

ENDO PHARMACEUTICALS HOLDINGS INC

Form 10-Q

November 09, 2006

[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 SEPTEMBER 30, 2006.

OR

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

Commission file number: 001-15989

ENDO PHARMACEUTICALS HOLDINGS INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or other jurisdiction of

incorporation or organization)

13-4022871
(I.R.S. Employer

Identification Number)

100 Endo Boulevard

Chadds Ford, Pennsylvania 19317

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

(Address of Principal Executive Offices)

(610) 558-9800

(Registrant's Telephone Number, Including Area Code)

Not applicable

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

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

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

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐

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

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

Common Stock, \$0.01 par value: 133,508,201 shares as of November 2, 2006.

Table of Contents

ENDO PHARMACEUTICALS HOLDINGS INC.

INDEX

<u>Forward-Looking Statements</u>	Page 3
<u>PART I. FINANCIAL INFORMATION</u>	
Item 1. <u>Financial Statements</u>	4
<u>Condensed Consolidated Balance Sheets (Unaudited) September 30, 2006 and December 31, 2005</u>	4
<u>Condensed Consolidated Statements of Operations (Unaudited) Three and Nine Months ended September 30, 2006 and 2005</u>	5
<u>Condensed Consolidated Statements of Cash Flows (Unaudited) Nine Months ended September 30, 2006 and 2005</u>	6
<u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>	7
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	21
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	34
Item 4. <u>Controls and Procedures</u>	35
<u>PART II. OTHER INFORMATION</u>	
Item 1. <u>Legal Proceedings</u>	35
Item 1A. <u>Risk Factors</u>	35
Item 2. <u>Changes in Securities and Use of Proceeds</u>	35
Item 3. <u>Defaults Upon Senior Securities</u>	35
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	35
Item 5. <u>Other Information</u>	35
Item 6. <u>Exhibits</u>	36
<u>SIGNATURES</u>	
	37

Table of Contents

Forward Looking Statements

This document contains information that includes or is based on forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act.

These statements, including estimates of future net sales, future net income and future earnings per share, contained in the section titled Management's Discussion and Analysis of Financial Condition and Results of Operations, which is included in documents incorporated by reference, 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, or similar expressions are forward-looking statements. We have based these forward-looking statements on our current expectations and projections about the growth of our business, our financial performance and the development of our industry. Because these statements reflect our current views concerning future events, these forward-looking statements involve risks and uncertainties. Investors should note that many factors, as more fully described or incorporated by reference in Item 1A Risk Factors in this document, supplement, and as otherwise enumerated herein, could affect our future financial results and could cause our actual results to differ materially from those expressed in forward-looking statements contained in this document. Important factors that could cause our actual results to differ materially from the expectations reflected in the forward-looking statements in this document include those factors described or incorporated by reference in this document under Item 1A titled Risk Factors, including, among others:

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

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

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

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

significant cash payments we may be required to make to Endo Pharma LLC pursuant to a tax sharing agreement;

market acceptance of our future products;

government regulation of the pharmaceutical industry;

our dependence on a small number of products;

our dependence on outside manufacturers for the manufacture of our products;

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

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

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

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

our ability to protect our proprietary technology;

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

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

regulatory or other limits on the availability of controlled substances that constitute the active ingredients of some of our products and products in development;

the availability of third-party reimbursement for our products;

the outcome of any pending or future litigation or claims by the government; and

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.

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 SEC. Also note that we provide the preceding cautionary discussion of risks, uncertainties and possibly inaccurate assumptions relevant to our business. These are factors that, individually or in the aggregate, we think could cause our actual results to differ materially from expected and historical results. We note these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider the preceding to be a complete discussion of all potential risks or uncertainties.

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

	September 30,	December 31,
	2006	2005
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 674,650	\$ 500,956
Accounts receivable, net	259,924	290,826
Income taxes receivable		66,461
Inventories, net	68,354	50,983
Prepaid expenses and other current assets	8,889	14,445
Deferred income taxes	61,244	69,714
Total current assets	1,073,061	993,385
PROPERTY AND EQUIPMENT, Net	35,617	38,001
GOODWILL	181,079	181,079
OTHER INTANGIBLES, Net	111,604	99,065
NOTE RECEIVABLE	51,874	48,925
OTHER ASSETS	9,865	11,223
TOTAL ASSETS	\$ 1,463,100	\$ 1,371,678
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 113,375	\$ 94,787
Accrued expenses	157,802	214,276
Due to Endo Pharma LLC	128,091	200,450
Income taxes payable	16,145	
Total current liabilities	415,413	509,513
DEFERRED INCOME TAXES	18,484	14,637
OTHER LIABILITIES	2,461	4,158
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Preferred Stock, \$0.01 par value; 40,000,000 shares authorized; none issued		
Common Stock, \$0.01 par value; 175,000,000 shares authorized; 133,396,813 and 132,800,873 issued and outstanding at September 30, 2006 and December 31, 2005, respectively	1,334	1,328
Additional paid-in capital	680,555	619,336
Retained earnings	344,057	220,992
Accumulated other comprehensive income	796	1,714
Total stockholders' equity	1,026,742	843,370

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

TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	\$ 1,463,100	\$ 1,371,678
---	--------------	--------------

See Notes to Condensed Consolidated Financial Statements.

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

	Three Months Ended		Nine Months ended	
	September 30,		September 30,	
	2006	2005	2006	2005
NET SALES	\$ 217,125	\$ 245,241	\$ 650,188	\$ 579,375
COST OF SALES	44,406	61,399	143,551	133,242
GROSS PROFIT	172,719	183,842	506,637	446,133
COSTS AND EXPENSES:				
Selling, general and administrative	87,850	47,075	252,281	156,282
Research and development	14,456	22,382	59,382	70,822
Depreciation and amortization	4,636	4,144	12,944	11,438
Impairment of other intangible asset		5,515		5,515
OPERATING INCOME	65,777	104,726	182,030	202,076
INTEREST INCOME, Net of interest expense of \$217, \$453, \$1,072 and \$1,412, respectively	6,851	2,689	17,072	6,657
INCOME BEFORE INCOME TAX	72,628	107,415	199,102	208,733
INCOME TAX	27,737	40,862	76,037	79,319
NET INCOME	\$ 44,891	\$ 66,553	\$ 123,065	\$ 129,414
NET INCOME PER SHARE:				
Basic	\$ 0.34	\$ 0.50	\$ 0.92	\$ 0.98
Diluted	\$ 0.33	\$ 0.50	\$ 0.92	\$ 0.97
WEIGHTED AVERAGE SHARES:				
Basic	133,270	132,376	133,067	132,075
Diluted	134,147	133,532	133,961	133,122

See notes to Condensed Consolidated Financial Statements.

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

	Nine Months Ended	
	September 30,	September 30,
	2006	2005
OPERATING ACTIVITIES:		
Net income	\$ 123,065	\$ 129,414
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	12,944	11,438
Stock-based compensation	9,337	
Accretion of interest on note receivable	(930)	(930)
Deferred income taxes	15,015	(16,811)
Tax benefits of stock options exercised		7,602
Amortization of deferred financing costs	287	287
Impairment of other intangible asset		5,515
Loss on disposal of property and equipment	975	221
Selling, general and administrative expenses to be funded by Endo Pharma LLC	41,330	2,000
Changes in assets and liabilities which provided (used) cash:		
Accounts receivable	30,902	(114,508)
Inventories	(17,371)	8,495
Note receivable	(2,019)	(1,983)
Prepaid and other assets	5,139	2,170
Accounts payable	21,712	21,080
Accrued expenses	(41,825)	45,431
Due to Endo Pharma LLC	(5,624)	
Income taxes receivable/payable	82,606	71,738
Net cash provided by operating activities	275,543	171,159
INVESTING ACTIVITIES:		
Purchase of property and equipment	(8,882)	(8,412)
Proceeds from the sale of property and equipment	94	1
License fees	(32,900)	(14,500)
Other investments		(1,700)
Net cash used in investing activities	(41,688)	(24,611)
FINANCING ACTIVITIES:		
Capital lease obligations repayments	(1,856)	(1,753)
Tax sharing payments to Endo Pharma LLC	(96,715)	(21,422)
Tax benefits of stock options exercised	32,106	
Exercise of Endo Pharmaceuticals Holdings Inc. Stock Options	6,304	9,080
Net cash used in financing activities	(60,161)	(14,095)
NET INCREASE IN CASH AND CASH EQUIVALENTS	173,694	132,453
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	500,956	278,034
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 674,650	\$ 410,487

SUPPLEMENTAL INFORMATION:

Interest paid	\$ 1,519	\$ 805
Income taxes paid	\$ 15,533	\$ 16,900
SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES		
Purchase of property and equipment financed by capital leases	\$ 218	\$ 4,233
Change in accrual for purchases of property and equipment	\$ (3,124)	\$ 1,248

See Notes to Condensed Consolidated Financial Statements.

Table of Contents

ENDO PHARMACEUTICALS HOLDINGS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2006

1. BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission for interim financial information. In the opinion of management, the accompanying condensed consolidated financial statements of Endo Pharmaceuticals Holdings Inc. (the Company or we or Endo) and its subsidiaries, which are unaudited, include all normal and recurring adjustments necessary to present fairly the Company's financial position as of September 30, 2006 and the results of our operations and our cash flows for the periods presented. The accompanying condensed consolidated balance sheet as of December 31, 2005 is derived from the Company's audited 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, 2005 contained in the Company's Annual Report on Form 10-K. Certain prior period amounts, within the statements of operations and the statement cash flows, have been reclassified to conform to the current period presentation.

2. RECENT ACCOUNTING PRONOUNCEMENTS

In November 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 151, *Inventory Costs, an amendment of ARB No. 43, Chapter 4*. The purpose of this statement is to clarify the accounting of abnormal amounts of idle facility expense, freight, handling costs and waste material. ARB No. 43 stated that under some circumstances these costs may be so abnormal that they are required to be treated as current period costs. SFAS No. 151 requires that these costs be treated, as current period costs regardless if they meet the criteria of so abnormal. In addition, the statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provision of this Statement was effective for inventory costs incurred beginning on January 1, 2006. The adoption of SFAS No. 151 did not have a material impact on the Company's results of operations or financial position.

In December 2004, the FASB issued SFAS No. 153, *Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29*. SFAS No. 153 was effective for nonmonetary asset exchanges occurring after January 1, 2006. The adoption of SFAS No. 153 did not have a material impact on the Company's results of operations or financial position.

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections*, a replacement of APB Opinion No. 20 and Statement No. 3. SFAS 154 changes the requirements for the accounting and reporting of a change in accounting principle. SFAS No. 154 applies to all voluntary changes in accounting principle as well as to changes required by an accounting pronouncement that does not include specific transition provisions. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The adoption of SFAS No. 154 did not have a material impact on the Company's results of operations or financial position.

In July 2006, the FASB issued FASB Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109, Accounting for Income Taxes*. FIN 48 creates a single model to address uncertainty in tax positions. FIN 48 clarifies the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. In addition, FIN 48 clearly scopes out income taxes from SFAS No. 5, *Accounting for Contingencies*. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company is currently evaluating the impact of the adoption of this Interpretation on its financial statements.

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

In September 2006, the SEC staff issued Staff Accounting Bulletin No. 108 (SAB 108), *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*. SAB 108 was issued in order to

Table of Contents

eliminate the diversity of practice surrounding how public companies quantify financial statement misstatements. In SAB 108, the SEC staff established an approach that requires quantification of financial statement misstatements based on the effects of the misstatements on each of the company's financial statements and the related financial statement disclosures. This model is commonly referred to as a dual approach because it requires quantification of errors under both the iron curtain and the roll-over methods. SAB 108 permits existing public companies to initially apply its provisions either by (i) restating prior financial statements as if the dual approach had always been used or (ii) recording the cumulative effect of initially applying the dual approach as adjustments to the carrying values of assets and liabilities as of January 1, 2006 with an offsetting adjustment recorded to the opening balance of retained earnings. Use of the cumulative effect transition method requires detailed disclosure of the nature and amount of each individual error being corrected through the cumulative adjustment and how and when it arose. The Company does not expect the impact of the adoption of SAB 108 on its financial statements to be material.

3. INVENTORIES, NET

Inventories are comprised of the following at September 30, 2006 and December 31, 2005, respectively (in thousands):

	September 30,	December 31,
	2006	2005
Raw Materials	\$ 6,148	\$ 13,094
Work-in-Process	19,940	7,868
Finished Goods	42,266	30,021
Total	\$ 68,354	\$ 50,983

4. LICENSE AND COLLABORATION AGREEMENTS*DURECT Corporation*

In January 2006, DURECT and Endo entered into Amendment No. 3 to the DURECT CHRONOGESIC License Agreement. Prior to this amendment, in addition to other specified termination rights provided to both parties, the Agreement provided Endo with a right to terminate the Agreement starting January 1, 2006 in the event that DURECT had not commenced a specified clinical trial for the CHRONOGESICTM product candidate on or before January 1, 2006, *provided that* Endo provided DURECT written notice of such termination prior to January 31, 2006. Under Amendment No. 3, the foregoing termination right was amended to provide Endo with the right to terminate the Agreement in the event that (i) DURECT had not delivered to Endo on or before March 31, 2007 a written notice that a human pharmacokinetic trial had been completed with the CHRONOGESICTM product candidate, together with a full study report of the results of the trial or (ii) Endo, determines, in its sole discretion, to terminate the Agreement during the sixty-day period after DURECT's delivery of such notice, *provided that*, in each case Endo delivers to DURECT its written notice of termination prior to April 30, 2007. Under Amendment No. 3, Endo shall not be responsible for any development costs for the CHRONOGESICTM product candidate prior to May 1, 2007. Commencing on May 1, 2007, unless the Agreement is earlier terminated by Endo, Endo will fund 50% of the ongoing development costs for the CHRONOGESICTM product candidate in accordance with the terms of the Agreement.

Noven Pharmaceuticals, Inc.

On March 2, 2006, we amended our license agreement with Noven, effective as of December 31, 2005, to terminate the provisions of the agreement applicable to the generic fentanyl patch product. As part of such amendment, Endo received a right of first negotiation for certain future generic fentanyl patch products that Noven may develop.

ZARS Pharma

On January 6, 2006, we entered into an agreement with ZARS Pharma for the North American rights to SyneraTM (lidocaine 70 mg and tetracaine 70 mg) topical patch. SyneraTM is for use on intact skin to provide local dermal anesthesia in children and adults. Approved by the U.S. Food and Drug Administration on June 23, 2005, SyneraTM became commercially available in June 2006.

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

Under the terms of this agreement, we paid ZARS an upfront fee of \$11 million and \$8 million upon the commercial launch of the product in June 2006, both of which we capitalized as an intangible asset during the nine months ended September 30, 2006 representing the fair value of these rights, and we may be required to make additional payments to ZARS of up to approximately \$19 million upon achievement of certain milestones. We are amortizing this intangible asset over its

Table of Contents

estimated useful life of 10 years. We are also required to pay ZARS royalties on net sales of SyneraTM. As of September 30, 2006, we have deferred the recognition of net sales of Synera of approximately \$1.3 million.

SkyePharma, Inc.

SkyePharma, Inc. and the Company have decided to discontinue their development and commercialization of the Propofol IDD-DTM product candidate due to developmental challenges encountered in attempting to achieve the targeted product profile. This decision does not affect the companies' agreement related to DepoDur[®].

5. GOODWILL AND OTHER INTANGIBLES

Our goodwill and other intangible assets consist of the following at September 30, 2006 and December 31, 2005, respectively (in thousands):

	September 30, 2006	December 31, 2005
Goodwill	\$ 181,079	\$ 181,079
Amortizable Intangibles:		
Licenses	\$ 131,100	\$ 112,100
Patents	3,200	3,200
	134,300	115,300
Less accumulated amortization	(22,696)	(16,235)
Other Intangibles, net	\$ 111,604	\$ 99,065

Goodwill and other intangibles represent a significant portion of our assets and stockholders' equity. As of September 30, 2006, goodwill and other intangibles comprised approximately 20% of our total assets and 29% of our stockholders' equity. During the nine months ended September 30, 2006, licenses increased by \$19 million as a result of the acquisition of the rights to Synera (See Note 4). SFAS No. 142, Goodwill and Other Intangible Assets, prescribes a two-step method for determining goodwill impairment. In the first step, we determine the fair value of our one reporting unit. If the net book value of our reporting unit exceeds the fair value, we would then perform the second step of the impairment test which requires allocation of our reporting unit's fair value to all of its assets and liabilities in a manner similar to a purchase price allocation, with any residual fair value being allocated to goodwill. An impairment charge will be recognized only when the implied fair value of our reporting unit's goodwill is less than its carrying amount. As a result of the significance of goodwill, our results of operations and financial position in a future period could be negatively impacted should an impairment of goodwill occur.

We have one reportable segment, pharmaceutical products. Goodwill arose as a result of the August 26, 1997 acquisition of certain branded and generic pharmaceutical products, related rights and certain assets of the then DuPont Merck Pharmaceutical Company (n/k/a Bristol-Myers Squibb Pharma Company) and our July 17, 2000 acquisition of Algos Pharmaceutical Corporation, or Algos. Although goodwill arose in two separate transactions, the components of our operating segment have been integrated and are managed as one reporting unit. Our components extensively share assets and other resources with the other components of our business and have similar economic characteristics. In addition, our components do not maintain discrete financial information. Accordingly, the components of our business have been aggregated into one reporting unit and are evaluated as such for goodwill impairment. Goodwill is evaluated for impairment on an annual basis on January 1st of each year unless events or circumstances indicate that an impairment may have occurred between annual dates. On January 1, 2006 and 2005, our goodwill was evaluated for impairment and, based on the fair value of our reporting unit, no impairment was identified.

The cost of licenses are either expensed immediately or, if capitalized, are stated at cost, less accumulated amortization and are amortized using the straight-line method over their estimated useful lives ranging from ten to twenty years, with a weighted average useful life of approximately 15 years. The determination to capitalize amounts related to licenses is based on management's judgments with respect to stage of development, the nature of the rights acquired, alternative future uses, developmental and regulatory issues and challenges, the net realizable value of such amounts based on projected sales of the underlying products, the commercial status of the underlying products and/or various other competitive factors. We determine amortization periods for licenses based on our assessment of various factors impacting estimated useful lives and cash flows of the acquired rights. Such factors include the expected launch date of the product, the strength of the intellectual property protection of

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

the product and various other competitive, developmental and regulatory issues, and contractual terms. Significant changes to any of these factors may result in a reduction in the useful life of the license and an acceleration of related amortization expense, which could cause our operating income, net income and earnings per share to decrease. The value of these licenses is subject to continuing scientific, medical and marketplace uncertainty. During the nine months ended

Table of Contents

September 30, 2005, the Company expensed \$20 million with respect to the acquisitions of marketing and development license rights for two products that are currently in development. We expensed the cost of these license rights based on the fact that we acquired both marketing and development rights for products that do not have regulatory approval and that do not have currently identifiable alternative future uses. As such, it was determined that the cost of the right to develop the products and the cost of the right to market the products were inextricably linked and therefore expensed in the accompanying financial statements. Patents acquired in the Algos merger are stated at cost, less accumulated amortization, and are amortized using the straight-line method over their estimated useful lives of seventeen years.

Licenses and patents are assessed for impairment, in accordance with Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS No. 144), whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. The impairment testing involves comparing the carrying amount of the asset to the forecasted undiscounted future cash flows of the product. In the event the carrying value of the asset exceeds the undiscounted future cash flows of the product and the carrying value is not considered recoverable, an impairment exists. An impairment loss is measured as the excess of the asset's carrying value over its fair value, calculated using a discounted future cash flow method. An impairment loss would be recognized in net income in the period that the impairment occurs. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. As a result of the significance of our amortizable intangibles, any recognized impairment loss could have a material adverse impact on our financial position and/or results of operations. During the nine months ended September 30, 2006, due to the delay in the anticipated commercial success of DepoDur®, we evaluated our SkyePharma intangible asset, which had a net book value of \$15.1 million at September 30, 2006, for impairment and determined that an impairment did not exist at such time. However, we will continue to monitor this asset, and a continued lack of forecasted commercial success could lead to an impairment loss in a future period.

Estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2005 is as follows (in thousands):

2006	\$ 8,756
2007	9,177
2008	9,177
2009	9,177
2010	9,177

6. NOTE RECEIVABLE

In July 2004, we entered into a license agreement and a loan agreement with Vernalis Development Limited, or Vernalis, under which Vernalis agreed to exclusively license to us rights to market Frova® (frovatriptan) in North America. Under the loan agreement, we provided Vernalis with a loan of \$50 million in August 2004. The loan was primarily used to make a payment in full and final settlement of the amounts due to Elan Corporation from Vernalis in connection with Vernalis' reacquisition of the North American rights to Frova®. At our election, we are able to offset \$20 million of the \$40 million menstrual migraine indication approval milestone and 50% of all royalties to be paid under the license agreement to Vernalis to repay the loan. To the extent not previously repaid, the loan is due in full after five years. Interest is at the rate of 5% per annum payable semi-annually. However, Vernalis has the option to defer payment of interest and increase the loan outstanding each time an interest payment becomes due. Vernalis has elected to defer the payment of the first four semi-annual interest amounts otherwise due January 31 and July 31 totaling approximately \$5.0 million.

We estimated that an approximate fair market rate of interest for this type of secured loan was 8% per annum and therefore recorded the note receivable at its present value at inception of \$43.8 million. The note receivable is being accreted up to its face amount at maturity using the effective interest method, and thus the effective interest rate over the five-year term will be 8% per annum. The difference of \$6.2 million between the face amount of the note and its present value at inception was treated as additional consideration paid to acquire the license rights and has been included in Other Intangibles.

7. COMPREHENSIVE INCOME

Comprehensive income includes the following components for the three and nine months ended September 30, 2006 and 2005 (in thousands):

Table of Contents

	Three Months Ended		Nine Months Ended	
	September 30, 2006	September 30, 2005	September 30, 2006	September 30, 2005
Net income	\$ 44,891	\$ 66,553	\$ 123,065	\$ 129,414
Other comprehensive income:				
Unrealized gains/(losses) on securities, net of tax	218	1,667	(918)	3,381
Total comprehensive income	\$ 45,109	\$ 68,220	\$ 122,147	\$ 132,795

8. COMPENSATION RELATED TO STOCK OPTIONS**Endo Pharma LLC 1997 Executive and Employee Stock Option Plans and Endo Pharma LLC 2000 Supplemental Executive and Employee Stock Option Plans**

On November 25, 1997, the Company established the 1997 Employee Stock Option Plan and the 1997 Executive Stock Option Plan (collectively, the 1997 Stock Option Plans). On July 17, 2000, the 1997 Stock Option Plans were amended and restated. The Endo Pharma LLC 1997 Stock Option Plans are these amended and restated 1997 Stock Options Plans and reserved an aggregate of 25,615,339 shares of common stock of the Company held by Endo Pharma LLC for issuance. Stock options granted under the Endo Pharma LLC 1997 Stock Option Plans expire on August 26, 2007. Upon exercise of these stock options, only currently outstanding shares of common stock of the Company held by Endo Pharma LLC are issued. Exercise of these stock options has not and will not result in the issuance of additional shares in the Company and does not dilute the ownership interests of our public stockholders.

Pursuant to the Algos merger and related recapitalization of the Company on July 17, 2000, the Endo Pharma LLC 2000 Supplemental Stock Option Plans were established. The Endo Pharma LLC 2000 Supplemental Stock Option Plans reserved an aggregate of 10,672,314 shares of common stock of the Company held by Endo Pharma LLC for issuance. Stock options granted under the Endo Pharma LLC 2000 Supplemental Stock Option Plans expire on August 26, 2007. The Endo Pharma LLC 2000 Supplemental Stock Option Plans became effective on January 1, 2003, resulting in the issuance of 10,672,314 stock options to certain employees and members of management. No additional shares of Company common stock have been or will be issued as a result of the exercise of these stock options, because these stock options are exercisable only into shares of Company common stock that are held by Endo Pharma LLC. Accordingly, exercise of these stock options has not and will not result in the issuance of additional shares in the Company and does not dilute the ownership interests of our public stockholders.

Endo Pharmaceuticals Holdings Inc. 2000 and 2004 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. As of September 30, 2006, only stock options have been awarded under both plans. Stock options granted under the 2000 and 2004 Stock Incentive Plans generally vest over four years and expire ten years from the date of grant. Unlike the stock options granted under the Endo Pharma LLC Stock Option Plans, the exercise of the stock options granted pursuant to the Endo Pharmaceuticals Holdings Inc. 2000 and 2004 Stock Incentive Plans will dilute the ownership interests of our public stockholders.

Stock-Based Compensation

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

Table of Contents

January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of Statement No. 123(R). Results for prior periods have not been restated.

As a result of adopting Statement No. 123(R) on January 1, 2006, the Company's income before income taxes and net income for the three months ended September 30, 2006, are \$3.8 million (\$3.3 million in selling, general and administrative expenses and \$0.5 million in research and development expenses) and \$2.3 million lower, respectively, and for the nine months ended September 30, 2006, are \$9.3 million (\$8.2 million in selling, general and administrative expenses and \$1.1 million in research and development expenses) and \$5.8 million lower, respectively, than if it had continued to account for share-based compensation under Opinion 25. Basic and diluted earnings per share for the three months ended September 30, 2006 are both \$0.02 lower, and for the nine months ended September 30, 2006 are both \$0.04 lower, than if the Company had not adopted Statement No. 123(R).

Prior to the adoption of Statement No. 123(R), the Company presented all tax benefits of deductions resulting from the exercise of stock options as operating cash flows in the Statement of Cash Flows. Statement No. 123(R) requires the cash flows resulting from the tax benefits resulting from tax deductions in excess of the compensation cost recognized for those options (excess tax benefits) to be classified as financing cash flows. The \$32.1 million excess tax benefit classified as a financing cash inflow would have been classified as an operating cash inflow if the Company had not adopted Statement No. 123(R).

The following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of Statement No. 123 to options granted under the Company's stock-based compensation plans for the three and nine months ended September 30, 2005 (in thousands, except per share data). For purposes of this pro forma disclosure, the value of the options is estimated using a Black-Scholes option-pricing model and amortized to expense over the options' vesting periods.

	Three Months Ended September 30, 2005	Nine Months Ended September 30, 2005
Net income, as reported	\$ 66,553	\$ 129,414
Deduct: Total stock-based employee compensation expense determined under fair value based methods for all awards	(1,865)	(5,437)
Add: Tax effect of stock-based employee compensation expense under fair value based methods	710	2,066
Pro forma net income	\$ 65,398	\$ 126,043
Basic earnings per share, as reported	\$ 0.50	\$ 0.98
Basic earnings per share, pro forma	\$ 0.49	\$ 0.95
Diluted earnings per share, as reported	\$ 0.50	\$ 0.97
Diluted earnings per share, pro forma	\$ 0.49	\$ 0.95
Weighted average shares outstanding		
Basic	132,376	132,075
Diluted	133,532	133,122

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

A summary of the activity under 2000 and 2004 Stock Incentive Plans for the nine months ended September 30, 2006 is as follows:

Table of Contents

			Weighted	
	Number of	Weighted	Average	Aggregate
	Shares	Average	Remaining	Intrinsic
		Exercise Price	Contractual Term	Value
Outstanding, January 1, 2006	3,299,430	\$ 14.78		
Granted	1,549,865	\$ 28.93		
Exercised	(595,940)	\$ 10.58		
Forfeited	(185,147)	\$ 22.50		
Expired	(5,972)	\$ 18.56		
Outstanding, September 30, 2006	4,062,236	\$ 20.44	7.92	\$ 49,233,588
Vested and expected to vest, September 30, 2006	3,895,024	\$ 20.20	7.88	\$ 48,119,376
Exercisable, September 30, 2006	1,594,137	\$ 13.74	6.63	\$ 29,978,763

The total intrinsic value of options exercised during the nine months ended September 30, 2006 was \$12.5 million. The weighted-average grant date fair value of the stock options granted in the nine months ended September 30, 2006 and 2005 were \$15.69 per option and \$11.02 per option, respectively, determined using the following assumptions:

	2006	2005
Average expected term (years)	6.25	5.0
Risk-free interest rate	4.61%	3.69%
Dividend yield	0.00	0.00
Expected volatility	50%	58%

As of September 30, 2006, the total remaining unrecognized compensation cost related to non-vested stock options amounted to \$29.5 million. The weighted average remaining requisite service period of the non-vested stock options was 2.8 years. This unrecognized compensation cost does not include the impact of any future stock-based compensation awards.

A summary of the activity under the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans for the nine months ended September 30, 2006 is as follows:

			Weighted	
	Number of	Weighted	Average	Aggregate
	Shares	Average	Remaining	Intrinsic
		Exercise Price	Contractual Term	Value
Outstanding, January 1, 2006	2,809,265	\$ 2.42		
Granted		\$		
Exercised	(2,474,007)	\$ 2.42		
Forfeited	(182)	\$ 2.42		
Outstanding, vested and exercisable, September 30, 2006	335,076	\$ 2.42	0.35	\$ 10,095,840

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

As of September 30, 2006, there was no remaining unrecognized compensation cost related to non-vested stock options granted pursuant to the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans.

9. RELATED PARTY TRANSACTIONS

Tax Sharing Agreement. On July 14, 2000, Endo Pharma LLC was formed in connection with the Algos merger to ensure that the stock options granted pursuant to the Endo Pharma LLC Stock Option Plans diluted only the Endo common stock held by persons and entities that held such shares prior to our merger with Algos. Endo Pharma LLC is a limited liability company that held approximately 15% of our common stock at December 31, 2005 but less than 1% of our common stock as of September 30, 2006, in which affiliates of Kelso & Company and certain members of management have an interest. Upon the exercise of these stock options, only currently outstanding shares of our common stock held by Endo Pharma LLC have been and will be delivered. Because Endo Pharma LLC, and not us, has been and will provide the shares upon the exercise of these options, we have entered into a tax sharing agreement with Endo Pharma LLC under which we are required to pay to Endo Pharma LLC the amount of the tax benefits usable by us as a result of the exercise of these stock options into shares of our common stock held by Endo Pharma LLC. As of September 30, 2006, approximately 35 million of these stock options had been exercised into shares of our common stock held by Endo Pharma LLC. Upon exercise of any of these Endo Pharma LLC stock options, we generally will be permitted to deduct as a compensation charge, for federal

Table of Contents

income tax purposes, an amount equal to the difference between the market price of our common stock and the exercise price paid upon exercise of these options (as of September 30, 2006, approximately \$747 million), which is estimated to result in a tax benefit amount of approximately \$288 million. Under the tax sharing agreement, we are required to pay this \$288 million, \$153 million of which has already been paid as of September 30, 2006, to Endo Pharma LLC to the extent that a compensation charge deduction is usable by us to reduce our taxes and based upon the assumption that all other deductions of Endo are used prior thereto. Additionally, as part of the tax sharing agreement, Endo Pharma LLC will reimburse us for the after-tax employer payroll taxes paid by us as a result of the exercise of the 35 million options discussed above. We have paid approximately \$11 million in employer payroll taxes, of which Endo Pharma LLC will reimburse us for approximately \$7 million which represents the after-tax employer payroll tax paid by us for the periods from 2001 through September 30, 2006. As of September 30, 2006, our net liability due to Endo Pharma LLC is approximately \$128.1 million, approximately \$99.1 million of which was paid in October 2006. All payments made and accrued pursuant to the tax sharing agreement have been reflected as a reduction of stockholders' equity in the accompanying financial statements. The estimated tax benefit amount payment to Endo Pharma LLC attributable to Endo Pharma LLC stock options exercised may increase if certain holders of Endo Pharma LLC stock options exercise additional stock options in the future.

During the nine months ended September 30, 2006, approximately 2.5 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised. Since the attributable compensation charge deductions are usable to reduce our taxes in 2006, we are obligated, under our amended tax sharing agreement, to pay to Endo Pharma LLC an additional tax benefit amount of approximately \$29 million, which is included in our net liability due to Endo Pharma LLC of \$128.1 million referred to above. Fifty percent of the estimated tax benefit amount attributable to these exercises and any additional tax benefits attributable to the exercise of stock options granted under the Endo Pharma LLC stock option plans in 2006 will be due within 15 business days of the date we receive an opinion on our final audited 2006 financial statements from our independent registered public accounting firm, and the remaining tax benefit amount attributable to 2006 is due within 30 business days of the date on which we file our 2006 tax return with the Internal Revenue Service.

As of September 30, 2006, there were approximately 0.3 million stock options remaining to be exercised under the Endo Pharma LLC stock option plans. Using a weighted average exercise price of \$2.42 per share and an assumed tax rate of 38.25%, if all of these remaining stock options under the Endo Pharma LLC stock option plans were vested and exercised, and assuming the price of our common stock was \$32.55 per share, the closing price on September 29, 2006, we would generally be able to deduct, for income tax purposes, compensation of approximately \$9 million, which could result in a tax benefit amount of approximately \$3 million payable to Endo Pharma LLC in 2007 and beyond.

As of September 30, 2006, there were approximately 0.8 million stock options remaining to be granted under the Endo Pharma LLC stock option plans. Using a weighted average exercise price of \$2.42 per share and an assumed tax rate of 38.25%, if all of these remaining stock options under the Endo Pharma LLC stock option plans were granted, vested and exercised, and assuming the price of our common stock was \$32.55 per share, the closing price on September 29, 2006, we would generally be able to deduct, for income tax purposes, compensation of approximately \$24 million, which could result in a tax benefit amount of approximately \$9 million payable to Endo Pharma LLC in 2007 and beyond (See *Executive Compensation* below).

Settlement of Contingent Obligation. During the nine months ended September 30, 2005, the Company reached an agreement with an individual to compensate him a total of \$2 million for past services rendered to the Company. This agreement was finalized in May 2005, and the \$2 million was recorded in selling, general and administrative expenses during the nine months ended September 30, 2005. Endo Pharma LLC made these payments totaling \$2 million on behalf of the Company, and they have been treated as capital contributions by Endo Pharma LLC.

Executive Compensation. In March 2006, Endo Pharma LLC advised our board of directors that it intended to pay a one-time cash bonus to each of Mr. Peter Lankau, our President and Chief Executive Officer, Ms. Caroline Manogue, our Executive Vice President, Chief Legal Officer and Secretary, and Mr. Jeffrey Black, our former Executive Vice President, Chief Financial Officer and Treasurer in the amount of \$3 million, \$6 million and \$10 million, respectively, in recognition of their significant contributions to our success. These bonus payments have been recorded in selling, general and administrative expenses during the nine months ended September 30, 2006. These payments were made by the Company in April 2006 and repaid to us by Endo Pharma LLC in the third quarter of 2006. In addition, only a portion of these bonus payments will be deductible for federal and state income tax purposes. We are not required to pay nor will we pay to Endo Pharma LLC the amount of any of the tax benefits related to these bonus payments pursuant to the Tax Sharing Agreement between us and Endo Pharma LLC. These bonuses will be funded entirely by Endo Pharma LLC, with no contribution by us and they have been treated as a capital contribution by Endo Pharma LLC.

Endo Pharma LLC has also informed us that, in connection with its eventual winding up, it would make a special allocation to Ms. Carol Ammon, our Chairman of the Board and former Chief Executive Officer, of approximately \$22

Table of Contents

million, with all or a portion of Ms. Ammon's payment being satisfied by granting to her the remaining unallocated Endo Pharma LLC stock options of approximately 0.8 million shares under the Endo Pharma LLC stock option plans. This amount has been recorded in selling, general and administrative expenses during the nine months ended September 30, 2006 and as a capital contribution by Endo Pharma LLC. This grant of options to Ms. Ammon is currently expected to be made in the last quarter of 2006, as determined by Endo Pharma LLC. The exercise of these stock options (assuming they are granted and exercised) will result in compensation charges which we will be permitted to deduct for income tax purposes. Under the terms of the Tax Sharing Agreement, we would be required to pay to Endo Pharma LLC the amount of the tax benefit usable by us as a result of the exercise of these stock options into shares of our common stock held by Endo Pharma LLC. Upon the exercise of the stock options granted under the Endo Pharma LLC stock option plans, only currently outstanding shares of our common stock held by Endo Pharma LLC will be received by holders of such options upon exercise. The exercise of stock options pursuant to Endo Pharma LLC stock option plans does not increase the number of our shares outstanding, and only dilutes the equity holdings of the members of Endo Pharma LLC and not the equity holdings of our other stockholders. If the 0.8 million stock options are granted and exercised by Ms. Ammon, using a weighted average exercise price of \$2.42 per share and an assumed tax rate of 38.25%, and assuming the price of our common stock was \$32.55 per share, the closing price on September 29, 2006, we would generally be able to deduct, for income tax purposes, compensation of approximately \$24 million, which could result in a tax benefit amount of approximately \$9 million payable to Endo Pharma LLC in 2007 and beyond.

10. COMMITMENTS AND CONTINGENCIES

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

Novartis Consumer Health, Inc.

On May 3, 2001, we entered into a long-term manufacturing and development agreement with Novartis Consumer Health, Inc. whereby Novartis has agreed to manufacture certain of our commercial products and products in development. We are required to purchase, on an annual basis, a minimum amount of product from Novartis. The purchase price per product is equal to a predetermined amount per unit, subject to periodic adjustments. This agreement initially had a five-year term, with automatic five-year renewals thereafter. In August 2005, we extended this agreement until 2011, with automatic five-year renewals thereafter. We are required to purchase a minimum of \$7.8 million per year through December 31, 2009. Either party may terminate this agreement on three-years' notice, effective at any time after December 31, 2006. In addition, should we terminate this agreement effective prior to December 31, 2011 upon three-years' notice, we must pay Novartis certain early termination fees. Either party may also terminate this agreement on account of a material breach by the other.

Teikoku Seiyaku Co., Ltd.

Under the terms of this agreement, Teikoku, a Japanese manufacturer, manufactures Lidoderm® at its Japanese facility for commercial sale by us in the United States. We also have an option to extend the supply area to other territories within a defined period of time. The purchase price for the product is equal to a predetermined amount per unit of product. The term of this agreement is from November 23, 1998 until the shorter of (1) the expiration of the last to expire patent that is licensed to us from Hind Healthcare Inc. or (2) November 20, 2011. This agreement may be terminated for material breach by either party and by us if the Hind Healthcare license agreement is terminated.

Mallinckrodt Inc.

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

General

In addition to the manufacturing and supply agreements described above, we have agreements with (1) UPS Supply Chain Solutions, Inc. (f/d/b/a Livingston Healthcare Services, Inc.) for customer service support, warehouse and distribution services and certain financial functions that expires in 2010, (2) Kunitz and Associates Inc. for assistance with adverse event reporting and (3) PPD Development, LP for clinical

development services, business development support and medical

Table of Contents

information services. Although we have no reason to believe that these agreements will not be honored, failure by any of these third parties to honor their contractual obligations may have a materially adverse effect on our business, financial condition and/or results of operations.

License Agreements, Milestones and Royalties

Hind Healthcare Inc.

Under the terms of the Hind License Agreement, royalties are recorded as a reduction to net sales due to the nature of the license agreement and the characteristics of the license involvement by Hind in Lidoderm®. The royalty rate is 10% of net sales through the shorter of (1) the expiration of the last licensed patent or (2) November 20, 2011, including a minimum royalty of at least \$500,000 per year. During the three months ended September 30, 2006 and 2005, we accrued \$14.1 million and \$13.7 million for these royalties to Hind, respectively. During the nine months ended September 30, 2006 and 2005, we accrued \$43.5 million and \$31.9 million for these royalties to Hind, respectively.

Penwest Pharmaceuticals

Under the terms of the amended and restated strategic alliance agreement with Penwest Pharmaceuticals Co. (Penwest), Penwest is entitled to receive royalties equal to a percentage beginning at 50%, which could decline to 40% based upon the achievement of certain criteria, of the net realization (as defined in the agreement) of oxymorphone ER, now known as Opana® ER. 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 this product on account of their concern about their ability to access external capital funding opportunities in the future. Accordingly, we were responsible for funding 100% of the remaining costs of bringing Opana® ER to market, which was approved by the FDA in June 2006 and launched in July 2006. We expect to recoup, from the future royalties due to Penwest, the full amount of what Penwest should have contributed in the pre-approval period had it not exercised such right. As September 30, 2006, no recoveries from Penwest have been recorded. In August 2006, Penwest announced that it intended to initiate the formal dispute resolution process provided for under the terms of the contract that governs the companies' agreement for Opana® ER. While Penwest acknowledged that it owes to us Penwest's share of the development costs relating to Opana® ER from the pre-launch period beginning on March 18, 2003, the companies hold different interpretations of the contract language for the post-launch period. In particular, Penwest views that it has no obligation to reimburse us for any of the losses incurred during the launch phase of Opana® ER. In addition, we will recognize 100% of the losses attributable to Opana® ER during its launch phase but expect to recover Penwest's share of these losses from the expected future profits of Opana® ER, which will be recognized as an increased share of the profits at that time. After reviewing the matter and consulting with our outside legal counsel, we believe the agreement supports the position that both partners should share equally in not only the profits but also any losses incurred from the up-front costs associated with launching the product prior to its achieving profitability. While we anticipate that the mediation process will facilitate further discussion, and we believe that our position will prevail, there is no assurance that the parties will reach an acceptable conclusion to this issue without resorting to arbitration. As of September 30, 2006, we have deferred the recognition of net sales of Opana ER and Opana of approximately \$12.7 million.

DURECT Corporation

In January 2006, DURECT and Endo entered into Amendment No. 3 to the DURECT CHRONOGESIC License Agreement. Prior to this amendment, in addition to other specified termination rights provided to both parties, the Agreement provided Endo with a right to terminate the Agreement starting January 1, 2006 in the event that DURECT had not commenced a specified clinical trial for the CHRONOGESIC™ product candidate on or before January 1, 2006, *provided that* Endo provided DURECT written notice of such termination prior to January 31, 2006. Under Amendment No. 3, the foregoing termination right was amended to provide Endo with the right to terminate the Agreement in the event that (i) DURECT had not delivered to Endo on or before March 31, 2007 a written notice that a human pharmacokinetic trial had been completed with the CHRONOGESIC™ product candidate, together with a full study report of the results of the trial or (ii) Endo, determines, in its sole discretion, to terminate the Agreement during the sixty-day period after DURECT's delivery of such notice, *provided that*, in each case Endo delivers to DURECT its written notice of termination prior to April 30, 2007. Under Amendment No. 3, Endo shall not be responsible for any development costs for the CHRONOGESIC™ product candidate prior to May 1, 2007. Commencing on May 1, 2007, unless the Agreement is earlier terminated by Endo, Endo will fund 50% of the ongoing development costs for the CHRONOGESIC™ product candidate in accordance with the terms of the Agreement. Endo will also reimburse DURECT for a portion of its prior development costs upon the achievement of certain milestones. Milestone payments made by Endo under the DURECT CHRONOGESIC License Agreement could total up to \$52.0 million. Endo and DURECT will share profits equally, based on projected financial performance of CHRONOGESIC. In addition, the DURECT CHRONOGESIC License Agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. The DURECT CHRONOGESIC License Agreement generally lasts until the underlying patents on the product expire. With

Table of Contents

respect to termination rights, the DURECT CHRONOGESIC License Agreement permits Endo to terminate its continued participation under a number of circumstances, one of which could require Endo to pay DURECT up to \$10.0 million.

On March 14, 2005, we announced that we signed an agreement that gives us the exclusive license to develop and commercialize DURECT's sufentanil-containing transdermal patch in the U.S. and Canada (the DURECT Sufentanil Agreement). The sufentanil patch, which is in early-stage clinical development, is intended to provide relief of moderate-to-severe chronic pain for up to seven days. We have assumed all remaining development and regulatory filing responsibility for this product, including the funding thereof. Under the terms of the DURECT Sufentanil Agreement, in April 2005, we paid DURECT a \$10 million upfront fee, which was expensed as research and development in the first quarter of 2005, with additional payments of approximately \$35 million upon achievement of predetermined regulatory and commercial milestones. We will also pay royalties to DURECT on net sales of the sufentanil transdermal patch. In addition, the DURECT Sufentanil Agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. The DURECT Sufentanil Agreement will continue in effect until terminated. The DURECT Sufentanil Agreement provides each party with specified termination rights, including the right of each party to terminate the DURECT Sufentanil Agreement upon material breach of the DURECT Sufentanil Agreement by the other party and the right of Endo to terminate the DURECT Sufentanil Agreement at any time without cause subject to a specified notice period.

SkyePharma, Inc.

Under the terms of our agreement with SkyePharma, we are required to pay to SkyePharma a share of DepoDur® sales revenue, which share may increase from 20% initially, to a maximum of 60%, of net sales as sales achieve certain thresholds. In addition, future milestone payments of \$15 million and \$20 million may be due SkyePharma in the first calendar year in which net sales of DepoDur® exceed \$125 million and \$175 million, respectively. Under the terms of the agreement, SkyePharma supplies the finished product to us. In July 2006, SkyePharma announced that their independent audit report included in the Company's UK Annual Report and Annual Report on Form 20-F for the year ended December 31, 2005 contained an explanatory paragraph relating to the Company's ability to continue as a going concern. In the event of any interruption in the manufacture and supply of this product, there can be no assurance that we could make alternative arrangements on a timely basis, if at all. Such interruption could impact our results of operations and lead to an impairment of our SkyePharma license intangible asset, which has a net book value of approximately \$15.1 million at September 30, 2006.

In addition, this agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. This agreement generally lasts until the underlying patents on the product expire. With respect to termination rights, this agreement permits Endo to terminate its continued participation under a number of circumstances, one of which could have required us to pay SkyePharma \$5.0 million.

EpiCept Corp.

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

Vernalis Development Limited

Under the terms of our license agreement with Vernalis, under which Vernalis agreed to exclusively license to us rights to market the product Frova® (frovatriptan) in North America, we will make anniversary payments for the first two years of \$15 million in 2005 and 2006 (the first \$15 million anniversary payment was made in September 2005), and a \$40 million milestone payment upon FDA approval for the menstrual migraine indication for Frova®. At our election, we are able to offset \$20 million of the \$40 million menstrual migraine indication approval milestone and 50% of all royalties to be paid under the license agreement to repay the \$50 million loan we provided to Vernalis in August 2004 (See Note 6). In addition, Vernalis will receive one-time milestone payments for achieving defined annual net sales targets. These sales milestone payments increase based on increasing net sales targets ranging from a milestone of \$10 million on \$200 million in net sales to a milestone of \$75 million on \$1.2 billion in net sales. These sales milestones could total up to \$255 million if all of the defined net sales targets are achieved. Under the terms of the license agreement, we will begin paying royalties to Vernalis based on the net sales of Frova® after January 1, 2007. 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, is related to our license agreement with Vernalis. Pursuant to the license agreement, Vernalis had retained rights to co-promote Frova® in the United States. Vernalis has exercised its co-promotion option, and the co-promotion agreement, as amended, sets forth the certain specific terms and conditions governing such co-promotion and amends, restates and supersedes certain sections of the

Table of Contents

license agreement. Under the terms of both the license and co-promotion agreements, both as amended, we reimburse Vernalis for certain defined costs of their sales personnel beginning in January 2006.

Orexo AB

Our agreement with Orexo provides for us to make additional license fees and payments based on development and regulatory milestones, which may total up to \$22.1 million through FDA approval of Rapinyl's New Drug Application, \$12.5 million of which has been recorded through September 30, 2006, \$5.2 million of which has been included in research and development expense during the nine months ended September 30, 2006. This agreement also provides for royalties upon commercial sales and may include sales milestones, up to \$39.2 million, if defined sales thresholds are achieved. In addition, this license agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of this license agreement is until the later of (i) the expiration of the applicable patents or (ii) the expiration of any market exclusivity right related to Rapinyl. We can terminate the license agreement under certain circumstances, including upon six months' written notice, and we may be required to pay a termination fee of up to \$750,000.

ProEthic Pharmaceuticals, Inc.

On March 14, 2005, we entered into an agreement with ProEthic Pharmaceuticals, Inc. for the U.S. and Canadian rights to develop and commercialize a once-daily ketoprofen-containing topical patch. Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID) generally used for the treatment of inflammation and pain and currently available in the U.S. only in oral form. Currently in Phase II clinical trials in the U.S., the ketoprofen patch is being developed for the localized treatment of acute pain associated with soft-tissue injuries such as tendonitis or joint sprains and strains. Under the terms of the agreement, in March 2005, we made a \$10 million upfront payment, which was expensed as research and development during the nine months ended September 30, 2005, we recorded a \$5 million milestone payment during the nine months ended September 30, 2006 based upon the achievement of certain criteria which has been included in research and development expense, and we could be required to make additional payments of approximately \$8 million for the achievement of certain regulatory and other milestones. We will also pay royalties on net sales of the ketoprofen patch. In addition, the license agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of this license agreement shall be until the later of (i) the expiration of the applicable patents or (ii) the tenth (10th) anniversary of the date of the first commercial sale of the product. We can terminate the agreement at any time upon no more than ninety (90) days' written notice.

Zars Pharma

On January 6, 2006, we entered into an agreement with ZARS Pharma for the North American rights to Synera™ (lidocaine 70 mg and tetracaine 70 mg) topical patch. Synera™ is for use on intact skin to provide local dermal anesthesia in children and adults. Approved by the FDA on June 23, 2005, Synera™ became commercially available in June 2006. Under the terms of this agreement, we paid ZARS an upfront fee of \$11 million and another \$8 million in June 2006 upon the first commercial shipment of the product, both of which were capitalized as an intangible asset during the nine months ended September 30, 2006, and we may be required to make additional payments to ZARS of up to approximately \$19 million upon achievement of certain milestones. We are also required to pay ZARS royalties on net sales of Synera™.

Life Sciences Opportunities Fund (Institutional) II, L.P.

On December 12, 2003, we entered into a subscription agreement to invest up to \$10 million into Life Sciences Opportunities Fund (Institutional) II, L.P., a Delaware limited partnership formed to carry out investments in life science companies. As part of this investment, we are able to capitalize on the knowledge of LOF Partners, LLC, the general partner, of and its access to, life sciences entities with promising pharmaceutical assets, technologies and management talent and on the general partner's wide range of industry contacts and resources. As of September 30, 2006, we have invested \$2.7 million in this partnership and are accounting for this investment utilizing the equity method.

Employment Agreements

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

Research Contracts

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

Table of Contents

Collaboration Agreements

We have also entered into certain collaboration agreements with third parties for the development of pain management products. Potential milestone payments pursuant to these contracts could total up to \$89 million. These agreements require us to share in the development costs of such products and grant marketing rights to us for such products. If our third party partners are unable or unwilling to fund their portion of the collaboration project with us, this may adversely affect our results of operations and cash flows in the foreseeable future.

Legal Proceedings

While we cannot predict the outcome of the following legal proceedings, we believe that the claims against us are without merit, and we intend to vigorously defend our position. An adverse outcome in any of these proceedings could have a material adverse effect on our current and future financial position and results of operations. No amounts have been accrued with respect to any of these unsettled legal proceedings at September 30, 2006.

Purdue Pharma L.P., et al. v. Endo Pharmaceuticals Inc., et al., Index No. 00 Civ. 8029 (SHS) (S.D.N.Y.); Purdue Pharma L.P., et al. v. Endo Pharmaceuticals Inc., et al., Index No. 01 Civ. 2109 (SHS) (S.D.N.Y.); Purdue Pharma L.P., et al. v. Endo Pharmaceuticals Inc., et al., Index No. 01 Civ. 8177 (SHS) (S.D.N.Y.)

On October 20, 2000, The Purdue Frederick Company and related companies (Purdue) filed suit against us and our subsidiary, Endo Pharmaceuticals Inc. (EPI), in the U.S. District Court for the Southern District of New York alleging that EPI's bioequivalent version of Purdue's OxyContin® (oxycodone hydrochloride extended-release tablets), 40mg strength, infringes three of its patents. This suit arose after EPI provided the plaintiffs with notice that its ANDA submission for a bioequivalent version of Purdue's OxyContin®, 40mg strength, challenged the listed patents for OxyContin® 40mg tablets. On March 13, 2001 and August 30, 2001, Purdue filed two more suits for infringement of the same patents against us and EPI in the Southern District of New York, in response to EPI's ANDA amendments adding bioequivalent versions of the 10, 20 and 80 mg strengths of OxyContin®. In each of the three cases, EPI pleaded counterclaims that the patents asserted by Purdue are invalid, unenforceable and/or not infringed by EPI's formulation of oxycodone hydrochloride extended-release tablets, and that Purdue violated antitrust laws by enforcing fraudulently procured patents.

The trial of the patent claims in all three of the suits against us and EPI concluded on June 23, 2003. On January 5, 2004, the district court issued an opinion and order holding that, while Endo infringes the three Purdue patents, the patents are unenforceable due to inequitable conduct. The district court dismissed the patent claims against us and EPI, declared the patents invalid, and enjoined Purdue from further enforcement of the patents. On June 7, 2005, the U.S. Court of Appeals for the Federal Circuit in Washington, D.C. affirmed the district court's decision that, while Endo's oxycodone extended-release tablets infringe the Purdue patents, the patents are unenforceable. On June 21, 2005, Purdue filed a petition with the Federal Circuit seeking rehearing of the appeal.

On February 1, 2006, the Federal Circuit granted Purdue's motion for rehearing, vacated the June 7, 2005 decision of the district court, and remanded the case to the district court for further proceedings. The Federal Circuit's decision on rehearing directed the district court to give further consideration to its previous finding of unenforceability due to inequitable conduct. The Federal Circuit also affirmed the district court's finding that EPI's oxycodone extended-release tablets infringe the Purdue patents.

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

Litigation similar to that described above may also result from products we currently have in development, as well as those that we may develop in the future. We, however, cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against us.

Table of Contents

Pricing Litigation

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

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

One previously reported case, *County of Erie v. Abbott Laboratories, Inc., et al.*, originally filed in the Supreme Court of the State of New York, Erie County, is now pending in the United States District Court for the Western District of New York. Two other previously reported cases containing similar allegations to the case brought by the County of Erie naming EPI and numerous other pharmaceutical companies, *County of Oswego v. Abbott Laboratories, Inc., et al.*, originally filed in the Supreme Court of the State of New York, Oswego County, and *County of Schenectady v. Abbott Laboratories, Inc., et al.*, originally filed in the Supreme Court of the State of New York, Schenectady County, are both now pending in the United States District Court for the Northern District of New York.

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

There is a previously reported case 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, and now removed to and pending in the United States District Court for the Southern District of Mississippi. Prior to removal, the State of Mississippi offered to enter an agreed order of dismissal with respect to Endo, and Endo filed a notice of acceptance of that offer in Hinds County Chancery Court. Endo is now listed as a terminated party for purposes of the litigation in the United States District Court for the Southern District of Mississippi.

The Company intends to contest all of these cases vigorously. Litigation similar to that described above may also be brought by other plaintiffs in various jurisdictions. However, we cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against the Company.

Other Legal Proceedings

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

Table of Contents**11. Earnings Per Share**

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

	Three Months Ended		Nine Months Ended	
	September 30, 2006	September 30, 2005	September 30, 2006	September 30, 2005
Numerator:				
Net income available to common stockholders	\$ 44,891	\$ 66,553	\$ 123,065	\$ 129,414
Denominator:				
For basic per share data weighted average shares	133,270	132,376	133,067	132,075
Effect of dilutive stock options	877	1,156	894	1,047
For diluted per share data weighted average shares	134,147	133,532	133,961	133,122
Basic earnings per share	\$ 0.34	\$ 0.50	\$ 0.92	\$ 0.98
Diluted earnings per share	\$ 0.33	\$ 0.50	\$ 0.92	\$ 0.97

12. Subsequent Events

In October 2006, the Company acquired all of the outstanding stock of RxKinetix, Inc., a privately held company headquartered in Boulder, Colo., that develops new formulations of FDA-approved compounds for oral mucositis and other supportive care oncology conditions. The purchase price included an up-front payment of up to \$20 million, with the potential for up to an additional \$95 million in contingent earn-out payments based on clinical development and regulatory milestones.

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

Except for the historical information contained in this Report, this Report, including the following discussion, contains forward-looking statements that involve risks and uncertainties. See "Forward-Looking Statements" beginning on page 3 of this Report.

Overview

We are a specialty pharmaceutical company with market leadership in pain management. We are engaged in the research, development, sale and marketing of branded and generic prescription pharmaceuticals used primarily to treat and manage pain. According to Wolters Kluwer Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled \$18.7 billion in 2005. This represents an approximately 6% compounded annual growth rate since 2001. Our primary area of focus within this market is analgesics and, specifically, opioid analgesics. In 2005, analgesics were the fourth most prescribed medication in the United States with over 246 million prescriptions written for this classification. Opioid analgesics is a segment that comprised approximately 89% of the analgesics prescriptions for 2005. Total U.S. sales for the opioid analgesic segment were \$8.2 billion in 2005, representing a compounded annual growth rate of 10% since 2001.

We have a portfolio of branded products that includes established brand names such as Lidoderm®, Percocet®, Frova®, Percodan® and DepoDur®. Branded products comprised approximately 71% of our net sales in 2005, with 51% of our net sales coming from Lidoderm®. Our non-branded generic portfolio, which accounted for 29% of net sales in 2005, currently consists of products primarily focused in pain management, with our generic oxycodone extended-release tablets accounting for 14% of our net sales in 2005. We focus on selective generics that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing.

We have established research and development expertise in analgesics and devote significant resources to this effort so that we can maintain and develop our product pipeline. Our late-stage branded product pipeline includes one filed Supplemental New Drug Application, or sNDA, two products in Phase III clinical trials and two products in Phase II clinical trials.

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

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

Table of Contents

Through a dedicated sales force of approximately 590 sales representatives in the United States, we market our branded pharmaceutical products to high-prescribing physicians in pain management, neurology, surgery, anesthesiology, oncology and primary care. Our sales force also targets retail pharmacies and other healthcare professionals throughout the United States.

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

Our wholly owned subsidiary, Endo Pharmaceuticals Inc., commenced operations in 1997 by acquiring certain pharmaceutical products, related rights and assets of The DuPont Merck Pharmaceutical Company, which subsequently became DuPont Pharmaceuticals Company and was thereafter purchased by the Bristol Myers Squibb Pharma Company in 2001. Endo Pharmaceuticals Inc. was formed by some members of the then-existing management of DuPont Merck and an affiliate of Kelso & Company who were also parties to the purchase agreement, under which we acquired these initial assets. We were incorporated in Delaware as a holding company on November 18, 1997.

Recent Developments

In October 2006, the Company acquired all of the outstanding stock of RxKinetix, Inc., a privately held company headquartered in Boulder, Colo., that develops new formulations of FDA-approved compounds for oral mucositis and other supportive care oncology conditions. The purchase price included an up-front payment of up to \$20 million, with the potential for up to an additional \$95 million in contingent earn-out payments based on clinical development and regulatory milestones.

On June 7, 2005, the U.S. Court of Appeals for the Federal Circuit in Washington, D.C. affirmed the district court's decision that, while Endo's oxycodone extended-release tablets infringe the Purdue patents, the patents are unenforceable. On June 21, 2005, Purdue filed a petition with the Federal Circuit seeking rehearing of the appeal. On February 1, 2006, the Federal Circuit granted Purdue's motion for rehearing, vacated the June 7, 2005 decision of the district court, and remanded the case to the district court for further proceedings. The Federal Circuit's decision on rehearing directed the district court to give further consideration to its previous finding of unenforceability due to inequitable conduct. The Federal Circuit also affirmed the district court's finding that EPI's oxycodone extended-release tablets infringe the Purdue patents. Following the remand, we entered into settlement discussions with Purdue. On August 28, 2006, we executed a settlement agreement with Purdue pursuant to which we will continue selling our oxycodone extended-release products until December 31, 2006. We and EPI, as well as our manufacturers, distributors, purchasers, and patients, are released from all liability for infringement of Purdue's patents in connection with EPI's prior and future sales of these products. Though the settlement agreement has been submitted to the U.S. Federal Trade Commission and the Antitrust Division of the Department of Justice as required by statute, the release will survive unless overturned by a court order. On October 6, 2006, the district court entered a Consent Judgment, the effect of which is to conclude the litigation in accordance with the terms of the settlement agreement. See Item 3. Legal Proceedings for further information.

Our executive vice president, chief financial officer and treasurer Jeffrey R. Black retired in August 2006. In August 2006, we appointed Joyce LaViscount, vice president of financial analysis and planning, as chief accounting officer pursuant to regulatory requirements. A nationally recognized executive search firm is leading the search to replace Mr. Black, which has included both internal and external candidates.

On July 19, 2006, we and Vernalis plc announced that we had submitted to the FDA a supplemental New Drug Application (sNDA) for Frova® (frovatriptan succinate) 2.5 mg tablets for the short-term (six days per month) prevention of menstrual migraine (MM). This submission contains data from previously reported pivotal Phase III studies that met their primary efficacy endpoints of reduction in incidence in MM. If the sNDA is approved by the FDA, Frova® will be the only triptan indicated in the U.S. for the prevention of MM. Currently, Frova® is FDA-approved for the acute treatment of migraine attacks with or without aura in adults where a clear diagnosis of migraine has been established.

On June 23, 2006, we announced that the U.S. Food and Drug Administration (FDA) granted final approval of the company's New Drug Applications (NDAs) for its extended-release and immediate-release formulations of oxymorphone hydrochloride. These products are now known under the trade names Opana® ER tablets and Opana® tablets. A new oral extended-release opioid analgesic option for patients, Opana® ER is indicated for the relief of moderate-to-severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time and is not intended to be used

Table of Contents

on an as-needed basis. This is the first time oxymorphone will be available in an oral, extended-release formulation. Opana® ER will be available in 5mg, 10mg, 20mg and 40mg tablets. Opana® (the immediate release version) is indicated for the relief of moderate-to-severe acute pain where the use of an opioid is appropriate and will be available in 5mg and 10mg tablets. Both products became commercially available in the U.S. in July 2006. On August 17, 2006, we commented on Penwest Pharmaceuticals' announcement that it intended to initiate the formal dispute resolution process provided for under the terms of the contract that governs the companies' agreement for Opana® ER. While Penwest in its press release acknowledged that it owes to us Penwest's share of the development costs relating to Opana® ER from the pre-launch period beginning on March 18, 2003, the companies hold different interpretations of the contract language for the post-launch period. Penwest is our development partner for Opana® ER. In particular, Penwest views that it has no obligation to reimburse us for any of the losses incurred during the launch phase of Opana® ER. Since March 2003, when Penwest opted out of funding its share of the development of Opana® ER, as was its right under the agreement, we funded all of the product's development costs and expect to recover those costs as a reduction in future royalty payments to Penwest. In addition, we will recognize 100% of the losses attributable to Opana® ER during its launch phase but expect to recover Penwest's share of these losses from the expected future profits of Opana® ER, which will be recognized as an increased share of the profits at that time. After reviewing the matter and consulting with its outside legal counsel, we believe the agreement supports the position that both partners should share equally in not only the profits but also any losses incurred from the up-front costs associated with launching the product prior to its achieving profitability. While we anticipate that the mediation process will facilitate further discussion, and we believe that our position will prevail, there is no assurance that the parties will reach an acceptable conclusion to this issue without resorting to arbitration.

On March 15, 2006, Brian T. Clingen and Michael W. Mitchell resigned from our board of directors in order to devote more time to their respective current activities. In addition, Michael B. Goldberg and David I. Wahrhaftig, both managing directors of Kelso, also resigned from our board of directors effective on the same date; these resignations are consistent with Kelso's practice of not having its partners serve on the boards of directors of public companies unless Kelso's level of beneficial stock ownership in the company is significant and warrants such participation. Following such resignations, our board of directors had seven board members, including John J. Delucca who was appointed on January 6, 2006 to replace Endo board member Frank J. Loverro, a managing director of Kelso, who resigned as a board member on that date. On April 20, 2006, we announced the appointment of Michel de Rosen to our Board of Directors. An independent, outside director, Mr. de Rosen is also a member of the Nominating Committee of the Board of Directors. Mr. de Rosen has served as the chairman of the board of directors of ViroPharma Incorporated since September 2002, president and chief executive officer since August 2000, and as a director since May 2000. From 1993 to 1999, Mr. de Rosen held several key positions in Rhone-Poulenc Pharma and Rhone-Poulenc Rorer (now Sanofi-Aventis), including chairman and chief executive officer from May 1995 until December 1999. Mr. de Rosen began his career at the French Ministry of Finance and subsequently served in several leading government positions. Mr. de Rosen also served in various executive roles in industry prior to 1993. Mr. de Rosen also is a director of ABB Ltd. On August 9, 2006, we announced the appointment of George F. Horner III to our board of directors. Mr. Horner, the former chief executive officer and director of Vicuron Pharmaceuticals Inc. and current President and Chief Executive Officer of Prestwick Pharmaceuticals, Inc., replaces Joseph T. O'Donnell, Jr., who resigned. Mr. O'Donnell, who had served on the Endo board since 2000, had to relinquish his directorship due to a change in employment that precluded him from serving on other corporate boards. We continue to have an active process to identify potential candidates qualified to serve as members of our board of directors and may propose such persons for election or appointment in the future.

On January 6, 2006, we announced the appointment of John J. Delucca to our Board of Directors. An independent, outside director, Mr. Delucca also has been appointed as the Chairman of the audit committee of the Board of Directors. He replaced Frank J. Loverro, a managing director of Kelso & Company, who had been a member of the Board since July 2000 and who resigned on January 6, 2006. Mr. Delucca, 62, was executive vice president and chief financial officer of the REL Consultancy Group until his retirement in 2004. Prior to that, he served as chief financial officer and executive vice president, finance & administration, of Coty, Inc., from 1999 to 2002. From 1993 to 1999, he was senior vice president and treasurer of RJR Nabisco, Inc. During his career, he also served in executive positions for Hascoe Associates, Inc., The Lexington Group, the Trump Group, International Controls Corp., and Textron, Inc. Mr. Delucca is currently a non-executive director and chairs the audit committees of ITC Deltacom, Enzo Biochem, Inc. and The Elliot Company. He also serves as a non-executive director and deputy chairman of the audit committee of British Energy PLC.

In January 2006, the Company signed a license agreement with ZARS Pharma that granted the Company the exclusive North American rights to the Synera™ (lidocaine 70 mg and tetracaine 70 mg) topical anesthetic patch. On June 19, 2006, we announced the commercial availability of Synera (lidocaine 70mg and tetracaine 70mg). Synera is the first self-contained topical patch for prevention of pain associated with superficial venous access and superficial dermatological procedures in patients three years of age and older.

Table of Contents

In January 2006, the Company completed a public offering of 15,000,000 shares of its common stock by certain of its stockholders. All of these shares were already issued and outstanding, except for approximately 40,000 shares representing shares underlying outstanding stock options. Endo Pharma LLC sold the majority of the shares sold. Certain members of management have an ownership interest in Endo Pharma LLC. Shares were also sold by management and certain members of the board of directors of the Company. In March 2006, the Company completed a public offering of 10,510,108 shares of its common stock by certain of its stockholders. All of these shares were already issued and outstanding, except for approximately 26,250 shares representing shares underlying outstanding stock options. Endo Pharma LLC sold the majority of the shares sold. Shares were also sold by certain members of management and certain members of the board of directors of the Company. Following completion of these offerings, Endo Pharma LLC holds less than 1% of Endo's outstanding common stock.

Our quarterly results have fluctuated in the past, and may continue to fluctuate. These fluctuations are primarily due to the timing of new product launches, purchasing patterns of our customers, market acceptance of our products, the impact of competitive products and pricing as well as charges incurred for compensation related to stock options and compensation paid by Endo Pharma LLC, impairment of intangible assets, and upfront, milestone and certain other payments made or accrued pursuant to licensing agreements.

Critical Accounting Policies and Estimates

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

Revenue Recognition

Our net sales consist of revenues from sales of our pharmaceutical products, less estimates for chargebacks, rebates, sales incentives and allowances, certain royalties and returns and losses. We recognize revenue for product sales when title and risk of loss has passed to the customer, which is typically upon delivery to the customer, when estimated provisions for chargebacks, rebates, sales incentives and allowances, certain royalties and returns and losses are reasonably determinable, and when collectibility is reasonably assured. Revenue from the launch of a new product is recognized when the conditions above are met and when the product has achieved market acceptance, which is typically based on dispensed prescription data and other information obtained during the period following launch.

Sales Deductions

When we recognize revenue from the sale of our products, we simultaneously record an adjustment to revenue for estimated chargebacks, rebates, sales incentives and allowances, certain royalties and returns and losses. These provisions are estimated based on historical experience, estimated future trends, estimated customer inventory levels, current contract sales terms with our wholesale and indirect customers and other competitive factors. If the assumptions we used to calculate these adjustments do not appropriately reflect future activity, our financial position, results of operations and cash flows could be impacted. The provision for chargebacks is one of the most significant and the most complex estimate used in the recognition of our revenue. We establish contract prices for indirect customers who are supplied by our wholesale customers. A chargeback represents the difference between our invoice price to the wholesaler and the indirect customer's contract price. Provisions for estimating chargebacks are calculated primarily using historical chargeback experience, estimated wholesaler inventory levels and estimated future trends. We also establish contracts with wholesalers, chain stores and indirect customers that provide for rebates, sales incentives and other allowances. Some customers receive rebates upon attaining established sales volumes. We estimate rebates, sales incentives and other allowances based upon the terms of the contracts with our customers, historical experience, estimated inventory levels of our customers and estimated future trends. We estimate an accrual for Medicaid and Medicare Part D rebates as a reduction of revenue at the time product sales are recorded. The Medicaid and Medicare Part D rebate reserves are estimated based upon the historical payment experience,

Table of Contents

historical relationship to revenues and estimated future trends. Medicaid pricing programs involve particularly difficult interpretations of statutes and regulatory guidance, which are complex and thus our estimates could differ from actual experience. Royalties represent amounts accrued pursuant to the license agreement with Hind Healthcare Inc. (Hind). Royalties, payable to Hind, are recorded as a reduction to net sales due to the nature of the license agreement and the characteristics of the license involvement by Hind in Lidoderm®. Royalties are paid to Hind at a rate of 10% of net sales of Lidoderm®. Our return policy allows customers to receive credit for expired products within three to six months prior to expiration and within one year after expiration. We estimate the provision for product returns based upon the historical experience of returns for each product, historical relationship to revenues, estimated future trends, estimated customer inventory levels and other competitive factors. We continually monitor the factors that influence each type of sales deduction and make adjustments as necessary. During the nine months ended September 30, 2006, adjustments for prior periods' sales deduction accruals amounted to approximately \$4 million related to the reversal of 2005 excess accruals.

Inventories

Inventories consist of finished goods held for distribution, raw materials and work in process. Our inventories are stated at the lower of cost or market. Cost is determined by the first-in, first-out method. We write down inventories to net realizable value based on forecasted demand and market conditions, which may differ from actual results.

Goodwill and Other Intangibles

Goodwill and other intangibles represent a significant portion of our assets and stockholders' equity. As of September 30, 2006, goodwill and other intangibles comprised approximately 20% of our total assets and 29% of our stockholders' equity. During the nine months ended September 30, 2006, licenses increased by \$19 million as a result of the acquisition of the rights to Synera (See Note 4 in Part I. Item 1.). SFAS No. 142, *Goodwill and Other Intangible Assets*, prescribes a two-step method for determining goodwill impairment. In the first step, we determine the fair value of our one reporting unit. If the net book value of our reporting unit exceeds the fair value, we would then perform the second step of the impairment test which requires allocation of our reporting unit's fair value to all of its assets and liabilities in a manner similar to a purchase price allocation, with any residual fair value being allocated to goodwill. An impairment charge will be recognized only when the implied fair value of our reporting unit's goodwill is less than its carrying amount. As a result of the significance of goodwill, our results of operations and financial position in a future period could be negatively impacted should an impairment of goodwill occur.

We have one reportable segment, pharmaceutical products. Goodwill arose as a result of the August 26, 1997 acquisition of certain branded and generic pharmaceutical products, related rights and certain assets of the then DuPont Merck Pharmaceutical Company (n/k/a Bristol-Myers Squibb Pharma Company) and the July 17, 2000 acquisition of Algos. Although goodwill arose in two separate transactions, the components of our operating segment have been integrated and are managed as one reporting unit. Our components extensively share assets and other resources with the other components of our business and have similar economic characteristics. In addition, our components do not maintain discrete financial information. Accordingly, the components of our business have been aggregated into one reporting unit and are evaluated as such for goodwill impairment. Goodwill is evaluated for impairment on an annual basis on January 1st of each year unless events or circumstances indicate that an impairment may have occurred between annual dates. On January 1, 2006 and 2005, our goodwill was evaluated for impairment and, based on the fair value of our reporting unit, no impairment was identified.

The cost of licenses are either expensed immediately or, if capitalized, are stated at cost, less accumulated amortization and are amortized using the straight-line method over their estimated useful lives ranging from ten to twenty years, with a weighted average useful life of approximately 15 years. The determination to capitalize amounts related to licenses is based on management's judgments with respect to stage of development, the nature of the rights acquired, alternative future uses, developmental and regulatory issues and challenges, the net realizable value of such amounts based on projected sales of the underlying products, the commercial status of the underlying products and/or various other competitive factors. We determine amortization periods for licenses based on our assessment of various factors impacting estimated useful lives and cash flows of the acquired rights. Such factors include the expected launch date of the product, the strength of the intellectual property protection of the product and various other competitive, developmental and regulatory issues, and contractual terms. Significant changes to any of these factors may result in a reduction in the useful life of the license and an acceleration of related amortization expense, which could cause our operating income, net income and earnings per share to decrease. The value of these licenses is subject to continuing scientific, medical and marketplace uncertainty. During the nine months ended September 30, 2005, the Company expensed \$20 million with respect to the acquisitions of marketing and development license rights for two products that are currently in development. We expensed the cost of these license rights based on the fact that we acquired both marketing and development rights for products that do not have regulatory approval and that do not have currently identifiable alternative future uses. As such, it was determined that the cost of the right to develop the products and the cost of the right to market the products were inextricably linked and therefore expensed in the

Table of Contents

accompanying financial statements. Patents acquired in the Algos merger are stated at cost, less accumulated amortization, and are amortized using the straight-line method over their estimated useful lives of seventeen years.

Licenses and patents are assessed for impairment, in accordance with Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS No. 144), whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. The impairment testing involves comparing the carrying amount of the asset to the forecasted undiscounted future cash flows of the product. In the event the carrying value of the asset exceeds the undiscounted future cash flows of the product and the carrying value is not considered recoverable, an impairment exists. An impairment loss is measured as the excess of the asset's carrying value over its fair value, calculated using a discounted future cash flow method. An impairment loss would be recognized in net income in the period that the impairment occurs. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. As a result of the significance of our amortizable intangibles, any recognized impairment loss could have a material adverse impact on our financial position and/or results of operations. During the nine months ended September 30, 2006, due to the delay in the anticipated commercial success of DepoDur®, we evaluated our SkyePharma intangible asset, which had a net book value of \$15.1 million at September 30, 2006, for impairment and determined that an impairment did not exist at such time. However, we will continue to monitor this asset, and a continued lack of forecasted commercial success could lead to an impairment loss in a future period.

Our goodwill and other intangible assets consist of the following at September 30, 2006 and December 31, 2005, respectively (in thousands):

	September 30, 2006	December 31, 2005
Goodwill	\$ 181,079	\$ 181,079
Amortizable Intangibles:		
Licenses	\$ 131,100	\$ 112,100
Patents	3,200	3,200
	134,300	115,300
Less accumulated amortization	(22,696)	(16,235)
Other Intangibles, net	\$ 111,604	\$ 99,065

Estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2005 is as follows (in thousands):

2006	\$ 8,756
2007	9,177
2008	9,177
2009	9,177
2010	9,177

Income Taxes

Provisions for income taxes are calculated on reported pre-tax income based on current tax laws, statutory tax rates and available tax incentives and planning opportunities in various jurisdictions in which we operate. Such provisions differ from the amounts currently receivable or payable because certain items of income and expense are recognized in different time periods for financial reporting purposes than for income tax purposes. Significant judgment is required in determining income tax provisions and evaluating tax positions. We establish reserves for income tax when, despite the belief that our tax positions are fully supportable, there remain certain positions that may be challenged and possibly disallowed by various authorities. The tax provision and related accruals include the impact of such reasonably estimable losses as deemed appropriate.

Contingencies

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

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

Table of Contents**Stock-Based Compensation**

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

As a result of adopting Statement No. 123(R) on January 1, 2006, the Company's income before income taxes and net income for the three months ended September 30, 2006, are \$3.8 million (\$3.3 million in selling, general and administrative expenses and \$0.5 million in research and development expenses) and \$2.3 million lower, respectively, and for the nine months ended September 30, 2006, are \$9.3 million (\$8.2 million in selling, general and administrative expenses and \$1.1 million in research and development expenses) and \$5.8 million lower, respectively, than if it had continued to account for share-based compensation under Opinion 25. Basic and diluted earnings per share for the three months ended September 30, 2006 are both \$0.02 lower, and for the nine months ended September 30, 2006 are both \$0.04 lower, than if the Company had not adopted Statement No. 123(R).

For all of the Company's stock-based compensation plans, the fair value of each grant was estimated at the date of grant using the Black-Scholes option-pricing model. Black-Scholes utilizes assumptions related to volatility, the risk-free interest rate, the dividend yield (which is assumed to be zero, as the Company has not paid cash dividends to date and does not currently expect to pay cash dividends) and the expected term of the option. Expected volatilities utilized in the model are based mainly on the historical volatility of the Company's stock price and other factors. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. The expected term of the option was calculated using the simplified method. Changes in the inputs and assumptions can materially affect the measure of the estimated fair value of our employee stock options. Also, the accounting estimate of stock-based compensation expense is reasonably likely to change from period to period as further stock options are granted and adjustments are made for stock option forfeitures and cancellations.

As of September 30, 2006, the total remaining unrecognized compensation cost related to non-vested stock options amounted to \$29.5 million. The weighted average remaining requisite service period of the non-vested stock options was 2.8 years. This unrecognized compensation cost does not include the impact of any future stock-based compensation awards.

Results of Operations**Net Sales**

Our net sales consist of revenues from sales of our pharmaceutical products, less estimates for chargebacks, rebates, sales incentives and allowances, certain royalties and returns and losses. We recognize revenue for product sales when title and risk of loss has passed to the customer, which is typically upon delivery to the customer, when estimated provisions for chargebacks, rebates, sales incentives and allowances, certain royalties and returns and losses are reasonably determinable, and when collectibility is reasonably assured. Revenue from the launch of a new product is recognized when the conditions above are met and when the product has achieved market acceptance, which is typically based on dispensed prescription data and other information obtained during the period following launch. Our shipping terms are generally free on board customer's destination.

The following table presents our net sales by product category for the three months and nine months ended September 30, 2006 and 2005.

	Three Months Ended September 30, 2006 2005		Nine Months Ended September 30, 2006 2005	
	(in thousands)		(in thousands)	
Lidoderm®	\$ 127,390	\$ 124,337	\$ 393,284	\$ 288,901
Percocet®	25,264	28,771	74,901	80,955
Frova®	9,090	10,278	29,108	25,086

DepoDur™

586

740

2,146

2,996

Table of Contents

Other brands	2,156	2,673	8,692	8,142
Total brands	164,486	166,799	508,131	406,080
Oxycodone extended release	18,971	49,266	43,263	78,485
Other generics	33,668	29,176	98,794	94,810
Total generics	52,639	78,442	142,057	173,295
Total net sales	\$ 217,125	\$ 245,241	\$ 650,188	\$ 579,375

The following table presents our net sales of select products as a percentage of total net sales for the three months and nine months ended September 30, 2006 and 2005.

	Three Months Ended		Nine Months Ended	
	September 30, 2006	September 30, 2005	September 30, 2006	September 30, 2005
Lidoderm®	59%	51%	61%	50%
Percocet®	12%	12%	12%	14%
Frova®	4%	4%	4%	4%
DepoDur™				1%
Other brands	1%	1%	1%	1%
Total brands	76%	68%	78%	70%
Oxycodone extended release	9%	20%	7%	14%
Other generics	15%	12%	15%	16%
Total generics	24%	32%	22%	30%
Total net sales	100%	100%	100%	100%

Three Months Ended September 30, 2006 Compared to the Three Months Ended September 30, 2005

Net Sales. Net sales for the three months ended September 30, 2006 decreased by 11% to \$217.1 million from \$245.2 million in the comparable 2005 period. This decrease in net sales was primarily due to the decrease in the net sales of our generic oxycodone extended-release product. Net sales of our generic oxycodone extended-release product decreased by 61% to \$19.0 million from \$49.3 million in the comparable 2005 period, primarily due to the introduction of generic competition in December 2005. This decrease was partially offset by an increase in the net sales of Lidoderm® to \$127.4 million from \$124.3 million in the comparable 2005 period due to the continued prescription growth of the product as well as a shift in enrollees, based on estimated patient enrollment, from Medicaid to Medicare under Medicare Part D, which resulted in a net decrease in the rebate accruals, offset by a lower level of net sales compared to demand sales of Lidoderm®, resulting from the inventory de-stocking by one of our major wholesale customers. Generic competition with our products may have a material impact on our results of operations and cash flows in the future. Due primarily to the expected increases in the net sales of Lidoderm® and the launch of our Opana® ER and Opana® products, partially offset by generic competition with our generic oxycodone extended-release tablets, Percocet®, and Endocet®, we expect net sales in 2006 to be approximately \$880 to \$910 million. There can be no assurance of Endo achieving these results.

Gross Profit. Gross profit for the three months ended September 30, 2006 decreased by 6% to \$172.7 million from \$183.8 million in the comparable 2005 period. Gross profit margins increased to 80% in 2006 versus 75% for the 2005 period. Our gross profit margins increased as a result of a shift in enrollees, based on estimated patient enrollment, from Medicaid to Medicare under Medicare Part D, as noted above and due to the write-off of approximately \$5 million in inventory costs related to the transdermal fentanyl patch in the 2005 period. We expect gross profit, as a percentage of net sales, to increase slightly in 2006 versus 2005 due to the factors noted above.

Selling, General and Administrative Expenses. Selling, general and administrative expenses for the three months ended September 30, 2006 increased by 87% to \$87.9 million from \$47.1 million in the comparable 2005 period. This increase was primarily due to an increase in sales and

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

promotional efforts in 2006 over the comparable 2005 period due to our continued investment in our commercial business and our infrastructure to support our products and pipeline, including the addition of 220 sales representatives and the launch expenses for Opana® ER and Opana® and the recording of stock-based compensation expense of approximately \$3.3 million as a result of the adoption of SFAS 123(R) on January 1, 2006. During 2006, we anticipate our SG&A expenses will be higher than in 2005 as we increase our level of investment in educational and promotional activities as well as overall support of our business, including supporting the pre-launch and launch activities for Opana® ER and Opana®.

Table of Contents

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2006 decreased to \$14.5 million from \$22.4 million in the comparable 2005 period. This decrease is primarily attributable to \$6.5 million in milestone payments, incurred in the third quarter of 2005, to Orexo related to Rapinyl™. Excluding milestone payments to partners, for the full year, we anticipate increasing our research and development spending in 2006 over 2005, primarily for continuing clinical development of Rapinyl™, our topical ketoprofen patch and our transdermal sufentanil patch.

Depreciation and Amortization. Depreciation and amortization for the three months ended September 30, 2006 increased to \$4.6 million from \$4.1 million in the comparable 2005 period primarily due to an increase in amortization expense as a result of Synera license rights acquired in 2006 and an increase in depreciation expense as a result of an increase in capital expenditures. We expect depreciation and amortization to continue to increase as we increase our capital expenditures and as we continue to license in products and technologies.

Impairment of Other Intangible Asset. For the three months ended September 30, 2005, the impairment of other intangible asset is due to the FDA's decision not to approve Noven's currently pending Abbreviated New Drug Application for its developmental transdermal fentanyl patch and represents the unamortized portion of the upfront license fee that we paid Noven in February 2004.

Interest Income, Net. Interest income, net for the three months ended September 30, 2006 increased to \$6.9 million compared to \$2.7 million in the comparable 2005 period. This change is substantially due to the increased interest income earned as a result of higher cash balances and higher returns earned during the third quarter of 2006 compared to the third quarter of 2005.

Income Tax. Income tax for the three months ended September 30, 2006 decreased to \$27.7 million from \$40.9 million in the comparable 2005 period. This decrease is due to the decrease in income before income tax for the three months ended September 30, 2006.

Nine Months Ended September 30, 2006 Compared to the Nine Months Ended September 30, 2005

Net Sales. Net sales for the nine months ended September 30, 2006 increased by 12% to \$650.2 million from \$579.4 million in the comparable 2005 period. This increase in net sales was primarily due to the increase in the net sales of Lidoderm® partially offset by the decrease in the net sales of our generic oxycodone extended-release product. Net sales of Lidoderm® increased to \$393.3 million from \$288.9 million in the comparable 2005 period due to the continued prescription growth of the product as well as a shift in enrollees, based on estimated patient enrollment, from Medicaid to Medicare under Medicare Part D, which resulted in a net decrease in the rebate accruals. Net sales of our generic oxycodone extended-release product decreased by 45% to \$43.3 million from \$78.5 million in the comparable 2005 period, primarily due to the introduction of generic competition in December 2005.

Gross Profit. Gross profit for the nine months ended September 30, 2006 increased by 14% to \$506.6 million from \$446.1 million in the comparable 2005 period. Gross profit margins increased to 78% from 77%. This increase is primarily attributable to a shift in enrollees, based on estimated patient enrollment, from Medicaid to Medicare under Medicare Part D, as noted above.

Selling, General and Administrative Expenses. Selling, general and administrative expenses for the nine months ended September 30, 2006 increased by 61% to \$252.3 million from \$156.3 million in the comparable 2005 period. This increase was primarily due to the accrual of compensation expense and the related employer payroll taxes of approximately \$41.3 million, which will be funded entirely by Endo Pharma LLC and are related to the one-time bonuses Endo Pharma LLC awarded to certain of our executives (see Note 9. RELATED PARTY TRANSACTIONS - Executive Compensation), as well as the recording of stock-based compensation expense of approximately \$8.2 million as a result of the adoption of SFAS 123(R) on January 1, 2006 and an increase in sales and promotional efforts in 2006 over the comparable 2005 period due to our continued investment in our commercial business and our infrastructure to support our products and pipeline, including the addition of 220 sales representatives and the pre-launch and launch expenses for Opana® ER and Opana®.

Research and Development Expenses. Research and development expenses for the nine months ended September 30, 2006 decreased to \$59.4 million from \$70.8 million in the comparable 2005 period. This decrease is primarily related to \$20 million expensed during the nine months ended September 30, 2005 related to the upfront payments to license the topical ketoprofen patch and the transdermal sufentanil patch offset by approximately \$10.2 million in milestone payments recorded during the nine months ended September 30, 2006 primarily related to Rapinyl™ and the topical ketoprofen patch.

Table of Contents

Depreciation and Amortization. Depreciation and amortization for the nine months ended September 30, 2006 increased to \$12.9 million from \$11.4 million in the comparable 2005 period primarily due to an increase in amortization expense as a result of Synera license rights acquired in 2006 and an increase in depreciation expense as a result of an increase in capital expenditures.

Impairment of Other Intangible Asset. For the nine months ended September 30, 2005, the impairment of other intangible assets is due to the FDA's decision not to approve Noven's currently pending Abbreviated New Drug Application for its developmental transdermal fentanyl patch and represents the unamortized portion of the upfront license fee that we paid Noven in February 2004.

Interest Income, Net. Interest income, net for the nine months ended September 30, 2006 was \$17.1 million compared to \$6.7 million in the comparable 2005 period. This change is substantially due to the increased interest income earned as a result of higher cash balances and higher returns earned during the first nine months of 2006 compared to the first nine months of 2005.

Income Tax. Income tax for the nine months ended September 30, 2006 decreased to \$76.0 million from \$79.3 million in the comparable 2005 period. This decrease is due to the decrease in income before income tax for the nine months ended September 30, 2006 offset by an increase in our effective income tax rate to 38.2% from 38.0%. This change in the effective income tax rate is primarily related to certain compensation charges recorded in 2006 that will not be deductible for income tax purposes partially offset by research and development tax credits.

Liquidity and Capital Resources

Our principal source of liquidity is cash generated from operations. Under our credit facility, which expires in December 2006, we may borrow up to \$75.0 million on a revolving basis for certain purposes as described below. Our principal liquidity requirements are for working capital for operations, acquisitions, licenses, milestone payments and capital expenditures.

Net Cash Provided by Operating Activities. Net cash provided by operating activities increased to \$275.5 million for the nine months ended September 30, 2006 from \$171.2 million for the nine months ended September 30, 2005. Significant components of the \$275.5 million of operating cash flows for the nine months ended September 30, 2006 included net income of \$123.1 million, selling, general and administrative expenses to be funded by Endo Pharma LLC of \$41.3 million, decrease in accounts receivable of \$30.9 million due to collections of accounts receivable, increases in accounts payable of \$21.7 million and a decrease in income taxes receivable/payable of \$82.6 million primarily due to the receipt of income tax refunds and the timing of income tax payments partially offset by a \$41.8 million decrease in accrued expenses.

Net Cash Used in Investing Activities. Net cash used in investing activities increased to \$41.7 million for the nine months ended September 30, 2006 from \$24.6 million for the nine months ended September 30, 2005. During the nine months ended September 30, 2006, the Company paid \$8.9 million for capital expenditures and \$32.9 million for the acquisition of product rights to Synera and Frova. During the nine months ended September 30, 2005, the Company paid \$14,500 to Vernalis for the acquisition of the product rights to Frova, had capital expenditures of \$8.4 million primarily related to our new corporate office space in Chadds Ford, Pennsylvania and invested \$1.7 million in a limited partnership.

Net Cash Used in Financing Activities. Net cash used in financing activities increased to \$60.2 million for the nine months ended September 30, 2006 from \$14.1 million for the nine months ended September 30, 2005. The increase is primarily due to a \$96.7 million payment to Endo Pharma LLC pursuant to the tax sharing agreement in 2006 compared to a \$21.4 million payment to Endo Pharma LLC pursuant to the tax sharing agreement in 2005, partially offset by the tax benefits of stock options exercised of \$32.1 million in 2006.

Credit Facility. In December 2001, we amended and restated our senior secured credit facility with a number of lenders. This amended and restated credit facility provides us with a line of credit of \$75.0 million. The line of credit matures on December 21, 2006. At this time, we do not intend to renew this credit facility. Any loans outstanding under the amended and restated credit facility are secured by a first priority security interest in substantially all of our assets. The credit facility contains representations and warranties, covenants, including a covenant requiring us to maintain minimum EBITDA of \$50 million over the prior four-quarter period, events of default and other provisions customarily found in similar agreements. Our ability to borrow under the credit facility is dependent, among other things, on our compliance with those provisions. On April 30, 2004, we amended our credit facility to allow us to file a shelf registration statement on Form S-3, which we initially filed on April 30, 2004, providing for the sale by Endo Pharma LLC and certain other selling stockholders to be named therein, including certain of our directors and officers, from time to time, of up to 30 million currently issued and outstanding shares of our common stock. On July 13, 2004, we amended our credit facility to allow us to enter in the transaction with Vernalis. As of September 30, 2006, we have not borrowed any amounts under our credit facility.

Table of Contents

Tax Sharing Agreement. On July 14, 2000, Endo Pharma LLC was formed in connection with the Algos merger to ensure that the stock options granted pursuant to the Endo Pharma LLC Stock Option Plans diluted only the Endo common stock held by persons and entities that held such shares prior to our merger with Algos. Endo Pharma LLC is a limited liability company that held approximately 15% of our common stock at December 31, 2005 but less than 1% of our common stock as of September 30, 2006, in which affiliates of Kelso & Company and certain members of management have an interest. Upon the exercise of these stock options, only currently outstanding shares of our common stock held by Endo Pharma LLC have been and will be delivered. Because Endo Pharma LLC, and not us, has been and will provide the shares upon the exercise of these options, we have entered into a tax sharing agreement with Endo Pharma LLC under which we are required to pay to Endo Pharma LLC the amount of the tax benefits usable by us as a result of the exercise of these stock options into shares of our common stock held by Endo Pharma LLC. As of September 30, 2006, approximately 35 million of these stock options had been exercised into shares of our common stock held by Endo Pharma LLC. Upon exercise of any of these Endo Pharma LLC stock options, we generally will be permitted to deduct as a compensation charge, for federal income tax purposes, an amount equal to the difference between the market price of our common stock and the exercise price paid upon exercise of these options (as of September 30, 2006, approximately \$747 million), which is estimated to result in a tax benefit amount of approximately \$288 million. Under the tax sharing agreement, we are required to pay this \$288 million, \$153 million of which has already been paid as of September 30, 2006, to Endo Pharma LLC to the extent that a compensation charge deduction is usable by us to reduce our taxes and based upon the assumption that all other deductions of Endo are used prior thereto. Additionally, as part of the tax sharing agreement, Endo Pharma LLC will reimburse us for the after-tax employer payroll taxes paid by us as a result of the exercise of the 35 million options discussed above. We have paid approximately \$11 million in employer payroll taxes, of which Endo Pharma LLC will reimburse us for approximately \$7 million which represents the after-tax employer payroll tax paid by us for the periods from 2001 through September 30, 2006. As of September 30, 2006, our net liability due to Endo Pharma LLC is approximately \$128.1 million, approximately \$99.1 million of which was paid in October 2006. All payments made and accrued pursuant to the tax sharing agreement have been reflected as a reduction of stockholders' equity in the accompanying financial statements. The estimated tax benefit amount payment to Endo Pharma LLC attributable to Endo Pharma LLC stock options exercised may increase if certain holders of Endo Pharma LLC stock options exercise additional stock options in the future.

During the nine months ended September 30, 2006, approximately 2.5 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised. Since the attributable compensation charge deductions are usable to reduce our taxes in 2006, we are obligated, under our amended tax sharing agreement, to pay to Endo Pharma LLC an additional tax benefit amount of approximately \$29 million, which is included in our net liability due to Endo Pharma LLC of \$128.1 million referred to above. Fifty percent of the estimated tax benefit amount attributable to these exercises and any additional tax benefits attributable to the exercise of stock options granted under the Endo Pharma LLC stock option plans in 2006 will be due within 15 business days of the date we receive an opinion on our final audited 2006 financial statements from our independent registered public accounting firm, and the remaining tax benefit amount attributable to 2006 is due within 30 business days of the date on which we file our 2006 tax return with the Internal Revenue Service.

As of September 30, 2006, there were approximately 0.3 million stock options remaining to be exercised under the Endo Pharma LLC stock option plans. Using a weighted average exercise price of \$2.42 per share and an assumed tax rate of 38.25%, if all of these remaining stock options under the Endo Pharma LLC stock option plans were vested and exercised, and assuming the price of our common stock was \$32.55 per share, the closing price on September 29, 2006, we would generally be able to deduct, for income tax purposes, compensation of approximately \$9 million, which could result in a tax benefit amount of approximately \$3 million payable to Endo Pharma LLC in 2007 and beyond.

As of September 30, 2006, there were approximately 0.8 million stock options remaining to be granted under the Endo Pharma LLC stock option plans. Using a weighted average exercise price of \$2.42 per share and an assumed tax rate of 38.25%, if all of these remaining stock options under the Endo Pharma LLC stock option plans were granted, vested and exercised, and assuming the price of our common stock was \$32.55 per share, the closing price on September 29, 2006, we would generally be able to deduct, for income tax purposes, compensation of approximately \$24 million, which could result in a tax benefit amount of approximately \$9 million payable to Endo Pharma LLC in 2007 and beyond (See *Executive Compensation* below).

Settlement of Contingent Obligation. During the nine months ended September 30, 2005, the Company reached an agreement with an individual to compensate him a total of \$2 million for past services rendered to the Company. This agreement was finalized in May 2005, and the \$2 million was recorded in selling, general and administrative expenses during the nine months ended September 30, 2005. Endo Pharma LLC made these payments totaling \$2 million on behalf of the Company, and they have been treated as capital contributions by Endo Pharma LLC.

Executive Compensation. In March 2006, Endo Pharma LLC advised our board of directors that it intended to pay a one-time cash bonus to each of Mr. Peter Lankau, our President and Chief Executive Officer, Ms. Caroline Manogue, our

Table of Contents

Executive Vice President, Chief Legal Officer and Secretary, and Mr. Jeffrey Black, our former Executive Vice President, Chief Financial Officer and Treasurer in the amount of \$3 million, \$6 million and \$10 million, respectively, in recognition of their significant contributions to our success. These bonus payments have been recorded in selling, general and administrative expenses during the nine months ended September 30, 2006. These payments were made by the Company in April 2006 and repaid to us by Endo Pharma LLC in the third quarter of 2006. In addition, only a portion of these bonus payments will be deductible for federal and state income tax purposes. We are not required to pay nor will we pay to Endo Pharma LLC the amount of any of the tax benefits related to these bonus payments pursuant to the Tax Sharing Agreement between us and Endo Pharma LLC. These bonuses will be funded entirely by Endo Pharma LLC, with no contribution by us and they have been treated as a capital contribution by Endo Pharma LLC.

Endo Pharma LLC has also informed us that, in connection with its eventual winding up, it would make a special allocation to Ms. Carol Ammon, our Chairman of the Board and former Chief Executive Officer, of approximately \$22 million, with all or a portion of Ms. Ammon's payment being satisfied by granting to her the remaining unallocated Endo Pharma LLC stock options of approximately 0.8 million shares under the Endo Pharma LLC stock option plans. This amount has been recorded in selling, general and administrative expenses during the nine months ended September 30, 2006 and as a capital contribution by Endo Pharma LLC. This grant of options to Ms. Ammon is currently expected to be made in the last quarter of 2006, as determined by Endo Pharma LLC. The exercise of these stock options (assuming they are granted and exercised) will result in compensation charges which we will be permitted to deduct for income tax purposes. Under the terms of the Tax Sharing Agreement, we would be required to pay to Endo Pharma LLC the amount of the tax benefit usable by us as a result of the exercise of these stock options into shares of our common stock held by Endo Pharma LLC. Upon the exercise of the stock options granted under the Endo Pharma LLC stock option plans, only currently outstanding shares of our common stock held by Endo Pharma LLC will be received by holders of such options upon exercise. The exercise of stock options pursuant to Endo Pharma LLC stock option plans does not increase the number of our shares outstanding, and only dilutes the equity holdings of the members of Endo Pharma LLC and not the equity holdings of our other stockholders. If the 0.8 million stock options are granted and exercised by Ms. Ammon, using a weighted average exercise price of \$2.42 per share and an assumed tax rate of 38.25%, and assuming the price of our common stock was \$32.55 per share, the closing price on September 29, 2006, we would generally be able to deduct, for income tax purposes, compensation of approximately \$24 million, which could result in a tax benefit amount of approximately \$9 million payable to Endo Pharma LLC in 2007 and beyond.

Licenses and Collaboration Agreements. We enter into licenses and collaboration agreements to develop, use, market and promote certain of our products from or with other pharmaceutical companies and universities. A description of the material developments with respect to our significant third party license and collaboration agreements that took place during the nine months ended September 30, 2006 follows:

DURECT Corporation

In January 2006, DURECT and Endo entered into Amendment No. 3 to the DURECT CHRONOGESIC License Agreement. Prior to this amendment, in addition to other specified termination rights provided to both parties, the Agreement provided Endo with a right to terminate the Agreement starting January 1, 2006 in the event that DURECT had not commenced a specified clinical trial for the CHRONOGESIC™ product candidate on or before January 1, 2006, *provided that* Endo provided DURECT written notice of such termination prior to January 31, 2006. Under Amendment No. 3, the foregoing termination right was amended to provide Endo with the right to terminate the Agreement in the event that (i) DURECT had not delivered to Endo on or before March 31, 2007 a written notice that a human pharmacokinetic trial had been completed with the CHRONOGESIC™ product candidate, together with a full study report of the results of the trial or (ii) Endo, determines, in its sole discretion, to terminate the Agreement during the sixty-day period after DURECT's delivery of such notice, *provided that*, in each case Endo delivers to DURECT its written notice of termination prior to April 30, 2007. Under Amendment No. 3, Endo shall not be responsible for any development costs for the CHRONOGESIC™ product candidate prior to May 1, 2007. Commencing on May 1, 2007, unless the Agreement is earlier terminated by Endo, Endo will fund 50% of the ongoing development costs for the CHRONOGESIC™ product candidate in accordance with the terms of the Agreement.

Noven Pharmaceuticals, Inc.

On March 2, 2006, we amended our license agreement with Noven, effective as of December 31, 2005, to terminate the provisions of the agreement applicable to the generic fentanyl patch product. As part of such amendment, Endo received a right of first negotiation for certain future generic fentanyl patch products that Noven may develop.

Table of Contents

ZARS Pharma

On January 6, 2006, we entered into an agreement with ZARS Pharma for the North American rights to Synera™ (lidocaine 70 mg and tetracaine 70 mg) topical patch. Synera™ is for use on intact skin to provide local dermal anesthesia in children and adults. Approved by the U.S. Food and Drug Administration on June 23, 2005, Synera™ became commercially available in June 2006.

Under the terms of this agreement, we paid ZARS an upfront fee of \$11 million and \$8 million upon the commercial launch of the product in June 2006, both of which we capitalized as an intangible asset during the nine months ended September 30, 2006 representing the fair value of these rights, and we may be required to make additional payments to ZARS of up to approximately \$19 million upon achievement of certain milestones. We are amortizing this intangible asset over its estimated useful life of 10 years. We are also required to pay ZARS royalties on net sales of Synera™.

SkyePharma, Inc.

SkyePharma, Inc. and the Company have decided to discontinue their development and commercialization of the Propofol IDD-D™ product candidate due to developmental challenges encountered in attempting to achieve the targeted product profile. This decision does not affect the companies' agreement related to DepoDur®.

Orexo AB

Our agreement with Orexo provides for us to make additional license fees and payments based on development and regulatory milestones, which may total up to \$22.1 million through FDA approval of Rapinyl's New Drug Application, \$12.5 million of which has been recorded through September 30, 2006, \$5.2 million of which has been included in research and development expense during the nine months ended September 30, 2006.

ProEthic Pharmaceuticals, Inc.

Under the terms of the agreement, we recorded a \$5 million milestone payment during the nine months ended September 30, 2006 based upon the achievement of certain criteria which has been included in research and development expense, and we could be required to make additional payments of approximately \$8 million for the achievement of certain regulatory and other milestones.

Fluctuations. Our quarterly results have fluctuated in the past, and may continue to fluctuate. These fluctuations are primarily due to the timing of new product launches, purchasing patterns of our customers, market acceptance of our products, the impact of competitive products and pricing as well as charges incurred for compensation related to stock options and compensation paid by Endo Pharma LLC, impairment of intangible assets, and upfront, milestone and certain other payments made or accrued pursuant to licensing agreements. Further, a substantial portion of our net sales are through three wholesale drug distributors who in turn supply our products to pharmacies, hospitals and physicians. Accordingly, we are potentially subject to a concentration of credit risk with respect to our trade receivables.

Growth Opportunities. We continue to evaluate growth opportunities including strategic investments, licensing arrangements and acquisitions of product rights or technologies, which could require significant capital resources.

Non-U.S. Operations. We currently have no operations outside of the United States.

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

Recent Accounting Pronouncements

In November 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 151, *Inventory Costs, an amendment of ARB No. 43, Chapter 4*. The purpose of this statement is to clarify the accounting of abnormal amounts of idle facility expense, freight, handling costs and waste material. ARB No. 43 stated that under some circumstances these costs may be so abnormal that they are required to be treated as current period costs. SFAS No. 151 requires that these costs be treated, as current period costs regardless if they meet the criteria of so abnormal. In addition, the statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provision of this Statement was effective for inventory costs incurred beginning on January 1, 2006. The adoption of SFAS No. 151 did not have a material impact on the Company's results of operations or financial position.

Table of Contents

In December 2004, the FASB issued SFAS No. 153, *Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29*. SFAS No. 153 was effective for nonmonetary asset exchanges occurring after January 1, 2006. The adoption of SFAS No. 153 did not have a material impact on the Company's results of operations or financial position.

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections*, a replacement of APB Opinion No. 20 and Statement No. 3. SFAS 154 changes the requirements for the accounting and reporting of a change in accounting principle. SFAS No. 154 applies to all voluntary changes in accounting principle as well as to changes required by an accounting pronouncement that does not include specific transition provisions. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The adoption of SFAS No. 154 did not have a material impact on the Company's results of operations or financial position.

In July 2006, the FASB issued FASB Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109, Accounting for Income Taxes*. FIN 48 creates a single model to address uncertainty in tax positions. FIN 48 clarifies the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. In addition, FIN 48 clearly scopes out income taxes from SFAS No. 5, *Accounting for Contingencies*. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company is currently evaluating the impact of the adoption of this Interpretation on its financial statements.

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

In September 2006, the SEC staff issued Staff Accounting Bulletin No. 108 (SAB 108), *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*. SAB 108 was issued in order to eliminate the diversity of practice surrounding how public companies quantify financial statement misstatements. In SAB 108, the SEC staff established an approach that requires quantification of financial statement misstatements based on the effects of the misstatements on each of the company's financial statements and the related financial statement disclosures. This model is commonly referred to as a "dual approach" because it requires quantification of errors under both the iron curtain and the roll-over methods. SAB 108 permits existing public companies to initially apply its provisions either by (i) restating prior financial statements as if the "dual approach" had always been used or (ii) recording the cumulative effect of initially applying the "dual approach" as adjustments to the carrying values of assets and liabilities as of January 1, 2006 with an offsetting adjustment recorded to the opening balance of retained earnings. Use of the "cumulative effect" transition method requires detailed disclosure of the nature and amount of each individual error being corrected through the cumulative adjustment and how and when it arose. The Company does not expect the impact of the adoption of SAB 108 on its financial statements to be material.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

Foreign Currency Risk

While all of our net sales are within the United States and denominated in U.S. dollars, we purchase Lidoderm®, in U.S. dollars, from Teikoku Seiyaku Co., Ltd., a Japanese manufacturer. As part of the purchase agreement with Teikoku, there is a price adjustment feature that prevents the cash payment in U.S. dollars from falling outside of a certain pre-defined range in Japanese yen even if the spot rate is outside of that range. A 10% change in foreign currency exchange rates would not have a material impact on our financial condition, results of operations or cash flows.

Interest Rate Risk

The primary objective of our investment of cash surpluses is the protection of principal and, accordingly, we invest in taxable and tax-free money market funds with relatively short maturities. Therefore, our investment of cash surpluses is not subject to significant interest rate risk.

On December 21, 2001, we entered into a credit facility that provides for a line of credit of \$75.0 million. The line of credit matures on December 21, 2006. At this time, we do not intend to renew this credit facility. On April 30, 2004, we amended our credit facility to allow us to file a shelf registration statement on Form S-3, which we initially filed with the Securities and Exchange Commission on April 30, 2004. On July 13, 2004, we amended our credit facility to allow us to enter in the transaction with Vernalis. Borrowings under the new credit facility are variable rate borrowings. There are no

Table of Contents

amounts outstanding under the credit facility. We do not utilize financial instruments for trading purposes and hold no derivative financial instruments that could expose us to significant market risk. We monitor interest rates and enter into interest rate agreements as considered appropriate.

As of September 30, 2006, we have no other assets or liabilities that have significant interest rate sensitivity.

Investment Risk

At September 30, 2006, we had publicly traded equity securities comprised of DURECT Corporation common stock at fair value totaling \$6.3 million in Other assets. The fair value of this investment is subject to significant fluctuations due to the volatility of the stock market, changes in general economic conditions and changes in the financial condition of DURECT. Based on the fair value of the publicly traded equity securities we held at September 30, 2006, an assumed 25%, 40% and 50% adverse change in the market prices of this security would result in a corresponding decline in total fair value of approximately \$1.6 million, \$2.5 million and \$3.1 million, respectively.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

Our management, including our Chief Executive Officer and Chief Accounting Officer, has conducted an evaluation of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based upon that evaluation, our Chief Executive Officer and Chief Accounting Officer have concluded that our disclosure controls and procedures were effective for timely gathering, analyzing and disclosing the information we are required to disclose in our reports filed with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended.

Internal Control Over Financial Reporting

In addition, we evaluated our internal control over financial reporting, and there have been no changes in our internal control over financial reporting that occurred during the third quarter of 2006 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Notwithstanding the foregoing, we recently reported the resignation of Mr. Jeffrey R. Black, our former chief financial officer. Ms. Joyce N. LaViscount was promoted to chief accounting officer and is acting as our principal accounting and financial officer until a new chief financial officer is hired. Inherent with any change in management is a change in understanding of the control environment and the internal controls.

PART II

OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors

There has been no material change in our risk factors as previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2005 in response to Item 1A. to Part 1 of such Form 10-K, except for the amended risk factor below:

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

The Hatch Waxman Act permits the FDA to approve ANDAs for generic versions of branded drugs and what are referred to as 505(b)(2) applications for generic or branded versions of existing branded drugs. We refer to this process as the ANDA process. The ANDA process permits competitor companies to obtain marketing approval for a drug with the same active ingredient for the same uses but does not generally require the conduct and submission of clinical equivalency studies for that product. In place of such clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its product is bioequivalent to the branded product based on pharmacokinetic studies.

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

The Hatch Waxman Act requires an applicant for a drug that relies, at least in part, on data from the branded drug regarding the safety and efficacy of the same active ingredient, to notify us of their application and potential infringement of our patent rights. Upon receipt of this notice we would have 45 days to bring a patent infringement suit in federal district court against the company seeking to violate our patent rights. The discovery, trial and appeals process in such suits can take several years. If such a suit is commenced, the Hatch Waxman Act provides a 30-month stay on the FDA's approval of the competitor's application. If the litigation is resolved in favor of the applicant or the challenged patent expires during the 30-month stay period, the stay is lifted and the FDA's review of the application may be completed. Such litigation is often time-consuming and quite costly and may result in generic competition if such patent(s) are not upheld or if the generic competitor does not infringe such patent(s). We have recently learned that the Division of Bioequivalence, Office of Generic Drugs, Center for Drug Evaluation and Research (OGD) has issued, in response to an inquiry, bioequivalence recommendations regarding our patent-protected product, Lidoderm® (lidocaine topical patch 5%). We have learned that OGD has recommended a bioequivalence study characterizing the pharmacokinetic profile of lidocaine as well as a skin irritation/sensitization study of any lidocaine-containing patch formulation. This deviates from our understanding of the applicable regulations and of OGD's past practices, which, for a topically acting product such as Lidoderm®, have generally required demonstration of bioequivalence through a comparative clinical equivalency study. The filing of any ANDA or 505(b)(2) application in respect to any of our branded drugs, particularly Lidoderm®, could have an adverse impact on our stock price and, if the patents covering our branded drugs, including Lidoderm®, were not upheld in litigation or if the generic competitor is found to not infringe these patents, the resulting generic competition would have a material adverse effect on our net sales, gross profit, operating income, net income and cash flows.

Item 2. *Changes in Securities and Use of Proceeds.*

None.

Item 3. *Defaults Upon Senior Securities.*

None.

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

None.

Item 5. *Other Information.*

None.

Table of Contents

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

/s/ Joyce N. LaViscount
Name: Joyce N. LaViscount
Title: *Chief Accounting Officer*

Date: November 9, 2006

Table of Contents

Exhibit Index

Exhibit No.	Title
3.1	Amended and Restated Certificate of Incorporation of Endo Pharmaceuticals Holdings Inc. (Endo) (incorporated herein by reference to Exhibit 3.1 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
3.2	Amended and Restated By-laws of Endo (incorporated herein by reference to Exhibit 3.2 of the Form 10-Q for the Quarter ended March 31, 2003 filed with the Commission on May 14, 2003)
4.1	Amended and Restated Executive Stockholders Agreement, dated as of July 7, 2003, by and among Endo, Endo Pharma LLC (Endo LLC), Kelso Investment Associates V, L.P. (KIA V), Kelso Equity Partners V, L.P. (KEP V) and the Management Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.1 of the Form 10-Q for the Quarter ended June 30, 2003 filed with the Commission on August 14, 2003)
4.1.2	Amendment to Amended and Restated Executive Stockholders Agreement, dated as of June 28, 2004, by and among Endo, Endo LLC, KIA V, KEP V and the Management Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.1 of the Form 10-Q for the Quarter ended September 30, 2004 filed with the Commission on November 5, 2004) the Commission on July 1, 2003)
4.1.3	Amendment 2 to the Amended and Restated Stockholders Agreement, dated September 20, 2005, by and among the Company, Endo LLC, Kelso and certain Amending Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.1.3 of the Current Report on Form 8-K filed with the Commission on September 22, 2005)
4.2	Amended and Restated Employee Stockholders Agreement, dated as of June 5, 2003, by and among Endo, Endo LLC, KIA V, KEP V and the Employee Stockholders (as defined therein) (incorporated herein by reference to Exhibit 10.2 of Amendment No. 2 to the Form S-3 Registration Statement (Registration No. 333-105338) filed with the Commission on July 1, 2003)
4.2.2	Amendment to Amended and Restated Employee Stockholders Agreement, dated as of June 28, 2004, by and among Endo, Endo LLC, KIA V, KEPV and the Management Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.1 of the Form 10-Q for the Quarter ended September 30, 2004 filed with the Commission on November 5, 2004)
4.2.3	Amendment 2 to the Amended and Restated Employee Stockholders Agreement, dated September 20, 2005, by and among the Company, Endo LLC, Kelso and certain Amending Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.2.3 of the Current Report on Form 8-K filed with the Commission on September 22, 2005)
4.3	Employee Stockholders Consent and Release, effective September 20, 2005, by and among the Company, Endo LLC, Kelso and certain Employee Stockholders (as defined therein) signatory thereto (incorporated herein by reference to Exhibit 4.3 of the Current Report on Form 8-K filed with the Commission on September 22, 2005)
4.4	Registration Rights Agreement, dated as of July 17, 2000, by and between Endo and Endo LLC (incorporated herein by reference to Exhibit 4.4 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
4.5	Amendment to Registration Rights Agreement, dated as of June 30, 2003, by and between Endo and Endo LLC (incorporated herein by reference to Exhibit 10.1 of Amendment No. 2 to the Form S-3 Registration Statement (Registration No. 333-105338) filed with the Commission on July 1, 2003)
10.1	Shelf Registration Agreement, dated September 21, 2005, by and between Endo, Endo LLC and certain Management Stockholders (as defined therein) (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the Commission on September 22, 2005)
10.2	Shelf Registration Agreement, dated April 30, 2004, between Endo Pharmaceuticals Holdings Inc. and Endo Pharma LLC (incorporated herein by reference to Exhibit 10.2 of Amendment No. 1 to the Form S-3 Registration Statement (Registration No. 333-115032) filed with the Commission on June 10, 2004)
10.3	Amendment to Shelf Registration Agreement, dated June 10, 2004 between Endo Pharmaceuticals Holdings Inc. and Endo Pharma LLC (incorporated herein by reference to Exhibit 10.3 of Amendment No. 1 to the Form S-3 Registration Statement (Registration No. 333-115032) filed with the Commission on June 10, 2004)
10.4	[Intentionally Omitted.]

Table of Contents

- 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 Amended and Restated Credit Agreement, dated as of December 21, 2001, by and between Endo, Endo Pharmaceuticals, the Lenders Party Thereto and JPMorgan Chase Bank (incorporated by reference to Exhibit 10.7 of the Annual Report on Form 10-K for the Year Ended December 31, 2001 filed with the Commission on March 29, 2002)
- 10.8 Amendment No.1, dated as of April 30, 2004, to the Amended and Restated Credit Agreement dated as of December 21, 2001, among Endo, Endo Pharmaceuticals Inc., the Lenders thereto and JP Morgan Chase. (incorporated herein by reference to Exhibit 10.8 of the Form 10-Q for the Quarter ended March 31, 2004 filed with the Commission on May 10, 2004)
- 10.9 Amendment No.2, dated as of July 13, 2004, to the Amended and Restated Credit Agreement dated as of December 21, 2001, among Endo, Endo Pharmaceuticals Inc., the Lenders thereto and JP Morgan Chase. (incorporated herein by reference to Exhibit 10.9 of the Form 10-Q for the Quarter ended June 30, 2004 filed with the Commission on August 9, 2004)
- 10.10 Sole and Exclusive License Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals Inc. (Endo Pharmaceuticals) and Hind Health Care, Inc. (incorporated herein by reference to Exhibit 10.10 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.11 [Intentionally Omitted.]
- 10.12 [Intentionally Omitted.]
- 10.13 [Intentionally Omitted.]
- 10.14 Supply and Manufacturing Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals and Teikoku Seiyaku Co., Ltd (incorporated herein by reference to Exhibit 10.14 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.15 Supply Agreement, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt Inc. (Mallinckrodt) (incorporated herein by reference to Exhibit 10.15 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.16 Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt (incorporated herein by reference to Exhibit 10.16 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.16.1 First Amendment, effective July 1, 2000, to the Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt (incorporated herein by reference to Exhibit 10.16.1 of the Current Report on Form 8-K dated April 14, 2006)
- 10.16.2 Second Amendment, dated April 10, 2006, to the Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt (incorporated herein by reference to Exhibit 10.16.2 of the Current Report on Form 8-K dated April 14, 2006)
- 10.17 [Intentionally Omitted.]
- 10.18 Amended and Restated Strategic Alliance Agreement, dated as of April 2, 2002, by and between Endo Pharmaceuticals and Penwest Pharmaceuticals Co. (incorporated herein by reference to Exhibit 10.18 of the Quarterly Report on Form 10-Q for the Quarter Ended March 31, 2002 filed with the Commission on May 14, 2002)
- 10.19 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)

Table of Contents

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	[Intentionally Omitted.]
10.27	[Intentionally Omitted.]
10.29	Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo Pharmaceuticals and David Allen Harvey Lee, MD, Ph.D. (incorporated herein by reference to Exhibit 10.29 of the Current Report on Form 8-K dated August 31, 2001)
10.29.1	Letter Agreement, dated as of December 20, 2005, by and between Endo Pharmaceuticals and David Allen Harvey Lee, MD, Ph.D. (incorporated herein by reference to Exhibit 10.29.1 of the Current Report on Form 8-K dated December 21, 2005)
10.30	[Intentionally Omitted.]
10.31	[Intentionally Omitted.]
10.32	[Intentionally Omitted.]
10.33	[Intentionally Omitted.]
10.34	Lease Agreement, dated as of May 5, 2000, by and between Endo Pharmaceuticals and Painters Crossing One Associates, L.P. (incorporated herein by reference to Exhibit 10.34 of the Registration Statement filed with the Commission on June 9, 2000)
10.34.1	Amendment to Lease Agreement, dated as of November 6, 2006, by and between Endo Pharmaceuticals and Painters Crossing One Associates, L.P.
10.35	Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo and Caroline B. Manogue (formerly Berry) (incorporated herein by reference to Exhibit 10.35 of the Current Report on Form 8-K dated August 31, 2001)
10.35.1	Letter Agreement, dated as of December 20, 2005, by and between Registrant and Caroline B. Manogue (formerly Berry) (incorporated herein by reference to Exhibit 10.35.1 of the Current Report on Form 8-K dated December 21, 2005)
10.36	Amended and Restated Employment Agreement, dated as of December 20, 2005, by and between Endo and Peter A. Lankau (incorporated herein by reference to Exhibit 10.36 of the Current Report on Form 8-K dated December 21, 2005)
10.37	Endo Pharmaceuticals Holdings Inc. 2004 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.37 of the Form 10-Q for the Quarter ended June 30, 2004 filed with the Commission on August 9, 2004)
10.38	[Intentionally Omitted.]
10.39	Master Development and Toll Manufacturing Agreement, dated as of May 3, 2001, by and between Novartis Consumer Health, Inc. and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.39 of the Form 10-Q for the Quarter Ended June 30, 2001 filed with the Commission on August 14, 2001)
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)

Table of Contents

- 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 [Intentionally Omitted.]
- 10.41 Policy of Endo Pharmaceuticals Holdings Inc. Relating to Insider Trading in Company Securities and Confidentiality of Information (incorporated herein by reference to Exhibit 10.41 of the Form 10-Q for the Quarter ended March 31, 2005 filed with the Commission on May 10, 2005)
- 10.42 Development, Commercialization and Supply License Agreement, dated as of November 8, 2002, by and between DURECT Corporation and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.42 of the Current Report on Form 8-K dated November 14, 2002)
- 10.42.2 Amendment to Development, Commercialization and Supply License Agreement, dated January 28, 2004, between DURECT Corporation and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.42.2 of the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on March 15, 2004)
- 10.42.3 Amendment No. 2 to the Development, Commercialization and Supply License Agreement, dated November 22, 2004, between DURECT Corporation and Endo Pharmaceuticals Inc. (incorporated herein by reference to Exhibit 10.42.3 of the Current Report on Form 8-K dated November 29, 2004)
- 10.42.4 Amendment No. 3 to the Development, Commercialization and Supply License Agreement, dated January 20, 2006, between DURECT Corporation and Endo Pharmaceuticals Inc. (incorporated herein by reference to Exhibit 10.42.4 of the Current Report on Form 8-K dated January 25, 2006)
- 10.43 Development and Marketing Strategic Alliance Agreement, dated as of December 31, 2002, by and among Endo Pharmaceuticals, SkyePharma, Inc. and SkyePharma Canada, Inc. (incorporated herein by reference to Exhibit 10.43 of the Current Report on Form 8-K dated January 8, 2003)
- 10.43.2 Amendment to Development and Marketing Strategic Alliance Agreement, dated March 2, 2004, between Endo Pharmaceuticals, SkyePharma, Inc. and SkyePharma Canada, Inc. (incorporated herein by reference to Exhibit 10.43.2 of the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on March 15, 2004)
- 10.44 Lease Agreement, dated as of January 6, 2003, by and between Endo Pharmaceuticals and Dawson Holding Company (incorporated by reference to Exhibit 10.44 of the Annual Report on Form 10-K for the Year Ended December 31, 2002 filed with the Commission on March 27, 2003)
- 10.45 Lease Agreement, dated as of November 13, 2003, by and between Endo Pharmaceuticals and Painters Crossing Two Associates, L.P. (incorporated herein by reference to Exhibit 10.45 of the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on March 15, 2004)
- 10.45.1 Amendment to Lease Agreement, dated as of February 16, 2005, by and between Endo Pharmaceuticals and Painters Crossing Two Associates, L.P. (incorporated herein by reference to Exhibit 10.45.1 of the Current Report on Form 8-K dated February 18, 2005)
- 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.
- 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)

Table of Contents

- 10.48.1 Co-Promotion Agreement, dated as of July 1, 2005, by and between Endo Pharmaceuticals Inc. and Vernalis Development Limited (incorporated by reference to Exhibit 10.48.1 of the Current Report on Form 8-K dated July 8, 2005)
- 10.48.2 Second Amendment, dated as of December 12, 2005, to the License Agreement by and between Endo Pharmaceuticals Inc. and Vernalis Development Limited (incorporated by reference to Exhibit 10.48.2 of the Current Report on Form 8-K dated December 29, 2005)
- 10.48.3 First Amendment, dated as of December 12, 2005, to the Co-Promotion Agreement by and between Endo Pharmaceuticals Inc. and Vernalis Development Limited (incorporated by reference to Exhibit 10.48.3 of the Current Report on Form 8-K dated December 29, 2005)
- 10.49 Loan Agreement, dated as of July 14, 2004, by and between Endo Pharmaceuticals and Vernalis Development Limited (incorporated herein by reference to Exhibit 10.49 of the Current Report on Form 8-K dated July 19, 2004)
- 31.1 Certification of the President and Chief Executive Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification of the Chief Accounting Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 Certification of the President and Chief Executive Officer of Endo pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2 Certification of the Chief Accounting Officer of Endo pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002