Our right to co-promote Sanctura and Sanctura XR® expires in September 2009. Accordingly, we are, and will continue to be, highly dependent on Allergan for the commercialization and marketing of Sanctura® and Sanctura XR® in the U.S. and for performance by Allergan of its obligations under the Allergan Agreement. If Allergan does not devote sufficient resources to effectively market Sanctura® and Sanctura XR®, or if Allergan fails to perform its obligations under the Allergan Agreement, including the payment of royalties, such failure could materially adversely affect our business and results of operations.

***Allergan's failure to successfully market and commercialize Sanctura® and Sanctura XR® may delay repayment of the Non-recourse Notes, and delay or prevent our receipt of future revenue from sales of Sanctura® and Sanctura XR®.***

Royalty payments in respect of net sales of Sanctura® and Sanctura XR® in the U.S. are entirely dependent on the actions, efforts and success of Allergan, over whom neither we nor our subsidiary Ledgemont Royalty Sub LLC, have control. Neither we nor our subsidiary, Ledgemont Royalty Sub LLC, can ensure that Allergan effectively maximizes the potential sales of Sanctura® and Sanctura XR®. We will receive no revenue from sales of Sanctura® and Sanctura XR® unless and until our subsidiary, Ledgemont Royalty Sub LLC, repays the Non-recourse Notes in full. If Ledgemont Royalty Sub LLC takes longer than anticipated to repay the Non-recourse Notes, or if it defaults on the Non-recourse Notes, in each case due to lower sales of Sanctura® and Sanctura XR® by Allergan, we may not receive future revenue from Sanctura® and Sanctura XR® as currently planned, or at all.

***Royalties under the Allergan Agreement may not be sufficient for our subsidiary to meet its payment obligations under the Non-recourse Notes.***

In August 2008, Indevus transferred to its wholly-owned subsidiary, Ledgemont Royalty Sub LLC, all of its rights under the Allergan Agreement. Ledgemont Royalty Sub LLC issued \$105.0 million in aggregate principal amount of Non-recourse Notes, which were secured by the assets of Ledgemont Royalty Sub LLC, including the rights to receive royalty payments from Allergan relating to future sales of Sanctura® and Sanctura XR® in the U.S. under the Allergan Agreement.

Ledgemont Royalty Sub LLC is entitled to receive certain minimum royalties under the Allergan Agreement, however, such minimum royalties may not be sufficient for Ledgemont Royalty Sub LLC to meet its payment obligations under the Non-recourse Notes. If Allergan is not successful in its sales and marketing efforts with respect to Sanctura® and Sanctura XR®, and royalties paid by Allergan to Ledgemont Royalty Sub LLC are not in excess of these minimum amounts, Ledgemont Royalty Sub LLC may not be able to meet its payment obligations under the Non-recourse Notes. In addition, Allergan's obligation to pay minimum royalties may be reduced, suspended or eliminated following certain adverse events pertaining to regulatory non-compliance, generic competition, lack of product supply and other events. Any such reduction, suspension or elimination of royalties could result in Ledgemont Royalty Sub LLC receiving significantly reduced or no royalties under the Allergan Agreement, in which case, Ledgemont Royalty Sub LLC may not be able to meet its payment obligations under the Non-recourse Notes.

An event of default under the Non-recourse Notes will occur if Ledgemont Royalty Sub LLC is unable to meet its interest payment obligations under the Non-recourse Notes from royalty payments received from Allergan, unless any interest payment shortfalls are satisfied in accordance with the terms of the indenture governing the Non-recourse Notes. An interest payment shortfall may be satisfied by capital contributions from the Company, however this right may not be exercised more than six times over the life of the Non-recourse Notes and no more than three consecutive times. In the event the Company is no longer permitted to make capital contributions to Ledgemont Royalty Sub LLC to satisfy interest payment shortfalls and the Company does not redeem the Non-recourse Notes, an event of default under the indenture governing the Non-recourse Notes will occur.

Upon the occurrence of an event of default under the indenture, the noteholders will have the right to accelerate the obligations of Ledgemont Royalty Sub LLC to pay amounts outstanding under the Non-recourse Notes and may exercise their remedies under the indenture, including assuming all rights to future payments from Allergan. The loss of our right to receive royalties from Allergan under the Allergan Agreement could materially adversely affect our business and results of operations.

***In certain circumstances, we may lose the potential to receive future royalty payments after the Non-recourse Notes are repaid in full or we may be required to pay damages for breaches of representations, warranties or covenants under certain of the Non-recourse Note financing agreements.***

In connection with the transfer of rights under the Allergan Agreement from Indevus to Ledgemont Royalty Sub LLC and the issuance of the Non-recourse Notes, Indevus made certain representations, warranties and covenants to Ledgemont Royalty Sub LLC, and Ledgemont Royalty Sub LLC made certain representations, warranties and covenants to the holders of the Non-recourse Notes. If there is a breach of these representations, warranties or covenants, such breach could trigger an event of default under the indenture governing the Non-recourse Notes.

Upon the occurrence of an event of default under the indenture, the noteholders will have the right to accelerate the

## **Table of Contents**

obligations of Ledgemont Royalty Sub LLC to pay amounts outstanding under the Non-recourse Notes and may exercise their remedies under the indenture, including assuming all rights to future payments from Allergan. The loss of our right to receive royalties from Allergan under the Allergan Agreement could materially adversely affect our business and results of operations.

***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 our products outside of the U.S. For example, we have agreements to license Vantas® in Canada, South Africa, Asia and Argentina. 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 our Annual Report on Form 10-K for the year ended December 31, 2008, 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® for marketing in the European Union and certain other foreign jurisdictions, we may not be able to file for regulatory approvals and 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.

***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 by its licensee, American Home Products Corporation, now Wyeth, in June 1996. 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 have had, and may in the future have, an adverse effect on the market price of our common stock and on our ability to obtain corporate collaborations or additional financing to satisfy cash requirements, to retain and attract qualified personnel, to develop and commercialize products on a timely and adequate basis, to acquire rights to additional products, and to obtain product liability insurance for other products at costs acceptable to us, or at all, any or all of 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 elected not to stay in the American Home Products national class action settlement of diet drug litigation and by those claimants who allege primary pulmonary hypertension, a serious disease involving the blood vessels in the lungs. 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., the manufacturer of 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.

## **Table of Contents**

*There are risks associated with our recent acquisition of Indevus Pharmaceuticals, Inc., including but not limited to our ability to integrate the business into ours.*

We are in the process of integrating the business and former employees of Indevus with Endo's previously existing business and employees. These transition and integration activities are complex and the Company may encounter unexpected difficulties or incur unexpected costs including:

the diversion of management's attention to integration matters;

difficulties in achieving expected synergies associated with the Indevus acquisition;

difficulties in the integration of operations and systems;

difficulties in the assimilation of employees; and

challenges in attracting and retaining key personnel.

As a result, the Company may not be able to realize the expected revenue growth and other benefits that it hopes to achieve from the Indevus acquisition. In addition, Endo may be required to spend additional time or money on integration that would otherwise be spent on the development and expansion of its business and services.

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

None.

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

None.

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

- (a) The Company's 2009 Annual Meeting of Stockholders was held on May 27, 2009.
- (b) The stockholders elected all of the Company's nominees for director. The stockholders also approved (1) an amendment to the Company's 2007 Stock Incentive Plan to add a number of additional performance goals to which performance-based awards may relate and (2) the appointment of Deloitte & Touche LLP as the Company's independent registered public accounting firm for 2009.
  - (1) *Election of Directors:*

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

	For	Withheld
John J. Delucca	109,111,496	2,937,243
David P. Holveck	109,379,711	2,669,028
Nancy J. Hutson, Ph.D.	109,415,550	2,633,189
Michael Hyatt	107,903,469	4,145,270
Roger H. Kimmel	109,415,437	2,633,302
Clive A. Meanwell, M.D., Ph.D.	67,343,320	44,705,419
William P. Montague	109,417,851	2,630,888
Joseph C. Scodari.	109,417,851	2,729,089
William F. Spengler.	109,314,237	2,734,502

- (2) *Approval of the amendment to the Company's 2007 Stock Incentive Plan to add a number of additional performance goals to which performance-based awards may relate*

For	98,375,037
Against	3,598,040
Abstained	1,561,308

- (3) *Approval of Appointment of Deloitte & Touche LLP*

For	109,988,538
Against	630,669
Abstained	1,429,531

**Table of Contents**

The foregoing matters are described in detail in the Company's definitive proxy statement dated April 29, 2009, relating to the Annual Meeting of Stockholders held on May 27, 2009.

**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.

**Table of Contents**

**SIGNATURES**

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

ENDO PHARMACEUTICALS HOLDINGS INC.  
(Registrant)

/s/ DAVID P. HOLVECK

Name: David P Holveck

Title: *President and Chief Executive Officer*

*(Principal Executive Officer)*

/s/ ALAN G. LEVIN

Name: Alan G. Levin

Title: *Executive Vice President, Chief Financial Officer*

*(Principal Financial Officer)*

Date: July 30, 2009



**Table of Contents**

**Exhibit Index**

<b>Exhibit No.</b>	<b>Title</b>
3.1	Amended and Restated Certificate of Incorporation of Endo Pharmaceuticals Holdings Inc. ( Endo ) (incorporated herein by reference to Exhibit 10.32 of the Form 10-Q for the Quarter ended June 30, 2008 filed with the Commission on August 1, 2008)
3.2	Amended and Restated By-laws of Endo (incorporated herein by reference to Exhibit 3.2 of the Form 10-Q for the Quarter ended March 31, 2008 filed with the Commission on May 2, 2008)
4.1	Amended and Restated Executive Stockholders Agreement, dated as of July 7, 2003, by and among Endo, Endo Pharma LLC ( Endo LLC ), Kelso Investment Associates V, L.P. ( KIA V ), Kelso Equity Partners V, L.P. ( KEP V ) and the Management Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.1 of the Form 10-Q for the Quarter ended June 30, 2003 filed with the Commission on August 14, 2003)
4.1.2	Amendment to Amended and Restated Executive Stockholders Agreement, dated as of June 28, 2004, by and among Endo, Endo LLC, KIA V, KEP V and the Management Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.1 of the Form 10-Q for the Quarter ended September 30, 2004 filed with the Commission on November 5, 2004) the Commission on July 1, 2003)
4.1.3	Amendment 2 to the Amended and Restated Stockholders Agreement, dated September 20, 2005, by and among the Company, Endo LLC, Kelso and certain Amending Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.1.3 of the Current Report on Form 8-K filed with the Commission on September 22, 2005)
4.2	Amended and Restated Employee Stockholders Agreement, dated as of June 5, 2003, by and among Endo, Endo LLC, KIA V, KEP V and the Employee Stockholders (as defined therein) (incorporated herein by reference to Exhibit 10.2 of Amendment No. 2 to the Form S-3 Registration Statement (Registration No. 333-105338) filed with the Commission on July 1, 2003)
4.2.2	Amendment to Amended and Restated Employee Stockholders Agreement, dated as of June 28, 2004, by and among Endo, Endo LLC, KIA V, KEPV and the Management Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.1 of the Form 10-Q for the Quarter ended September 30, 2004 filed with the Commission on November 5, 2004)
4.2.3	Amendment 2 to the Amended and Restated Employee Stockholders Agreement, dated September 20, 2005, by and among the Company, Endo LLC, Kelso and certain Amending Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.2.3 of the Current Report on Form 8-K filed with the Commission on September 22, 2005)
4.3	Employee Stockholders Consent and Release, effective September 20, 2005, by and among the Company, Endo LLC, Kelso and certain Employee Stockholders (as defined therein) signatory thereto (incorporated herein by reference to Exhibit 4.3 of the Current Report on Form 8-K filed with the Commission on September 22, 2005)
4.4	Registration Rights Agreement, dated as of July 17, 2000, by and between Endo and Endo LLC (incorporated herein by reference to Exhibit 4.4 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
4.5	Amendment to Registration Rights Agreement, dated as of June 30, 2003, by and between Endo and Endo LLC (incorporated herein by reference to Exhibit 10.1 of Amendment No. 2 to the Form S-3 Registration Statement (Registration No. 333-105338) filed with the Commission on July 1, 2003)
4.8	Indenture dated as of August 6, 2007 between Indevus and The Bank of New York Trust Company, N.A, as trustee (incorporated herein by reference to Exhibit 4.1 of the Indevus Current Report on Form 8-K filed with the Commission on August 7, 2007)
4.8.1	Supplemental Indenture, dated as of March 23, 2009, by and between Indevus and the The Bank of New York Mellon Trust Company, N.A. (formerly known as The Bank of New York Trust Company, N.A.) (incorporated herein by reference to Exhibit 10.1 to the Indevus Current Report on Form 8-K, dated March 23, 2009)
10.1	Shelf Registration Agreement, dated September 21, 2005, by and between Endo, Endo LLC and certain Management Stockholders (as defined therein) (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the Commission on September 22, 2005)

## **Table of Contents**

<b>Exhibit No.</b>	<b>Title</b>
10.2	Shelf Registration Agreement, dated April 30, 2004, between Endo Pharmaceuticals Holdings Inc. and Endo Pharma LLC (incorporated herein by reference to Exhibit 10.2 of Amendment No. 1 to the Form S-3 Registration Statement (Registration No. 333-115032) filed with the Commission on June 10, 2004)
10.3	Amendment to Shelf Registration Agreement, dated June 10, 2004 between Endo Pharmaceuticals Holdings Inc. and Endo Pharma LLC (incorporated herein by reference to Exhibit 10.3 of Amendment No. 1 to the Form S-3 Registration Statement (Registration No. 333-115032) filed with the Commission on June 10, 2004)
10.4	Agreement dated April 29, 2008 between Endo Pharmaceuticals Holdings Inc. and D. E. Shaw Valence Portfolios, L.L.C. (on behalf of itself and its affiliates that are members of the 13D Group with respect to the Endo common stock) (incorporated herein by reference to Exhibit 99.1 of the Current Report on Form 8-K/A dated May 1, 2008)
10.5	[Intentionally Omitted.]
10.6	Amended and Restated Tax Sharing Agreement, dated as of April 30, 2004 by and among Endo, Endo Inc. and Endo LLC (incorporated herein by reference to Exhibit 10.6 of the Form 10-Q for the Quarter ended March 31, 2004 filed with the Commission on May 10, 2004)
10.7	Convertible Bond Hedge Transaction Confirmation entered into by and between the Company and Deutsche Bank AG, London Branch, dated April 9, 2008 (incorporated herein by reference to Exhibit 10.7 of the Form 10-Q for the Quarter ended March 31, 2008 filed with the Commission on May 2, 2008)
10.8	Issuer Warrant Transaction Confirmation entered into by and between the Company and Deutsche Bank AG, London Branch, dated April 9, 2008 (incorporated herein by reference to Exhibit 10.8 of the Form 10-Q for the Quarter ended March 31, 2008 filed with the Commission on May 2, 2008)
10.9	Issuer Share Repurchase Transaction Confirmation entered into by and between the Company and Deutsche Bank AG, London Branch, dated April 9, 2008 (incorporated herein by reference to Exhibit 10.9 of the Form 10-Q for the Quarter ended March 31, 2008 filed with the Commission on May 2, 2008)
10.10	Sole and Exclusive License Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals Inc. ( Endo Pharmaceuticals ) and Hind HealthCare, Inc. (incorporated herein by reference to Exhibit 10.10 of the Registration Statement filed with the Commission on June 9, 2000)
10.11	Endo Pharmaceuticals Holdings Inc. Executive Deferred Compensation Plan (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K dated December 19, 2007)
10.12	Endo Pharmaceuticals Holdings Inc. 401(k) Restoration Plan (incorporated herein by reference to Exhibit 10.2 of the Current Report on Form 8-K dated December 19, 2007)
10.13	[Intentionally Omitted.]
10.14	Supply and Manufacturing Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals and Teikoku Seiyaku Co., Ltd (incorporated herein by reference to Exhibit 10.14 of the Registration Statement filed with the Commission on June 9, 2000)
10.14.1	First Amendment, dated April 24, 2007, to the Supply and Manufacturing Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals Inc. and Teikoku Seiyaku Co., Ltd. / Teikoku Pharma USA, Inc. (incorporated herein by reference to Exhibit 10.14.1 of the Current Report on Form 8-K dated April 30, 2007)
10.15	Supply Agreement, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt Inc. ( Mallinckrodt ) (incorporated herein by reference to Exhibit 10.15 of the Registration Statement filed with the Commission on June 9, 2000)
10.16	Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt (incorporated herein by reference to Exhibit 10.16 of the Registration Statement filed with the Commission on June 9, 2000)
10.16.1	First Amendment, effective July 1, 2000, to the Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt (incorporated herein by reference to Exhibit 10.16.1 of the Current Report on Form 8-K dated April 14, 2006)

## **Table of Contents**

- 10.16.2 Second Amendment, dated April 10, 2006, to the Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt (incorporated herein by reference to Exhibit 10.16.2 of the Current Report on Form 8-K dated April 14, 2006)
- 10.17 [Intentionally Omitted.]
- 10.18 Amended and Restated Strategic Alliance Agreement, dated as of April 2, 2002, by and between Endo Pharmaceuticals and Penwest Pharmaceuticals Co. (incorporated herein by reference to Exhibit 10.18 of the Quarterly Report on Form 10-Q for the Quarter Ended March 31, 2002 filed with the Commission on May 14, 2002)
- 10.18.1 Amendment, dated January 7, 2007, to the Amended and Restated Strategic Alliance Agreement, dated as of April 2, 2002, by and between Endo Pharmaceuticals Inc. and Penwest Pharmaceuticals Co. (incorporated herein by reference to Exhibit 10.18.1 of the Current report on Form 8-K dated January 11, 2007)
- 10.18.2 Amendment, dated July 14, 2008, to the Amended and Restated Strategic Alliance Agreement, dated as of April 2, 2002, by and between Endo Pharmaceuticals Inc. and Penwest Pharmaceuticals Co. (incorporated herein by reference to Exhibit 10.18.2 of the Quarterly Report on Form 10-Q for the Quarter Ended June 30, 2008 filed with the Commission on August 1, 2008)
- 10.18.3 Third Amendment to the Amended and Restated Strategic Alliance Agreement by and between Penwest Pharmaceuticals Co. and Endo Pharmaceuticals Inc., dated as of March 31, 2009 (incorporated herein by reference to Exhibit 10.18.3 of the Current report on Form 8-K dated April 6, 2009)
- 10.19 Agreement, dated as of February 1, 2000, by and between Endo Pharmaceuticals and UPS Supply Chain Solutions, Inc. (f/d/b/a Livingston Healthcare Services Inc.) (incorporated herein by reference to Exhibit 10.19 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.20 Medical Affairs Support Services Agreement, dated as of June 1, 1999, by and between Endo Pharmaceuticals and Kunitz and Associates, Inc. (incorporated herein by reference to Exhibit 10.20 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.21 Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.21 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
- 10.22 Endo LLC Amended and Restated 1997 Employee Stock Option Plan (incorporated herein by reference to Exhibit 10.22 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
- 10.23 Endo LLC Amended and Restated 1997 Executive Stock Option Plan (incorporated herein by reference to Exhibit 10.23 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
- 10.24 Endo LLC 2000 Amended and Restated Supplemental Employee Stock Option Plan (incorporated herein by reference to Exhibit 10.24 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
- 10.25 Endo LLC 2000 Amended and Restated Supplemental Executive Stock Option Plan (incorporated herein by reference to Exhibit 10.25 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
- 10.26 Separation Agreement, dated as of September 8, 2008, between the Endo Pharmaceuticals Holdings Inc. and Charles A. Rowland, Jr. (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K dated September 8, 2008)
- 10.27 Executive Employment Agreement between Endo Pharmaceuticals Holdings Inc. and Ivan Gergel, M.D., dated as of April 29, 2008 (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K dated March 25, 2009)
- 10.28 Amended and Restated Employment Agreement, dated as of December 19, 2007, by and between the Company and Nancy J. Wysenski (incorporated herein by reference to Exhibit 10.29 of the Form 10-K for the year ended December 31, 2007 filed with the Commission on February 26, 2008)
- 10.29 Auction-Rate Securities Rights Agreement, dated November 10, 2008, by and between Endo Pharmaceuticals and UBS AG (incorporated herein by reference to Exhibit 10.29 to the Form 10-K for the year ended December 31, 2008 filed with the Commission on March 2, 2009)
- 10.30 Employment Agreement, dated as of April 1, 2008, by and between Endo Pharmaceuticals Holdings Inc. and David P. Holveck (incorporated herein by reference to Exhibit 10.30 of the Current Report on Form 8-K dated March 12, 2008)

## **Table of Contents**

- 10.31 License and Supply Agreement by and by and among Novartis, AG, Novartis Consumer Health, Inc. and Endo Pharmaceuticals Inc. dated as of March 4, 2008 (incorporated herein by reference to Exhibit 10.31 of the Form 10-Q for the Quarter ended March 31, 2008 filed with the Commission on May 2, 2008)
- 10.31.1 Amendment No. 1 to the License and Supply Agreement by and by and among Novartis, AG, Novartis Consumer Health, Inc. and Endo Pharmaceuticals Inc. dated as of March 28, 2008 (incorporated herein by reference to Exhibit 10.31.1 of the Form 10-Q for the Quarter ended March 31, 2008 filed with the Commission on May 2, 2008)
- 10.32 Sales and Marketing Services Agreement, dated as of May 15, 2008 between Endo Pharmaceuticals and Ventiv Commercial Services, LLC (incorporated herein by reference to Exhibit 10.32 of the Form 10-Q for the Quarter ended June 30, 2008 filed with the Commission on August 1, 2008)
- 10.32.1 Amendment to the Sales and Marketing Services Agreement, dated as of January 29, 2009 between Endo Pharmaceuticals and Ventiv Commercial Services, LLC (incorporated herein by reference to Exhibit 10.32.1 to the Form 10-K for the year ended December 31, 2008 filed with the Commission on March 2, 2009)
- 10.32.2 Amendment to the Sales Representative Service Agreement, dated as of April 1, 2009 between Endo Pharmaceuticals Inc. and Ventiv Commercial Services, LLC (incorporated herein by reference to Exhibit 10.32.2 of the Current Report on Form 8-K dated April 7, 2009)
- 10.32.3 Amendment to the Sales Representative Services Agreement, dated as of May 11, 2009 between Endo Pharmaceuticals Inc. and Ventiv Commercial Services, LLC (incorporated herein by reference to Exhibit 10.32.2 of the Current Report on Form 8-K dated May April 7, 2009)
- 10.33 [Intentionally Omitted.]
- 10.34 Lease Agreement, dated as of May 5, 2000, by and between Endo Pharmaceuticals and Painters Crossing One Associates, L.P. (incorporated herein by reference to Exhibit 10.34 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.34.1 Amendment to Lease Agreement, dated as of November 6, 2006, by and between Endo Pharmaceuticals and Painters Crossing One Associates, L.P. (incorporated herein by reference to Exhibit 10.34.1 of the Form 10-Q for the quarter ended September 30, 2006 filed with the Commission on November 9, 2006)
- 10.35 Amended and Restated Employment Agreement, dated as of December 19, 2007, by and between the Company and Caroline B. Manogue (incorporated herein by reference to Exhibit 10.29 of the Form 10-K for the year ended December 31, 2007 filed with the Commission on February 26, 2008)
- 10.36 [Intentionally Omitted]
- 10.36.1 Separation Agreement, dated as of January 28, 2008, Endo Pharmaceuticals Holdings Inc. and Peter A. Lankau (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K dated January 30, 2008)
- 10.37 Endo Pharmaceuticals Holdings Inc. 2004 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.37 of the Form 10-Q for the Quarter ended June 30, 2004 filed with the Commission on August 9, 2004)
- 10.38 Endo Pharmaceuticals Holdings Inc. Amended and Restated 2007 Stock Incentive Plan (incorporated herein by reference to Exhibit B of the Definitive Proxy Statement on Schedule 14A filed with the Commission on April 29, 2009)
- 10.39 Master Development and Toll Manufacturing Agreement, dated as of May 3, 2001, by and between Novartis Consumer Health, Inc. and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.39 of the Form 10-Q for the Quarter Ended June 30, 2001 filed with the Commission on August 14, 2001)
- 10.39.1 First Amendment, effective February 1, 2003, to the Master Development and Toll Manufacturing Agreement between Endo Pharmaceuticals and Novartis Consumer Health, Inc. (incorporated herein by reference to Exhibit 10.39.1 of the Form 10-Q for the Quarter Ended June 30, 2005 filed with the Commission on August 8, 2005)
- 10.39.2 Second Amendment, effective as of December 1, 2004, to the Master Development and Toll Manufacturing Agreement between Endo Pharmaceuticals and Novartis Consumer Health, Inc. (incorporated herein by reference to Exhibit 10.39.2 of the Form 10-Q for the Quarter Ended June 30, 2005 filed with the Commission on August 8, 2005)
- 10.40 Lease Agreement between Painters Crossing Three Associates, L.P. and Endo Pharmaceuticals Inc. dated January 19, 2007 (incorporated herein by reference to Exhibit 10.40 of the Annual Report on Form 10-K for the Year Ended December 31, 2006 filed with the Commission on March 1, 2007)
- 10.40.1 First Amendment to Lease Agreement, dated as of March 3, 2008 by and between Partners Crossing Three Associates, L.P. and Endo Pharmaceuticals Inc. (incorporated herein by reference to Exhibit 10.40.1 of the Form 10-Q for the Quarter ended March 31, 2008)

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

filed with the Commission on May 2, 2008)

## **Table of Contents**

- 10.41 Policy of Endo Pharmaceuticals Holdings Inc. Relating to Insider Trading in Company Securities and Confidentiality of Information (incorporated herein by reference to Exhibit 10.41 of the Form 10-Q for the Quarter ended March 31, 2005 filed with the Commission on May 10, 2005)
- 10.42 Form of Indemnification Agreement (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K, dated May 8, 2009).
- 10.43 Employment Agreement between Endo Pharmaceuticals Holdings Inc. and Alan G. Levin (incorporated herein by reference to Exhibit 10.2 of the Current Report on Form 8-K, dated May 8, 2009).
- 10.44 Lease Agreement, dated as of January 6, 2003, by and between Endo Pharmaceuticals and Dawson Holding Company (incorporated by reference to Exhibit 10.44 of the Annual Report on Form 10-K for the Year Ended December 31, 2002 filed with the Commission on March 27, 2003)
- 10.45 Lease Agreement, dated as of November 13, 2003, by and between Endo Pharmaceuticals and Painters Crossing Two Associates, L.P. (incorporated herein by reference to Exhibit 10.45 of the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on March 15, 2004)
- 10.45.1 Amendment to Lease Agreement, dated as of February 16, 2005, by and between Endo Pharmaceuticals and Painters Crossing Two Associates, L.P. (incorporated herein by reference to Exhibit 10.45.1 of the Current Report on Form 8-K dated February 18, 2005)
- 10.45.2 Amendment to Lease Agreement, dated as of November 6, 2006, by and between Endo Pharmaceuticals and Painters Crossing Two Associates, L.P. (incorporated herein by reference to Exhibit 10.34.1 of the Form 10-Q for the quarter ended September 30, 2006 filed with the Commission on November 9, 2006)
- 10.46 License Agreement, dated as of February 25, 2004, by and between Endo Pharmaceuticals and Noven Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.46 of Amendment No. 2 to the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on June 25, 2004)
- 10.46.1 Termination Agreement, dated as of February 24, 2006, by and between Noven Pharmaceuticals, Inc. and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.46.1 of the Annual Report on Form 10-K for the Year Ended December 31, 2005 filed with the Commission on March 8, 2006)
- 10.47 Supply Agreement, dated as of February 25, 2004, by and between Endo Pharmaceuticals and Noven Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.47 of Amendment No. 2 to the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on June 25, 2004)
- 10.48 License and Co-Promotion Rights Agreement, dated as of July 14, 2004, by and between Endo Pharmaceuticals and Vernalis Development Limited (incorporated herein by reference to Exhibit 10.48 of the Current Report on Form 8-K dated July 19, 2004)
- 10.48.1 Co-Promotion Agreement, dated as of July 1, 2005, by and between Endo Pharmaceuticals Inc. and Vernalis Development Limited (incorporated by reference to Exhibit 10.48.1 of the Current Report on Form 8-K dated July 8, 2005)
- 10.48.2 Second Amendment, dated as of December 12, 2005, to the License Agreement by and between Endo Pharmaceuticals Inc. and Vernalis Development Limited (incorporated by reference to Exhibit 10.48.2 of the Current Report on Form 8-K dated December 29, 2005)
- 10.48.3 First Amendment, dated as of December 12, 2005, to the Co-Promotion Agreement by and between Endo Pharmaceuticals Inc. and Vernalis Development Limited (incorporated by reference to Exhibit 10.48.3 of the Current Report on Form 8-K dated December 29, 2005)

## **Table of Contents**

- 10.48.4 Third Amendment, dated as of July 23, 2007, to the License Agreement by and between Endo Pharmaceuticals Inc. and Vernalis Development Limited (incorporated by reference to Exhibit 10.48.4 of the Current Report on Form 8-K dated July 27, 2007)
- 10.48.5 Fourth Amendment, dated as of February 19, 2008, to the License Agreement by and between Endo Pharmaceuticals Inc. and Vernalis Development Limited (incorporated herein by reference to Exhibit 10.48.5 of the Form 10-K for the year ended December 31, 2007 filed with the Commission on February 26, 2008)
- 10.48.6 Agreement to Terminate the Co-Promotion Agreement by and between Endo Pharmaceuticals Inc. and Vernalis Development Limited, effective February 19, 2008 (incorporated herein by reference to Exhibit 10.48.6 of the Form 10-K for the year ended December 31, 2007 filed with the Commission on February 26, 2008)
- 10.49 Loan Agreement, dated as of July 14, 2004, by and between Endo Pharmaceuticals and Vernalis Development Limited (incorporated herein by reference to Exhibit 10.49 of the Current Report on Form 8-K dated July 19, 2004)
- 10.49.1 Agreement to Terminate the Loan Agreement by and between Endo Pharmaceuticals and Vernalis Development Limited, effective February 19, 2008 (incorporated herein by reference to Exhibit 10.49.1 of the Form 10-K for the year ended December 31, 2007 filed with the Commission on February 26, 2008)
- 10.50 Form of Stock Option Grant Agreement under the 2007 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.50 of the Form 10-K for the year ended December 31, 2008 filed with the Commission on March 2, 2009)
- 10.51 Form of Restricted Stock Unit Grant Agreement under the 2007 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.51 of the Form 10-K for the year ended December 31, 2008 filed with the Commission on March 2, 2009)
- 10.52 Agreement and Plan of Merger dated January 5, 2009, by and between Endo Pharmaceuticals Holdings Inc., BTB Purchaser, and Indevus Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K dated January 5, 2009)
- 10.52.1 Amendment, dated January 7, 2009 to the Agreement and Plan of Merger, by and between Endo Pharmaceuticals Holdings Inc., BTB Purchaser, and Indevus Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K dated January 7, 2009)
- 10.52.2 Amendment No. 2, dated February 4, 2009, to the Agreement and Plan of Merger, by and among Endo Pharmaceuticals Holdings, Inc., BTB Purchaser, and Indevus Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.1 of the Current Report on Form 8-K dated February 6, 2009)
- 10.53 Form of Stockholder Tender Agreement (incorporated herein by reference to Exhibit 10.2 of the Current Report on Form 8-K dated January 5, 2009)
- 10.54 Nebido® Contingent Cash Consideration Agreement, dated February 23, 2009, by and between Endo Pharmaceuticals Holdings Inc. and American Stock Transfer and Trust Company (incorporated herein by reference to Exhibit 10.54 of the Form 10-K for the year ended December 31, 2008 filed with the Commission on March 2, 2009)
- 10.55 Octreotide Contingent Cash Consideration Agreement, dated February 23, 2009, by and between Endo Pharmaceuticals Holdings Inc. and American Stock Transfer and Trust Company (incorporated herein by reference to Exhibit 10.55 of the Form 10-K for the year ended December 31, 2008 filed with the Commission on March 2, 2009)
- 10.56 Memorandum of Understanding, dated February 4, 2009, by and among (i) Wolf Popper LLP, counsel for Plaintiff Arthur Gober, CBM IRA Beneficiary Custodian, Beneficiary of Jerome Gober, (ii) Skadden, Arps, Slate, Meagher & Flom LLP, counsel for Defendants Endo Pharmaceuticals Holdings Inc. and BTB Purchaser Inc., (iii) The Weiser Law Firm, P.C., counsel for Plaintiff Martin Wexler, (iv) Young Conaway Stargatt & Taylor, LLP, counsel for Defendants Indevus Pharmaceuticals, Inc., Glenn L. Cooper, Andrew Ferrara, James C. Gale, Michael E. Hanson, Stephen C. McCluski, Cheryl P. Morley and Malcolm Morville, (v) Levi & Korsinsky LLP, counsel for Plaintiff Malena C. Schroeder and (vi) Johnson Bottini LLP, counsel for Plaintiff H. Steven Mishket (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K dated February 6, 2009)
- 10.57 Amended and Restated License, Commercialization and Supply Agreement executed September 18, 2007 between Indevus and Esprit Pharma, Inc. (incorporated herein by reference to Exhibit 10.1 to the Indevus Current Report on Form 8-K dated September 21, 2007)
- 10.58 Lease Agreement between National Patent Development Corporation and Cedar Brook Corporate Center, L.P. dated October 6, 1997 (incorporated herein by reference to Exhibit 10.9 to the Valera Registration Statement on Form S-1 (File No. 333-123288) filed with the Commission on December 9, 2005)

## **Table of Contents**

- 10.59 Amendment to Lease between Valera Pharmaceuticals, Inc. and Cedar Brook Corporate Center, L.P. dated January 7, 2004 (incorporated herein by reference to Exhibit 10.10 to the Valera Registration Statement on Form S-1 (File No. 333-123288) filed with the Commission on December 9, 2005)
- 10.60 Lease Agreement between Valera Pharmaceuticals, Inc. and Cedar Brook 7 Corporate Center, L.P. dated March 8, 2005 (incorporated herein by reference to Exhibit 10.11 to the Valera Registration Statement on Form S-1 (File No. 333-123288) filed with the Commission on December 9, 2005)
- 10.61 Agreement and Plan of merger, dated as of December 11, 2006, by and among Indevus, Hayden Merger Sub, Inc. and Valera Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.1 to the Indevus Current Report on Form 8-K, dated December 12, 2006)
- 10.62 License Agreement dated February 18, 1994 between Indevus and Rhone-Poulenc Rorer, S.A. (incorporated herein by reference to the Indevus Registration Statement on Form S-3 or Amendment I (File no. 33-75826))
- 10.63 Lease dated February 5, 1997 between Indevus and Ledgemont Realty Trust (incorporated herein by reference to Exhibit 10.87 to the Indevus Form 10-Q for the period ended December 31, 1996 filed with the Commission on February 14, 1997)
- 10.64 License Agreement effective as of November 26, 1999 between Madaus AG and Indevus (incorporated herein by reference to Exhibit 10.113 to the Indevus Form 10-K for the fiscal year ended September 30, 1999, filed with the Commission on December 28, 1999)
- 10.65 Indemnity and Release Agreement between American Home Products Corporation and Indevus dated as of May 30, 2001 (incorporated herein by reference to Exhibit 1.120 to the Indevus Form 10-Q for the period ended June 30, 2001, filed with the Commission on August 14, 2001)
- 10.66 Supply Agreement between Indevus and Madaus AG dated December 16, 2003 (incorporated herein by reference to Exhibit 10.129 to the Indevus Form 10-Q for the period ended December 31, 2002, filed with the Commission on February 14, 2003)
- 10.67 Development and License Agreement between Indevus and Shire Laboratories Inc. dated March 11, 2003 (incorporated herein by reference to Exhibit 10.130 to the Indevus Form 10-Q for the period ended March 31, 2003, filed with the Commission on April 13, 2003)
- 10.68 License, Commercialization and Supply Agreement dated April 6, 2004 between Indevus and Odyssey Pharmaceuticals Inc. (incorporated herein by reference to Exhibit 99.2 to the Indevus Current Report on Form 8-K dated April 19, 2004)
- 10.68.1 Amendment No. 1 to License, Commercialization and Supply Agreement dated April 30, 2005 between Indevus and Odyssey Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.143 to the Indevus Form 10-Q for the period ended March 31, 2005, filed with the Commission on May 10, 2005)
- 10.69 Indenture of Lease dated December 20, 2004 between Indevus and Mortimer B. Zuckerman and Edward H. Linde, Trustees of Hayden Office Trust (incorporated herein by reference to Exhibit 10.142 to the Indevus Form 10-Q for the period ended December 31, 2004, filed with the Commission on February 9, 2005)
- 10.70 Amendment and Consent Agreement dated May 14, 2005 between Indevus, Odyssey Pharmaceuticals, Inc., and Saturn Pharmaceuticals, Inc (incorporated herein by reference to Exhibit 10.1 to the Indevus Current Report on Form 8-K dated May 17, 2005)
- 10.71 License Agreement dated July 28, 2005 between Indevus and Schering Aktiengesellschaft (incorporated herein by reference to Exhibit 10.1 to the Indevus Current Report on Form 8-K dated August 2, 2005)
- 10.72 Manufacturing and Supply Agreement by and between Indevus and Schering AG, Germany dated on or about October 20, 2006 (incorporated herein by reference to Exhibit 10.158 to the Indevus Form 10-K for the fiscal year ended September 30, 2006, filed with the Commission on December 7, 2006)
- 10.73 License and Supply Agreement by and between Indevus and Madaus GmbH dated on or about November 3, 2006 (incorporated herein by reference to Exhibit 10.159 to the Indevus Form 10-K for the fiscal year ended September 30, 2006, filed with the Commission on December 7, 2006)
- 10.73.1 Amendment and Agreement by and between Indevus and Madaus GmbH dated on or about November 3, 2006 (incorporated herein by reference to Exhibit 10.160 to the Indevus Form 10-K for the fiscal year ended September 30, 2006, filed with the Commission on December 7, 2006)
- 10.74 API Supply Agreement by and between Indevus and Helsinn Chemicals SA and Helsinn Advanced Synthesis SA dated on or about November 22, 2006 (incorporated herein by reference to Exhibit 10.162 to the Indevus Form 10-K for the fiscal year ended September 30, 2006, filed with the Commission on December 7, 2006)





## **Table of Contents**

- 10.75     Supprelin Contingent Stock Rights Agreement, dated as of April 17, 2007, between Indevus and American Stock Transfer & Trust Company (incorporated herein by reference to Exhibit 10.1 to the Indevus Current Report on Form 8-K dated April 17, 2007)
- 10.75.1   Supplemental Supprelin CSR Agreement, dated as of March 23, 2009, by and between Endo American Stock Transfer & Trust (incorporated herein by reference to Exhibit 10.3 of the Current Report on Form 8-K dated March 23, 2009)
- 10.76     Stent Contingent Stock Rights Agreement, dated as of April 17, 2007, between Indevus and American Stock Transfer & Trust Company (incorporated herein by reference to Exhibit 10.2 to the Indevus Current Report on Form 8-K dated April 17, 2007)
- 10.76.1   Supplemental Stent CSR Agreement, dated as of March 23, 2009, by and between Endo American Stock Transfer & Trust (incorporated herein by reference to Exhibit 10.2 of the Current Report on Form 8-K dated March 23, 2009)
- 10.77     Octreotide Contingent Stock Rights Agreement, dated as of April 17, 2007, between Indevus and American Stock Transfer & Trust Company (incorporated herein by reference to Exhibit 10.3 to the Indevus Current Report on Form 8-K dated April 17, 2007)
- 10.77.1   Supplemental Octreotide CSR Agreement, dated as of March 23, 2009, by and between Endo American Stock Transfer & Trust (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K dated March 23, 2009)
- 10.78     Supply Agreement by and between Valera Pharmaceuticals, Inc. and Plantex USA Inc. (incorporated herein by reference to Exhibit 10.1 to the Valera Form 10-Q for the period ended June 30, 2006, filed with the Commission on August 9, 2006)
- 10.79     Form of License, Supply and Distribution Agreement by and between Indevus Pharmaceuticals, Inc. and Orion Corporation dated April 2, 2008 (incorporated herein by reference to Exhibit 10.208 to the Indevus Form 10-K for the fiscal year ending September 30, 2008, filed with the Commission on December 11, 2008)
- 10.80     Form of Purchase and Sale Agreement by and between Ledgemont Royalty Sub LLC and Indevus dated August 26, 2008 (incorporated herein by reference to Exhibit 10.215 to the Indevus Form 10-K for the fiscal year ending September 30, 2008, filed with the Commission on December 11, 2008)
- 10.81     Form of Note Purchase Agreement by and among Ledgemont Royalty Sub LLC, Indevus and the purchasers named therein dated August 26, 2008 (incorporated herein by reference to Exhibit 10.216 to the Indevus Form 10-K for the fiscal year ending September 30, 2008, filed with the Commission on December 11, 2008)
- 10.82     Form of Indenture by and between Ledgemont Royalty Sub LLC and U.S. Bank National Association dated August 26, 2008 (incorporated herein by reference to Exhibit 10.217 to the Indevus Form 10-K for the fiscal year ending September 30, 2008, filed with the Commission on December 11, 2008)
- 10.83     Form of Pledge and Security Agreement made by Indevus to U.S. Bank National Association, as Trustee, dated August 26, 2008 (incorporated herein by reference to Exhibit 10.218 to the Indevus Form 10-K for the fiscal year ending September 30, 2008, filed with the Commission on December 11, 2008)
- 10.84     Form of Development, License and Commercialization Agreement made by and between Indevus and Teva Pharmaceutical Industries Ltd., dated September 25, 2008 (incorporated herein by reference to Exhibit 10.219 to the Indevus Form 10-K for the fiscal year ending September 30, 2008, filed with the Commission on December 11, 2008)
- 10.85     First Amendment to Amended and Restated License, Commercialization and Supply Agreement between Indevus Pharmaceuticals, Inc. and Allergan USA, Inc. dated as of January 9, 2009 (incorporated herein by reference to Exhibit 10.1 to the Indevus Current Report on Form 8-K, dated January 15, 2009)
- 10.86     Agreement between National Patent Development Corporation and Dento-Med Industries, Inc. dated November 30, 1989 (incorporated herein by reference to Exhibit 10.17 to the Valera Registration Statement on Form S-1 (File No. 333-123288) filed with the Commission on December 9, 2005).
- 10.87     Contribution Agreement between Hydro Med Sciences, Inc. and GP Strategies Corporation dated June 30, 2000 (incorporated herein by reference to Exhibit 10.12 to the Valera Registration Statement on Form S-1 (File No. 333-123288) filed with the Commission on December 9, 2005).
- 10.88     Termination of Agreement dated September 12, 1990 between National Patent Development Corporation and The Population Council, Inc. dated October 1, 1997 (incorporated herein by reference to Exhibit 10.6 to the Valera Registration Statement on Form S-1 (File No. 333-123288) filed with the Commission on December 9, 2005).

**Table of Contents**

- 10.88.1 Amendment to the Termination of the Joint Development Agreement between GP Strategies Corporation and The Population Council, Inc. dated November 29, 2001 (incorporated herein by reference to Exhibit 10.7 to the Valera Registration Statement on Form S-1 (File No. 333-123288) filed with the Commission on December 9, 2005).
- 10.88.2 Amendment No. 2 to Termination Agreement between Valera Pharmaceuticals, Inc. and The Population Council, Inc. dated August 31, 2004 (incorporated herein by reference to Exhibit 10.8 to the Valera Registration Statement on Form S-1 (File No. 333-123288) filed with the Commission on December 9, 2005).
- 31.1 Certification of the Chief Executive Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification of the Chief Financial Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 Certification of the Chief Executive Officer of Endo pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2 Certification of the Chief Financial Officer of Endo pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002