

NOVEN PHARMACEUTICALS INC

Form 10-Q

November 09, 2007

**Table of Contents**

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**  
**FORM 10-Q**

Quarterly Report Pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934  
For the quarterly period ended September 30, 2007  
Commission file number 0-17254  
**NOVEN PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

STATE OF DELAWARE

59-2767632

(State or other jurisdiction of  
incorporation or organization)

(I.R.S. Employer  
Identification Number)

11960 S.W. 144th Street, Miami, FL 33186

(Address of principal executive offices) (Zip Code)  
(305) 253-5099

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 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.

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 Exchange Act).  
Yes  No

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

Class	Outstanding at October 31, 2007
Common stock \$.0001 par value	24,552,198

**NOVEN PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
**INDEX**

	Page No.
<b><u>PART I FINANCIAL INFORMATION</u></b>	
<u>Item 1 - Unaudited Condensed Consolidated Financial Statements</u>	3
<u>Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2007 and 2006</u>	3
<u>Condensed Consolidated Balance Sheets as of September 30, 2007 and December 31, 2006</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2007 and 2006</u>	5
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	6
<u>Item 2 - Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	26
<u>Item 3 - Quantitative and Qualitative Disclosures About Market Risk</u>	50
<u>Item 4 - Controls and Procedures</u>	50
<b><u>PART II OTHER INFORMATION</u></b>	
<u>Item 1 - Legal Proceedings</u>	51
<u>Item 1A - Risk Factors</u>	51
<u>Item 2 - Unregistered Sales of Equity Securities and Use of Proceeds</u>	57
<u>Item 5 - Other Information</u>	57
<u>Item 6 - Exhibits</u>	58
<b><u>SIGNATURES</u></b>	59
<u>EX-10.3 Asset Purchase Agreement</u>	
<u>EX-10.4 Development, License and Supply Agreement</u>	
<u>EX-10.5 Contract Manufacturing Agreement</u>	
<u>EX-10.6 Manufacturing and Supply Agreement</u>	
<u>EX-31.1 Section 302 CEO Certification</u>	
<u>EX-31.2 Section 302 CFO Certification</u>	
<u>EX-32.1 Section 906 CEO Certification</u>	
<u>EX-32.2 Section 906 CFO Certification</u>	

**Cautionary Factors:** Statements in this report that are not descriptions of historical facts are forward-looking statements provided under the safe harbor protection of the Private Securities Litigation Reform Act of 1995. Our actual results, performance and achievements may be materially different from those expressed or implied by such statements and readers should consider the risks and uncertainties associated with our business that are discussed in Item 1A of Part I of our Annual Report on Form 10-K for the year ended December 31, 2006 as supplemented by

Part II Item 1A Risk Factors of the quarterly reports on Form 10-Q filed in 2007, as well as other reports filed from time to time with the Securities and Exchange Commission.

Trademark Information: Vivelle<sup>®</sup>, Vivelle-Dot<sup>®</sup>, Estradot<sup>®</sup> and Menorest are trademarks of Novartis AG or its affiliated companies; CombiPatch<sup>®</sup> and Estalis<sup>®</sup> are registered trademarks of Vivelle Ventures LLC; Daytrana is a trademark of Shire Pharmaceuticals Ireland Limited; Depakote<sup>®</sup> is a registered trademark of Abbott Laboratories or its affiliates; Lithobid<sup>®</sup> and Pexeva<sup>®</sup> are registered trademarks of JDS Pharmaceuticals, LLC or its affiliates.

**Table of Contents**

## PART I. FINANCIAL INFORMATION

Item 1. Financial Statements**NOVEN PHARMACEUTICALS, INC. AND SUBSIDIARIES**

## Condensed Consolidated Statements of Operations

Three and Nine Months Ended September 30,

(in thousands, except per share amounts)

(unaudited)

	Three Months		Nine Months	
	2007	2006	2007	2006
Revenues:				
Product revenues Novogyne:				
Product sales	\$ 5,801	\$ 5,273	\$ 15,974	\$ 13,990
Royalties	2,100	1,791	5,764	5,138
Total product revenues Novogyne	7,901	7,064	21,738	19,128
Product revenues third parties	8,789	5,761	25,620	15,648
Total product revenues	16,690	12,825	47,358	34,776
Contract and license revenues:				
Contract	280	44	179	1,112
License	4,845	2,839	12,432	7,559
Contract and license revenues	5,125	2,883	12,611	8,671
Net revenues	21,815	15,708	59,969	43,447
Expenses:				
Cost of products sold Novogyne	4,286	3,702	10,530	10,304
Cost of products sold third parties	5,525	5,339	17,522	16,764
Total cost of products sold	9,811	9,041	28,052	27,068
Acquired in-process research and development	100,150		100,150	
Research and development	3,649	2,527	10,300	8,899
Selling, general and administrative	11,873	6,010	23,003	16,386
Total expenses	125,483	17,578	161,505	52,353
Loss from operations	(103,668)	(1,870)	(101,536)	(8,906)
Equity in earnings of Novogyne	10,948	8,234	25,025	19,323
Interest income, net	1,306	1,168	4,751	2,890

Edgar Filing: NOVEN PHARMACEUTICALS INC - Form 10-Q

Income (loss) before income taxes	(91,414)	7,532	(71,760)	13,307
Provision (benefit) for income taxes	(32,377)	2,501	(25,335)	4,439
Net income (loss)	\$ (59,037)	\$ 5,031	\$ (46,425)	\$ 8,868
Basic earnings (loss) per share	\$ (2.38)	\$ 0.21	\$ (1.87)	\$ 0.37
Diluted earnings (loss) per share	\$ (2.38)	\$ 0.20	\$ (1.87)	\$ 0.37
Weighted average number of common shares outstanding:				
Basic	24,792	23,954	24,787	23,768
Diluted	24,792	24,574	24,787	24,142

*The accompanying notes are an integral part of these statements.*

**Table of Contents****NOVEN PHARMACEUTICALS, INC. AND SUBSIDIARIES**

## Condensed Consolidated Balance Sheets

(in thousands, except share data)

(unaudited)

	September 30, 2007	December 31, 2006
<b><u>Assets</u></b>		
Current Assets:		
Cash and cash equivalents	\$ 11,253	\$ 9,144
Short-term investments available-for-sale, at fair value	61,100	144,455
Accounts receivable, net of allowances	9,818	5,038
Milestone payment receivable Shire		25,000
Accounts receivable Novogyne, net	6,903	7,693
Inventories	12,717	8,651
Net deferred income tax asset, current portion	9,000	4,400
Prepaid income taxes	4,103	3,416
Prepaid and other current assets	3,066	1,919
	117,960	209,716
Property, plant and equipment, net	36,827	37,501
Other Assets:		
Investment in Novogyne	24,664	23,296
Net deferred income tax asset	53,172	8,308
Intangible assets, net	40,326	2,317
Goodwill	14,359	
Deposits and other assets	697	227
	133,218	34,148
	\$ 288,005	\$ 281,365
<b><u>Liabilities and Stockholders Equity</u></b>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 7,159	\$ 5,184
Accrued compensation and related liabilities	6,271	5,308
Other accrued liabilities	20,508	2,085
Current portion of long-term obligations	3,502	109
Deferred rent credit	88	89
Deferred contract revenues	567	1,527
Deferred license revenues current portion	19,349	15,084
	57,444	29,386
Long-Term Liabilities:		

Edgar Filing: NOVEN PHARMACEUTICALS INC - Form 10-Q

Long-term obligations, less current portion	8,471	279
Deferred license revenues	82,536	74,188
Deferred contract revenues	7,356	
Other liabilities	1,227	837
	157,034	104,690
Commitments and Contingencies (Note 16)		
Stockholders' Equity:		
Preferred stock authorized 100,000 shares of \$.01 par value; no shares issued or outstanding		
Common stock authorized 80,000,000 shares, par value \$.0001 per share; issued and outstanding 24,873,943 at September 30, 2007 and 24,661,169 at December 31, 2006	2	2
Additional paid-in capital	116,287	109,912
Retained earnings	19,806	66,761
Treasury stock, at cost - 322,345 shares at September 30, 2007	(5,124)	
Common stock held in trust	(800)	
Deferred compensation obligation	800	
	130,971	176,675
	\$ 288,005	\$ 281,365

*The accompanying notes are an integral part of these statements.*

**Table of Contents**

**NOVEN PHARMACEUTICALS, INC.**  
Condensed Consolidated Statements of Cash Flows  
Nine Months Ended September 30,  
(in thousands)  
(unaudited)

	2007	2006
Cash flows from operating activities:		
Net income (loss)	\$ (46,425)	\$ 8,868
Adjustments to reconcile net income (loss) to net cash flows provided by operating activities:		
Depreciation, amortization and certain other noncash items	4,468	3,173
Stock-based compensation expense	3,118	2,358
Acquired in-process research and development expense	100,150	
Income tax benefits on exercise of stock options	461	2,401
Excess tax deduction from exercise of stock options	(390)	(1,639)
Deferred income tax benefit	(49,464)	(52)
Recognition of deferred license revenues	(12,432)	(7,559)
Equity in earnings of Novogyne	(25,025)	(19,323)
Distributions from Novogyne	18,465	17,644
Changes in operating assets and liabilities, net of acquisition:		
Increase in accounts receivable, net	(375)	(3,172)
Decrease in milestone payment receivable Shire	25,000	
Decrease in accounts receivable Novogyne, net	790	1,129
Increase in inventories	(1,745)	(273)
Decrease in prepaid income taxes	4,505	3,902
Increase in prepaid and other current assets	(910)	(1,124)
Increase in deposits and other assets	(2)	(15)
Decrease in accounts payable and accrued expenses	(4,564)	(988)
Decrease in accrued liability Shire	(419)	(5,069)
Decrease in accrued compensation and related liabilities	(509)	(1,042)
Increase in other accrued liabilities	11,244	555
Increase in deferred contract revenue, net	6,396	277
Increase in deferred license revenue	25,000	51,000
Increase in other liabilities	419	134
Amounts recoverable from Shire and offset against deferred license revenue related to Daytrana approval	45	14
Cash flows provided by operating activities	57,801	51,199
Cash flows from investing activities:		
Purchases of property, plant and equipment, net	(2,257)	(5,823)
Payments for intangible assets, net	(256)	(539)
Acquisition of JDS, net of cash acquired	(130,353)	
Purchase of company-owned life insurance	(260)	(185)
Purchases of short-term investments	(1,276,473)	(1,012,385)
Proceeds from sale of short-term investments	1,359,828	899,775
Cash flows used in investing activities	(49,771)	(119,157)
Cash flows from financing activities:		

Edgar Filing: NOVEN PHARMACEUTICALS INC - Form 10-Q

Issuance of common stock from exercise of stock options	2,531	8,080
Purchase of treasury stock	(5,124)	
Excess tax benefit from exercise of stock options	390	1,639
Payments under long-term obligations	(3,718)	(49)
Cash flows provided by (used in) financing activities	(5,921)	9,670
Net increase (decrease) in cash and cash equivalents	2,109	(58,288)
Cash and cash equivalents, beginning of period	9,144	66,964
Cash and cash equivalents, end of period	\$ 11,253	\$ 8,676

*The accompanying notes are an integral part of these statements.*

**Table of Contents**

**NOVEN PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
**Notes to Unaudited Condensed Consolidated Financial Statements**

**1. DESCRIPTION OF BUSINESS:**

Since its incorporation in Delaware in 1987, Noven Pharmaceuticals, Inc. ( Noven ) has been primarily engaged in the research, development, manufacture and marketing of advanced transdermal drug delivery technologies and prescription transdermal products.

On August 14, 2007 (the Closing Date ), Noven acquired JDS Pharmaceuticals, LLC ( JDS ), a privately-held specialty pharmaceutical company that currently markets two branded prescription psychiatry products through a targeted sales force and has several products in development. The acquisition of JDS was accounted for under the purchase method of accounting and the results of operations of JDS have been included in the consolidated results of Noven from the Closing Date through September 30, 2007 (see Note 3 Acquisition of JDS Pharmaceuticals, LLC ).

Noven and Novartis Pharmaceuticals Corporation ( Novartis ) entered into a joint venture, Vivelle Ventures LLC (d/b/a Novogyne Pharmaceuticals) ( Novogyne ), effective May 1, 1998, to market and sell women s prescription healthcare products in the United States and Canada. These products include Noven s transdermal estrogen delivery systems marketed under the brand names Vivelle®, Vivelle-Dot® and CombiPatch®. Noven accounts for its 49% investment in Novogyne under the equity method and reports its share of Novogyne s earnings as Equity in earnings of Novogyne on its Condensed Consolidated Statements of Operations. Noven defers the recognition of 49% of its profit on products sold to Novogyne until the products are sold by Novogyne to third party customers.

**2. BASIS OF PRESENTATION:**

In management s opinion, the accompanying unaudited condensed consolidated financial statements of Noven contain all adjustments (consisting of only normal recurring adjustments) necessary to present fairly, in all material respects, the consolidated financial position of Noven, the consolidated results of its operations, and its cash flows for the periods presented. Noven s business is subject to numerous risks and uncertainties including, but not limited to, those set forth in Part I Item 1A of Noven s Annual Report on Form 10-K for the year ended December 31, 2006 ( Form 10-K ), and as supplemented by Part II Item 1A Risk Factors of the quarterly reports on Form 10-Q filed in 2007. Accordingly, the results of operations and cash flows for the periods presented are not, and should not be construed as, necessarily indicative of the results of operations or cash flows which may be reported for the remainder of 2007 or for periods thereafter.

The accompanying unaudited condensed consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission for reporting on Form 10-Q. Pursuant to such rules and regulations, certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted. The unaudited condensed consolidated financial statements should be read in conjunction with the financial statements and the notes to the financial statements included in Noven s Form 10-K. The accounting policies followed for interim financial reporting are the same as those disclosed in Note 2 of the notes to the financial statements included in Noven s Form 10-K, as updated and supplemented by the following:

**Table of Contents**

**SEGMENT INFORMATION:**

With the addition of JDS, Noven's business is now comprised of two reportable segments: (i) the Transdermal Segment, which currently consists of research, development, manufacturing and licensing to partners of transdermal drug delivery technologies and prescription transdermal products, and (ii) the JDS Segment, which currently consists of development, marketing, sales and distribution of pharmaceutical products. Noven previously had one reportable segment. In accordance with Statement of Financial Accounting Standards No. 131 (SFAS No. 131), *Disclosures about Segments of an Enterprise and Related Information*, information for earlier periods has been recast. See Note 15 Segment Information for Noven's segmented financial reporting.

**REVENUE RECOGNITION:**

Substantially all of Noven's Transdermal Segment product revenues were related to the sale of transdermal product to its licensees, Novogyne, Novartis Pharma AG and its affiliates (Novartis Pharma), Shire and sanofi-aventis (Aventis) (see Notes 12 and 13). All of Noven's JDS Segment product revenues relate to the commercial sale of its two FDA-approved products, Lithobid® and Pexeva®. Revenues from product sales are recognized when both title and the risks and rewards of ownership have been transferred to the buyer.

Sales allowances for estimated discounts, rebates, returns, chargebacks and other sales allowances are established by Noven concurrently with the recognition of revenue. Sales allowances are established based upon consideration of a variety of factors, including, but not limited to, prescription data, customers' inventory reports and other information received from customers and other third parties of product in the distribution channel, customers' right of return, historical information by product, the number and timing of competitive products approved for sale, both historically and as projected, the estimated size of the market for Noven's products, current and projected economic and market conditions, anticipated future product pricing, future levels of prescriptions for the products and analyses that are performed. Management believes that the sales allowances are reasonably determinable and are based on the information available at that time to arrive at the best estimate.

The key assumptions management uses to arrive at its best estimate of sales allowances are its estimates of inventory levels in the distribution channel, future price changes and potential returns, as well as historical information by product. The estimates of prescription data, inventory at customers and in the distribution channel are subject to the inherent limitations of estimates that rely on third party data, as certain third party information may itself rely on estimates, and reflect other limitations. Chargebacks, discounts and allowances for doubtful accounts are estimated based on historical payment experience, historical relationships to revenues and contractual arrangements. Management believes that such estimates are readily determinable due to the limited number of assumptions involved and the consistency of historical experience.

Estimated rebates and returns involve more subjective judgments and are more complex in nature. Actual product returns, rebates and other sales allowances incurred are dependent upon future events. Management periodically monitors the factors that influence sales allowances and makes adjustments to these provisions when it believes that actual results may differ from established allowances. If conditions in future periods change, revisions to previous estimates may be required, potentially by significant amounts. Changes in the level of provisions for estimated product returns, rebates and other sales allowances will affect revenues.

**Table of Contents**

Noven establishes allowances for returns for product that has been recalled or that it believes is probable of being recalled. The methodology used by Noven to estimate product recall returns is based on the distribution and expiration dates of the affected product and overall trade inventory levels. These estimates are based on currently available information, and the ultimate outcome may be significantly different than the amounts estimated given the subjective nature and complexities inherent in this area and in the pharmaceutical industry.

Sales allowances for estimated discounts, chargebacks, doubtful accounts and certain rebates are recorded as reductions to accounts receivable. Sales allowances for returns, returns of recalled product, estimated Medicaid, managed care and certain other rebates are recorded as other accrued liabilities. Sales allowances are included in the consolidated balance sheets as of September 30, 2007 and December 31, 2006 as follows:

	September 30, 2007	December 31, 2006
Accounts receivable, net		
Gross receivable	\$ 10,130	\$ 5,105
Sales allowances and allowances for doubtful accounts	(312)	(67)
	\$ 9,818	\$ 5,038
Other accrued liabilities		
Sales allowances	\$ 8,372	\$ 2,085
Other accrued liabilities	12,136	2,085
	\$ 20,508	\$ 2,085

Noven believes that its revenue recognition policy is in compliance with the requirements of Securities and Exchange Commission Staff Accounting Bulletin Topic 13, Revenue Recognition .

**GOODWILL AND INTANGIBLE ASSETS:**

Intangible assets are stated at cost less accumulated amortization. Amortization is generally recorded by either the pattern in which the economic benefit is expected to be realized or the straight-line method as appropriate. Noven periodically reviews the original estimated useful lives of assets as well as the pattern in which the economic benefit is expected to be realized and makes adjustments when events indicate that the period and the pattern of economic benefit should be adjusted.

Noven accounts for acquired businesses using the purchase method of accounting which requires that the assets acquired and liabilities assumed be recorded at the date of acquisition at their respective fair values. The cost to acquire a business, including directly related transaction costs, is allocated to the underlying net assets of the acquired business in proportion to their respective fair values. Amounts allocated to acquired in-process research and development are expensed at the date of acquisition. Intangible assets are amortized over the expected life of the asset. Any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill. The judgments made in determining the estimated fair value assigned to each class of assets acquired and liabilities assumed, as well as asset lives, can materially impact Noven's results of operations. Fair values and useful lives are determined based on, among other factors, the expected future period of benefit of the asset, the various characteristics of the asset and projected cash flows.

**Table of Contents**

During the three months ended September 30, 2007 Noven recorded goodwill of \$14.4 million. Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets ( SFAS 142 ), addresses financial accounting and reporting for acquired goodwill and other intangible assets. SFAS No. 142 requires that goodwill and intangible assets with indefinite lives be measured for impairment at least annually or whenever events indicate that there may be an impairment. In order to determine if an impairment exists, Noven compares the reporting unit's carrying value to the reporting unit's fair value. If it is determined that the full carrying amount of an asset is not recoverable, an impairment loss is recorded in the amount by which the carrying amount of the asset exceeds its fair value. For purposes of this test, the JDS Segment is considered the reporting unit. Determining the reporting unit's fair value requires Noven to make estimates on market conditions and operational performance. Any resulting impairment loss could have a material adverse impact on Noven's financial condition and results of operations. See Note 8 Goodwill and Intangible Assets for additional information.

**ADVERTISING COSTS:**

Advertising costs are expensed as incurred. In addition, Noven's JDS Segment regularly carries inventory of sample product for distribution in the marketplace. Noven's policy is to immediately expense samples when the title and risk of loss for the samples transfers to Noven. Samples expense is included in selling, general and administrative expenses.

**SHIPPING AND HANDLING COSTS:**

Noven's JDS Segment does not charge customers for shipping and handling costs. Shipping and handling costs are included in cost of goods sold and were immaterial for the period from the Closing Date through September 30, 2007.

**3. ACQUISITION OF JDS PHARMACEUTICALS, LLC:**

Noven acquired JDS on August 14, 2007 pursuant to the terms of the Agreement and Plan of Merger, dated July 9, 2007 (the Merger Agreement ), among Noven, Noven Acquisition, LLC, a Delaware limited liability company and an indirect wholly owned subsidiary of Noven ( Merger Sub ), JDS and Satow Associates, LLC, solely in its capacity as representative of the equity holders of JDS (the Member Representative ). On the Closing Date, Merger Sub merged with and into JDS (the Merger ), with JDS continuing as the surviving company and as an indirect wholly owned subsidiary of Noven following the Merger.

The purchase price for the acquisition was \$125.0 million cash paid at closing, subject to certain working capital adjustments (the Merger Consideration ). On the Closing Date, a portion of the Merger Consideration in an amount equal to \$10.0 million was placed in an escrow account to be held until December 31, 2008 to satisfy any post-closing indemnity claims by Noven in connection with the Merger Agreement as well as certain expenses incurred by the Member Representative. Any adjustments resulting from these post-closing indemnity claims will effectively modify the consideration paid by Noven and as a result modify goodwill recognized. The Merger Consideration, which Noven funded from the sale of short-term investments, was paid at closing to the Member Representative for the benefit of holders of outstanding equity interests of JDS prior to the Merger.

The total purchase price for the JDS acquisition consisted of \$125.0 million paid at closing, approximately \$5.4 million of transaction costs consisting primarily of fees paid for financial advisory, legal, valuation and accounting services, and approximately \$0.5 million in connection with non-competition agreements entered into with two executives of JDS in connection with the Merger.

**Table of Contents**

The acquisition of JDS was accounted for under the purchase method of accounting. The purchase price was allocated to tangible and intangible assets acquired and liabilities assumed based on their estimated fair values at the Closing Date. The purchase price exceeded the amounts allocated to the tangible and intangible assets acquired and liabilities assumed by approximately \$14.4 million, which was classified as goodwill. The primary factors that contributed to a purchase price that resulted in the recognition of goodwill in Noven's acquisition of JDS are (i) the intellectual capital of the skilled sales, marketing and distribution personnel; and (ii) an organized experienced pharmaceutical sales force that is leveragable, both of which do not meet the criteria for recognition as an asset apart from goodwill. The allocation of purchase price has not been finalized due to the pending completion of the valuation and accordingly is subject to change.

The following table presents the preliminary allocation of the total purchase price for the acquisition of JDS (amounts in thousands):

Current assets, including cash of \$0.6 million	\$ 7,893
Property and equipment	362
Intangible assets	
Acquired in-process research and development expenses	100,150
Identifiable intangible assets	38,547
Goodwill	14,359
Other assets	163
Accrued expenses and other current liabilities	(15,344)
Long-term obligations assumed	(3,711)
Contingent milestones assumed	(11,500)
 Total purchase price	 \$ 130,919

*Acquired In-Process Research and Development ( IPR&D ) Intellectual Property*

IPR&D is defined by Financial Accounting Standards Board's (FASB) Interpretation No. 4, *Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method* ( FIN 4 ), as being a development project that has been initiated and achieved material progress but (i) has not yet reached technological feasibility or has not yet reached the appropriate regulatory approval; (ii) has no alternative future use; and (iii) the fair value is estimable with reasonable certainty. As required by FIN 4, the portion of the purchase price allocated to IPR&D of \$100.2 million was immediately expensed following the completion of the Merger and is reflected in the Noven's consolidated statement of operations for the three and nine months ended September 30, 2007.

A project-by-project valuation using the guidance in SFAS No. 141 and the American Institute of Certified Public Accountants Practice Aid *Assets Acquired in a Business Combination to Be Used In Research and Development Activities: A Focus on Software, Electronic Devices and Pharmaceutical Industries* has been conducted to determine the fair value of JDS's research and development projects that were in-process, but not yet completed as at the completion of the Merger.

The fair value of IPR&D has been determined by the income approach using the multi-period excess earnings method. The value of the projects has been based on the present value of probability adjusted incremental cash flows, after the deduction of contributory asset charges for other assets employed (including fixed assets, the assembled workforce and working capital). The probability weightings used to determine IPR&D cash flows ranged from 80% to 90%. The discount used to determine the present value of IPR&D cash flows was approximately 23%.

**Table of Contents**

The forecast of future IPR&D cash flows required various assumptions to be made including:  
 revenue that is likely to result from IPR&D projects, including estimated number of units to be sold, estimated selling prices, estimated market penetration, estimated market share, estimated year-over-year growth rates over the product life cycles and estimated sales allowances;

cost of sales for the potential product using historical data, industry data or other sources of market data;

sales and marketing expenses using historical data, industry data or other market data;

general and administrative expenses; and

research and development expenses.

In addition, Noven considered the following in determining the fair value of IPR&D:

the project's stage of completion;

the costs incurred to date;

the projected costs to complete the IPR&D projects;

the contribution, if any, of the acquired identifiable intangible assets;

the projected launch date of the products under development;

the estimated life of the products under development; and

the probability of success of launching a commercially viable product.

To the extent that an IPR&D project is expected to utilize the acquired identified intangible assets, the value of the IPR&D project has been reduced to reflect this utilization.

*Identifiable Intangible Assets*

The identifiable intangible assets acquired are attributable to the following categories: (dollar amounts in thousands):

	Fair Value	Asset life years <sup>(1)</sup>
Intellectual Property – approved products		
Pexeva®	\$ 33,040	10
Lithobid®	4,750	6
	37,790	
Non-competition agreements	530	2 - 3
Favorable lease	227	10 months
	\$ 38,547	

(1) Asset lives represent the economic period

of benefit over  
which  
management  
believes the  
asset will  
contribute to the  
future cash  
flows of Noven.

Intellectual Property – approved products

The fair value of the intellectual property rights (including technical processes and institutional understanding) associated with JDS' s products approved by the FDA has been determined by the income approach using the multi-period excess earnings method. Using the multi-period excess earnings method, the approved products intellectual property fair value

**Table of Contents**

has been based on the present value of the incremental after-tax cash flows attributable to the asset, after the deduction of contributory asset charges for other assets employed (including fixed assets, the assembled workforce and working capital). The forecast of future cash flows for approved products requires various assumptions as discussed in

Acquired In-Process Research and Development ( IPR&D ) Intellectual Property above.

The valuations of IPR&D intellectual property and identifiable intangible assets are based on information available at the time of the acquisition and the expectations and assumptions that (i) have been deemed reasonable by Noven's management; and (ii) would be available to and made by a market participant. No assurance can be given that the underlying assumptions or events incorporated into the valuations of such assets will occur as projected. For these reasons, among others, the actual cash flows may vary materially from forecasted future cash flows.

**Non-competition agreements**

In accordance with SFAS No. 141, the fair value of non-competition agreements entered into in connection with the Merger was recorded as an intangible asset and is being amortized on a straight-line basis over a period of two to three years, which is the expected period of benefit.

**Favorable Lease**

In accordance with SFAS No. 141, the fair value of a favorable lease contract was recorded as an intangible asset and is being amortized over a period of approximately 10 months, which is the period of expected benefit.

**Long-term liabilities assumed**

Noven assumed a long-term obligation in the Merger and, in accordance with SFAS No. 141 and EITF Issue No. 98-1, Valuation of Debt Assumed in a Purchase Business Combination, this liability was assigned an estimated fair value of \$3.7 million based on the present value of the estimated future cash flows at the date of acquisition. The long-term obligation was paid in full by Noven by October 2007.

Noven also assumed approximately \$11.5 million in purchase price contingent sales milestones related to JDS's acquisition of Pexeva® from Synthon Pharmaceuticals, Inc. As of the acquisition date, Noven determined that it was probable that these contingent sales milestones would be paid. Therefore, in accordance with SFAS No. 141, the contingent sales milestones were recorded as liabilities of \$11.5 million. The contingent sales milestones consist of the following:

\$1.0 million milestone payable when annual net sales of Pexeva® equal or exceed \$7.0 million but are less than \$8.0 million in each of 2007 or 2008, which milestone is increased to \$2.0 million if annual net sales exceed \$8.0 million in each of 2007 or 2008. Pexeva® net sales exceeded the \$8 million threshold for the 2007 Period.

\$1.25 million milestone payable for each of the first two years when annual net sales of Pexeva® equal or exceed \$10.0 million from 2007 to 2017. Pexeva® net sales exceeded this threshold for the 2007 Period.

\$5.0 million milestone payable in the first year that annual net sales of Pexeva® (or any paroxetine mesylate product) equal or exceed \$30.0 million from 2007 through 2017.

**Table of Contents***Supplemental disclosure of pro forma information*

The following represents the pro forma results of the ongoing operations for Noven and JDS as though the acquisition of JDS had occurred at the beginning of each of the three and nine month periods ended September 30, 2007 and 2006. The pro forma financial information for these periods includes the non-recurring adjustment of \$100.2 million for IPR&D expense for the nine months ended September 30, 2006. The pro forma information is not necessarily indicative of the results that would have resulted had the acquisition occurred at the beginning of the periods presented, nor is it necessarily indicative of future results. The pro forma information is as follows:

	Three Months		Nine Months	
	2007	2006	2007	2006
	(amounts in thousands, except per share data)			
Net revenue	\$ 25,247	\$ 19,820	\$ 74,699	\$ 56,191
Net income (loss)	4,835	2,281	7,197	(64,574)
Net earnings (loss) per share (Basic)	0.20	0.10	0.29	(2.72)
Net earnings (loss) per share (Diluted)	0.19	0.09	0.28	(2.72)

**4. RECLASSIFICATIONS:**

Certain reclassifications have been made to the prior period's balance sheet and statement of cash flows to conform to the current period's presentation.

**5. CASH FLOW INFORMATION:***Income Tax and Interest Payments*

Cash payments for income taxes, net of refunds, were \$16.2 million and \$0.8 million for the nine months ended September 30, 2007 and 2006, respectively. Cash payments for interest were not material for the nine months ended September 30, 2007 and 2006.

*Non-cash Operating Activities*

In 2002, the State of New Jersey enacted legislation that requires Novogyne to remit estimated state income tax payments on behalf of its owners, Noven and Novartis. Through September 30, 2007 and in 2006, Novogyne paid \$5.2 million and \$2.2 million, respectively, to the New Jersey Department of Revenue, representing Noven's portion of Novogyne's estimated state income tax payment. These payments were deemed a distribution to Noven from Novogyne.

On the Closing Date, Noven entered into a non-competition agreement for \$0.3 million with an executive of JDS which was paid by Noven's grant of 44,297 stock-settled appreciation rights (SSARs) and was recorded as an intangible asset.

*Non-cash Investing Activities*

During the nine months ended September 30, 2007, Noven entered into a capital lease obligation of \$0.1 million for new equipment.

**Table of Contents****6. RECENT ACCOUNTING PRONOUNCEMENTS:**

In February 2007, the Financial Accounting Standards Board ( FASB ) issued Statement of Financial Accounting Standards No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115 ( SFAS 159 ). This Statement permits entities to choose to measure many financial instruments and certain other items at fair value and applies to all entities, including not-for-profit organizations. Most of the provisions of this statement apply only to entities that elect the fair value option. However, the amendment to FASB Statement No. 115, Accounting for Certain Investments in Debt and Equity Securities, applies to all entities with available-for-sale and trading securities. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. Early adoption is permitted as of the beginning of a fiscal year that begins on or before November 15, 2007, provided the entity also elects to apply the provisions of FASB Statement No. 157, Fair Value Measurements. Noven is currently assessing the impact of adopting SFAS 159 and the impact it may have on Noven's results of operations and financial condition.

In June 2007, the FASB's Emerging Issue Task Force ( EITF ) issued EITF Issue No. 07-03, Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities ( EITF 07-03 ). This EITF requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the related services are performed. Entities should continue to evaluate whether they expect the goods to be delivered or services to be rendered. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. EITF 07-03 is effective for financial statements issued for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. Earlier adoption is permitted. Noven is currently assessing the impact of adopting EITF 07-03 and the impact it may have on Noven's results of operations and financial condition.

**7. INVENTORIES:**

The following are the major classes of inventories (amounts in thousands):

	September 30, 2007	December 31, 2006
Finished goods	\$ 4,187	\$ 893
Work in process	2,263	2,851
Raw materials	6,267	4,907
 Total	 \$ 12,717	 \$ 8,651

The Drug Enforcement Administration ( DEA ) controls access to controlled substances, including methylphenidate, the active ingredient in Daytrana. Shire plc ( Shire ) retains title to the active methylphenidate ingredient ( AMI ) in Daytrana. AMI is not included in Daytrana product revenues or in Noven's cost of products sold. Noven records AMI maintained at its manufacturing facility as consignment inventory and bears certain manufacturing risks of loss related to the AMI. These risks include the contractual obligation of Noven to reimburse Shire for the cost of AMI if Noven does not meet certain yield requirements of the finished product. Shire has a reciprocal obligation to pay Noven if the yield requirements are exceeded. Noven

**Table of Contents**

slightly exceeded the yield requirements for the nine months ended September 30, 2007, resulting in an immaterial payment from Shire to Noven. During the nine months ended September 30, 2007, Noven used \$5.0 million of AMI in the finished product. Noven had \$1.5 million and \$1.0 million of consignment AMI inventory on hand at September 30, 2007 and December 31, 2006, respectively, which is not reflected in the table above.

**8. GOODWILL AND INTANGIBLE ASSETS:**

The carrying amount of goodwill is \$14.4 million at September 30, 2007, all of which relates to Noven's acquisition of JDS.

Noven's intangible assets at September 30, 2007 are detailed in the table below (amounts in thousands):

	Gross carrying amount	Accumulated amortization	Net	Amortization period (in years)
Intellectual Property:				
Pexeva®	\$ 33,040	\$ (156)	\$ 32,884	10
Lithobid®	4,750	(173)	4,577	6
Noven patent development costs	4,620	(2,446)	2,174	8-10
	42,410	(2,775)	39,635	
Non-competition agreements	530	(28)	502	2-3
Favorable lease	227	(38)	189	10 months
	\$ 43,167	\$ (2,841)	\$ 40,326	

All intangible assets above, with the exception of the Noven patent development costs, were acquired on the Closing Date as part of the JDS acquisition. Amortization expense, which was \$0.5 and \$0.8 million for the three and nine months ended September 30, 2007, respectively, has been calculated on the following bases for each of the intangible assets in the above table:

Intellectual property is based on the pattern in which the economic benefit is expected to be realized and is included in cost of products sold.

Non-competition agreements are amortized on a straight-line basis and are included in selling, general and administrative expenses.

Favorable lease is based on escalating lease payments being amortized on a straight-lined basis and is included in selling, general and administrative expenses.

**Table of Contents**

Noven estimates that the annual amortization expense for intangible assets held at September 30, 2007 for each of the five years through 2012 are as follows (amounts in thousands):

	Remainder of 2007	2008	2009	2010	2011	2012
Cost of goods sold:						
Intellectual property	\$ 792	\$ 3,335	\$ 3,297	\$ 3,452	\$ 3,670	\$ 3,983
Selling, general and administrative:						
Non-competition agreements	55	221	171	55		
Favorable lease	74	115				
	129	336	171	55		
Total	\$ 921	\$ 3,671	\$ 3,468	\$ 3,507	\$ 3,670	\$ 3,983

**9. OTHER ACCRUED LIABILITIES:**

Other accrued liabilities consist of the following (amounts in thousands):

	September 30, 2007	December 31, 2006
Income taxes payable	\$ 5,900	\$ 204
Accrued medicaid and other rebates	3,399	
Accrued market withdrawal costs	3,258	
Accrued research and development costs	2,731	
Allowance for product returns	1,655	
Other accrued liabilities	3,565	1,881
Total other accrued liabilities	\$ 20,508	\$ 2,085

**10. EQUITY PLANS:**

Prior to January 1, 2006, all awards granted to employees under Noven's 1999 Long-Term Incentive Plan (the "1999 Plan") were stock options. In 2006, Noven began granting stock-settled stock appreciation rights ("SSARs") to employees and non-vested shares ("restricted stock") to non-employee directors in lieu of stock options. Noven accounts for these awards in accordance with Statement of Financial Accounting Standards No. 123 (revised 2004),

Share-Based Payment. At September 30, 2007, there were 2,669,414 stock options and 445,843 SSARs issued and outstanding under the 1999 Plan.

Noven granted 26,244 and 34,344 shares of restricted stock to its non-employee directors in May 2007 and 2006, respectively. The shares vest over each director's one-year service period at the end of each calendar quarter beginning with the end of the second quarter. As the shares vest, those shares that have been deferred by non-employee directors under Noven's deferred compensation plan are transferred into a rabbi trust maintained by Noven. In accordance with Emerging Issues Task Force 97-14, Accounting for Compensation Arrangements Where Amounts Earned are Held in a Rabbi Trust and Invested, the deferred shares were recorded at their fair value and classified as common stock held in trust. Since the deferral relates to Noven common stock, an offsetting amount was recorded as deferred compensation obligation in the stockholders' equity section of the balance sheet. As of September 30, 2007, there were

a total of 41,742 shares of common stock in the rabbi trust.

**Table of Contents**

On August 14, 2007, Noven granted 8,998 shares of restricted stock to a former executive of JDS for joining Noven's Board of Directors in connection with the Merger. The shares were vested immediately upon being granted and were expensed for the three and nine months ended September 30, 2007. Also on August 14, 2007, Noven granted 44,297 SSARs as settlement for a non-competition agreement with a former executive of JDS in connection with the Merger.

The following table summarizes information regarding Noven's restricted stock at September 30, 2007 (shares in thousands):

	Shares	Weighted Average Grant-Date Fair Value
Nonvested at December 31, 2006	8	\$ 17.47
Granted	35	21.28
Vested	(30)	19.54
Forfeited		
Nonvested at September 30, 2007	13	\$ 22.86

The assumptions used to value the SSARs for the three months ended September 30, 2007 and 2006 were as follows:

	2007	2006
Volatility	41.8%	52.8%
Risk free interest rate	4.50%	5.17%
Expected life (years)	4	5

Total stock-based compensation recognized in Noven's statements of operations for the three and nine months ended September 30, 2007 and 2006 was as follows (in thousands):

	Three Months		Nine Months	
	2007	2006	2007	2006
Selling, general and administrative	\$ 894	\$ 649	\$ 2,372	\$ 1,791
Research and development	127	109	381	333
Total cost of products sold	121	71	365	234
	\$ 1,142	\$ 829	\$ 3,118	\$ 2,358
Tax benefit recognized related to compensation expense	\$ 359	\$ 198	\$ 1,020	\$ 556

There were no stock-based compensation costs capitalized as part of inventory or fixed assets for the nine months ended September 30, 2007 or 2006.

Cash received from options exercised under all share-based payment arrangements for the nine months ended September 30, 2007 and 2006 was \$2.5 million and \$8.1 million,

**Table of Contents**

respectively. The tax benefit realized on the tax deductions from option exercises under stock-based compensation arrangements totaled \$0.5 million and \$2.4 million for the nine months ended September 30, 2007 and 2006, of which \$0.4 million and \$1.6 million was reported as cash flow from financing activities for the nine months ended September 30, 2007 and 2006, respectively.

Stock option and SSAR transactions related to the 1999 Plan are summarized as follows for the nine months ended September 30, 2007 (options/SSARs and aggregate intrinsic value in thousands):

	Options/ SSARs	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Term
Outstanding at beginning of the period	3,275	\$ 19.26		
Granted	49	17.23		
Exercised	(162)	15.64	\$ 1,581	
Canceled and expired	(47)	25.41		
Outstanding at end of the period	3,115	\$ 19.32	\$ 4,057	3.4
Outstanding and exercisable at end of the period	2,110	\$ 20.69	\$ 1,887	2.6
Vested or expected to vest at end of the period	2,728	\$ 19.51	\$ 3,275	3.4

As of September 30, 2007, the unamortized compensation expense that Noven expects to record in future periods related to currently outstanding unvested stock options, SSARs and restricted stock is approximately \$5.9 million before the effect of income taxes, of which \$1.0 million, \$2.5 million, \$1.6 million and \$0.8 million is expected to be incurred in the remainder of 2007 and in 2008, 2009 and 2010, respectively. The weighted-average period over which this compensation cost is expected to be recognized is two years.

**11. INCOME TAXES:**

On January 1, 2007, Noven adopted the provisions of, and began accounting for uncertainty in income taxes in accordance with, FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* an interpretation of FASB Statement 109 (FIN 48). This interpretation requires companies to determine whether it is more likely than not that a tax position will be sustained upon examination by the appropriate taxing authorities before any part of the benefit can be recorded in the financial statements. FIN 48 clarifies the accounting for income taxes by prescribing a minimum recognition threshold a tax position is required to meet before recognition in the financial statements. FIN 48 requires a two-step approach when evaluating a tax position based on recognition (Step 1) and measurement (Step 2).

Upon adoption of FIN 48, and as a result of the recognition and measurement of Noven's tax positions as of January 1, 2007, Noven recognized a charge of approximately \$0.5 million to the January 1, 2007 retained earnings balance. The gross amount of unrecognized tax benefits as of the date of adoption, January 1, 2007, was \$1.2 million, including \$0.3 million in interest and penalties. If the \$1.2 million was ultimately recognized, only \$0.9 million would affect the effective tax rate due to approximately \$0.3 million in federal tax benefit. As of September 30,

**Table of Contents**

2007 the gross amount of unrecognized tax benefits was approximately \$1.8 million. Interest and penalties related to income taxes are classified as a component of income tax expense. It is reasonably possible that the gross amount of unrecognized tax benefits may increase by approximately \$0.2 million within 12 months after September 30, 2007.

Noven is periodically audited by federal and state taxing authorities. The outcome of these audits may result in Noven being assessed taxes in addition to amounts previously paid. Federal tax returns for years 2004–2006 remain open and subject to examination by the Internal Revenue Service. Noven files and remits state income taxes in various states where Noven has determined it is required to file state income taxes, and Noven's filings with those states remain open for audit, inclusively, for the years 2002–2006. Noven is not aware of any examinations currently taking place related to its income taxes in any jurisdiction. It is possible that examinations may be initiated by any jurisdiction where Noven operates, or where it can be determined that Noven operates, and the results of which may increase Noven's income tax liabilities or decrease the amount of deferred tax assets and may also materially change the amount of unrecognized income tax benefits for tax positions taken.

At September 30, 2007 and December 31, 2006, net deferred tax assets were \$62.2 million and \$12.7 million, respectively. The net deferred tax asset at September 30, 2007 includes deferred tax assets related to the acquisition of JDS of \$38.0 million, of which substantially all relates to temporary differences on acquired IPR&D intangible assets acquired from JDS. Realization of this deferred tax asset depends upon the generation of sufficient future taxable income. A valuation allowance is established if it is more likely than not that all or a portion of the deferred tax asset will not be realized. JDS files separate state income tax returns in states where JDS has determined that it is required to file state income taxes. As a result, state deferred tax assets relating to JDS are evaluated separately in determining whether the state deferred tax assets are realizable. Noven expects that JDS will incur taxable losses in the next few years due to future expected clinical trial expenditures related to product development. These expected taxable losses create negative evidence indicating the need for a valuation allowance at September 30, 2007. Noven recorded a valuation allowance of \$3.4 million during the quarter ended September 30, 2007, due to uncertainties in realizing these state deferred tax assets based on Noven's projection of future state taxable income. If Noven determines, based on future JDS profitability that these state deferred tax assets are more likely than not to be realized, a release of all, or part, of the related valuation allowance could result in an immediate income tax benefit in the period the valuation allowance is released.

**12. CONTRACT AND LICENSE AGREEMENTS:***Daytrana*

Noven has developed a once-daily transdermal methylphenidate patch for Attention Deficit Hyperactivity Disorder (ADHD) called Daytrana. In the first quarter of 2003 Noven licensed to Shire the exclusive global rights to market Daytrana for payments by Shire of up to \$150.0 million. In consideration for this licensing transaction, Shire agreed to pay Noven as follows: (i) \$25.0 million was paid upon closing of the transaction in April 2003; (ii) \$50.0 million was paid in April 2006 upon receipt of final marketing approval by the FDA; and (iii) three installments of \$25.0 million each are payable upon Shire's achievement of \$25.0 million, \$50.0 million and \$75.0 million in annual Daytrana net sales, respectively. Shire launched the product in June 2006. Noven received the first \$25.0 million sales milestone in the 2007 first quarter, and the second \$25.0 million sales milestone in the 2007 third quarter. For purposes of the sales milestones, Shire's annual net sales are measured quarterly on a trailing 12-month basis, with each milestone payment due 45 days after the end of the first calendar quarter during which trailing 12-month sales exceed the applicable threshold. Noven is currently deferring and recognizing approval and sales milestones as license revenues on a straight-line basis, beginning on the date the milestone is achieved through the first quarter of 2013, which is Noven's current best estimate of the end of the useful economic life of the product. Noven also manufactures and supplies finished product for Shire.

*Amphetamine Transdermal System*

In addition to Noven's agreements with Shire related to Daytrana in June 2004 Noven entered into an agreement with Shire for the development of a transdermal amphetamine patch for ADHD, and in July 2006, Noven and Shire amended this agreement. Under the amended agreement, Shire paid Noven a non-refundable \$1.0 million in August 2006, in exchange for



**Table of Contents**

the option of purchasing, for an additional \$5.9 million, the exclusive developmental rights to the product. The amended agreement further provided that Noven would perform certain early-stage development activities which were previously to be performed by Shire. Noven completed a Phase I clinical study for the product in March 2007. In June 2007, Shire exercised its option to acquire the exclusive development rights to the product and Noven received the \$5.9 million option payment. This \$5.9 million, as well as the initial \$1.0 million received from Shire for the grant of the option, was included in deferred contract revenues on Noven's balance sheet as of September 30, 2007. Simultaneous with the \$5.9 million payment, Shire requested modifications to the patch formulation in order to align the amphetamine patch with Shire's future direction in ADHD, and has agreed to pay Noven for its development efforts in this regard.

*Pexeva®*

In November 2005, JDS entered into an asset purchase agreement with Synthron Pharmaceuticals, Inc. ( Synthron ) for the purchase of Pexeva®. In this transaction, JDS purchased certain assets related to Pexeva® including: the New Drug Application ( NDA ), intellectual property (including patents and trademarks) and certain finished goods inventory. The purchase of Pexeva® included a cash payment at the time of closing and an obligation to make certain future fixed payments and certain contingent payments.

Following the Merger, Noven became responsible for the possible future contingent payments of up to \$11.5 million under the asset purchase agreement with Synthron. See Note 3 Acquisition of JDS Pharmaceuticals, LLC Long-term Liabilities Assumed.

*Lithobid®*

In August 2004, JDS entered into an asset purchase agreement with Solvay Pharmaceuticals, Inc. ( Solvay ) for the purchase of Lithobid®. In this transaction, JDS purchased certain assets related to Lithobid® including: the NDA, intellectual property (including trademarks) and certain finished goods inventory, which was paid in full prior to the closing of the Merger. In connection with the acquisition of the product rights for Lithobid®, JDS entered into an agreement requiring Solvay to manufacture and supply Lithobid® for up to five years, subject to certain limitations. The manufacturing and supply agreement has been assigned by Solvay to ANI Pharmaceuticals, Inc.

*Lithium QD*

In March 2004, JDS entered into an asset purchase agreement with an unrelated third party to acquire certain U.S. and international patents and other intellectual property related to a once daily lithium carbonate product ( Lithium QD ) for the purpose of developing, obtaining regulatory approval, manufacturing and marketing the product in the United States, Canada and certain other countries. The asset purchase agreement provides for potential future payments to the seller of up to \$4.0 million subject to the achievement of certain development milestones. JDS has separately entered into an exclusive supply agreement for the manufacture of Lithium QD with another unrelated third party which also provides for additional potential contingent payments of up to \$2.0 million.

*Stavzor*

In April 2007, JDS entered into a development, license and supply agreement with Banner Pharmacaps Inc. ( Banner ) in which Banner licensed rights to a delayed release valproic acid product ( Stavzor ), as well as rights to future development of an extended release valproic acid product, in return for a payment at closing, royalties on future sales, and up to \$6.0 million in

**Table of Contents**

potential development milestone payments. The agreement also provides that Banner shall be the exclusive supplier of the products licensed under the agreement.

13. INVESTMENT IN VIVELLE VENTURES LLC (d/b/a NOVOGYNE):

Noven shares in the earnings of Novogyne, after satisfaction of an annual preferred return of \$6.1 million to Novartis, according to an established formula. Noven's share of Novogyne's earnings increases as Novogyne's product sales increase, subject to a cap of 49%. Novogyne earned sufficient income in the first quarter of 2007 and 2006 to meet Novartis' annual preferred return for those years and for Noven to recognize earnings from Novogyne under the formula.

During the three and nine months ended September 30, 2007 and 2006, Noven had the following transactions with Novogyne (in thousands):

	Three Months		Nine Months	
	2007	2006	2007	2006
Revenues:				
Product sales	\$ 5,801	\$ 5,273	\$ 15,974	\$ 13,990
Royalties	2,100	1,791	5,764	5,138
	\$ 7,901	\$ 7,064	\$ 21,738	\$ 19,128
Reimbursed expenses	\$ 6,940	\$ 7,125	\$ 21,046	\$ 21,043

As of September 30, 2007 and December 31, 2006, Noven had amounts due from Novogyne of \$6.9 million and \$7.7 million, respectively.

The unaudited condensed statements of operations of Novogyne for the three and nine months ended September 30, 2007 and 2006 are as follows (in thousands):

	Three Months		Nine Months	
	2007	2006	2007	2006
Gross revenues	\$ 45,224	\$ 39,204	\$ 125,432	\$ 112,138
Sales allowances	5,770	4,283	16,769	11,622
Sales return allowances	781	1,193	772	4,576
Sales allowances and returns	6,551	5,476	17,541	16,198
Net revenues	38,673	33,728	107,891	95,940
Cost of sales	8,152	7,529	22,994	22,212
Selling, general and administrative expenses	8,278	9,419	27,990	28,172
Income from operations	22,243	16,780	56,907	45,556
Interest income	286	250	783	564
Net income	\$ 22,529	\$ 17,030	\$ 57,690	\$ 46,120
Noven's equity in earnings of Novogyne	\$ 10,948	\$ 8,234	\$ 25,025	\$ 19,323



**Table of Contents**

The activity in the Investment in Novogyne account for the nine months ended September 30, 2007 is as follows (in thousands):

Investment in Novogyne, beginning of period	\$ 23,296
Equity in earnings of Novogyne	25,025
Cash distributions from Novogyne	(18,465)
Non-cash distribution from Novogyne (Note 4)	(5,192)
Investment in Novogyne, end of period	\$ 24,664

Subject to the approval of Novogyne's management committee, Novogyne may, from time to time, distribute cash to Novartis and Noven based upon a contractual formula. For the three and nine months ended September 30, 2007, Noven received cash distributions representing return on investment of \$7.5 million and \$18.5 million from Novogyne, respectively. For the three and nine months ended September 30, 2006, Noven received cash distributions representing return on investment of \$7.4 million and \$17.6 million from Novogyne, respectively. In addition, as discussed in Note 5, tax payments of \$5.2 million and \$2.2 million were made by Novogyne on Noven's behalf to the New Jersey Department of Revenue during the nine months ended June 30, 2007 and 2006, respectively. These amounts were recorded as reductions in the investment in Novogyne when received (or in the case of the tax payment, when paid).

**14. SHARE REPURCHASE PROGRAM:**

In the third quarter of 2007, Noven's Board of Directors authorized a share repurchase program under which Noven may acquire up to \$25.0 million of its common stock. As of September 30, 2007, Noven had repurchased 322,345 shares of its common stock at an aggregate price of approximately \$5.1 million. These shares remained in the treasury as of September 30, 2007.

**15. SEGMENT INFORMATION:**

Noven has two reportable segments, the Transdermal Segment, which currently consists of research, development, manufacture and licensing to partners of advanced transdermal drug delivery technologies and prescription transdermal products and the JDS Segment, which currently consists of development, marketing, sales and distribution of pharmaceutical products. Prior to the acquisition of JDS, Noven had one reportable segment. Additionally, certain general and administrative expenses are reported in Corporate/Other. Noven does not report depreciation expense, total assets and capital expenditures by segment as such information is not used by Noven's chief operating decision maker.

The accounting policies of the segments are the same as those described in Note 2 of the notes to the financial statements included in Noven's Form 10-K, as updated and supplemented by this Form 10-Q. The table below presents segment information for the periods identified and provides a reconciliation of segment information to total consolidated information. Reconciliations of segment information for the three and nine months ended September 30, 2006 are not presented as Noven had one segment during those periods. For the Transdermal Segment and the JDS Segment, segment income (loss) from operations represents segment gross profit less direct research and development expenses, acquired IPR&D and direct selling, general and administrative expenses.

**Table of Contents**

	For the three months ended September 30, 2007 (amounts in thousands)			
	Noven Transdermal	JDS (1)	Corporate Other	Consolidated
Net revenues	\$ 18,490	\$ 3,325	\$	\$ 21,815
Acquired in-process research and development		100,150		100,150
Income (loss) from operations	6,328	(101,650)	(8,346)	(103,668)
Equity in earnings of Novogyne	10,948			10,948

	For the nine months ended September 30, 2007 (amounts in thousands)			
	Noven Transdermal	JDS(1)	Corporate / Other	Consolidated
Net revenues	\$ 56,644	\$ 3,325	\$	\$ 59,969
Acquired in-process research and development		100,150		100,150
Income (loss) from operations	19,590	(101,650)	(19,476)	(101,536)
Equity in earnings of Novogyne	25,025			25,025

- (1) Includes JDS s results from the Closing Date through September 30, 2007.

**16. COMMITMENTS AND CONTINGENCIES:*****HT Studies***

As a result of the findings from the Women s Health Initiative ( WHI ) study and other studies previously disclosed in Noven s Form 10-K, the FDA has required that black box labeling be included on all menopausal hormone therapy ( HT ) products marketed in the United States to warn, among other things, that these products have been associated with increased risks for heart disease, heart attacks, strokes, and breast cancer and that they are not approved for heart disease prevention.

Researchers continue to analyze data from both arms of the WHI study and other studies. Other studies evaluating HT are currently underway or in the planning stages. The market for Noven s products could be adversely affected if these studies find that a transdermal estrogen patch is less beneficial than other dosage forms, and Noven could be subject to increased product liability risk if HT patch products are found to increase the risk of adverse health consequences. Noven is currently named as a defendant in six product liability lawsuits involving its HT products and Noven may have liability with respect to other actions in which it has not, to date, been made a party. See Litigation, Claims and Assessments below for a further discussion on related product liability lawsuits.

Since the July 2002 publication of the WHI and other study data, total United States prescriptions have declined for substantially all HT products, including Noven s products in the aggregate. Prescriptions for CombiPatch®, Noven s combination estrogen/progestin patch,

**Table of Contents**

continue to decline in the post-WHI environment. Novogyne recorded the acquisition of the marketing rights for Noven's CombiPatch® product at cost and Novogyne tests this asset for impairment on a periodic basis. Further adverse change in the market for HT products could have a material adverse impact on the ability of Novogyne to recover its investment in these rights, which could require Novogyne to record an impairment loss on the CombiPatch® intangible asset. Impairment of the CombiPatch® intangible asset would adversely affect Novogyne's and Noven's financial results. Management cannot predict whether these or other studies will have additional adverse effects on Noven's liquidity and results of operations, or Novogyne's ability to recover the net carrying value of the CombiPatch® intangible asset.

*Production Issues*

In July 2007, Noven submitted a response to the list of observations on Form 483 received from the FDA following an on-site inspection of Noven's manufacturing facilities. The majority of the observations in the Form 483 relate to the Daytrana patch and difficulties experienced by some patients in removing the release liner of the Daytrana patch, including certain product lots that utilize an enhanced release liner. No assurance can be given that Noven's response will be acceptable to the FDA or satisfactorily address the FDA's concerns, and there can be no assurance that the FDA will not take regulatory action that could adversely affect Noven's business, results of operations and financial position.

In September 2007, Shire initiated a voluntary market withdrawal of a portion of Daytrana product on the market primarily in response to feedback from patients and caregivers who experienced difficulty removing the release liner from some Daytrana patches. Noven will reimburse Shire for certain costs related to the withdrawal, which are estimated to be approximately \$3.3 million. Noven recognized this amount in allowances and expenses associated with the withdrawal in the third quarter of 2007. Specifically, revenues for the three months ended September 30, 2007 are net of approximately \$0.8 million in allowances for returns at Noven related to the withdrawal. In addition, for the three months ended September 30, 2007 Noven's cost of products sold includes \$0.3 million of AMI and destruction costs and selling, general and administrative expenses for the three months ended September 30, 2007 included \$2.2 million in withdrawal costs. No assurance can be given that the actual amount of the withdrawal costs will not exceed Noven's estimate.

In the first quarter of 2007, Noven and Shire implemented enhancements to the Daytrana release liner intended to improve ease of use of the patch. Noven's results of operations and financial position could be adversely affected if the Daytrana product that was not subject to the market withdrawal does not improve Daytrana's ease of use.

*Novogyne Supply Agreement*

Noven's supply agreement with Novogyne for Vivell® and Vivelle-Dot® patches expired in January 2003. While the parties have continued to operate in accordance with certain of the supply agreement's pricing terms, there is no assurance that the parties will continue to do so. Novogyne's designation of a new supplier and approval of a new supply agreement would require the affirmative vote of four of the five members of Novogyne's Management Committee. Since Noven appoints two members of Novogyne's Management Committee, both Novartis and Noven must agree on Novogyne's supplier.

*Litigation, Claims and Assessments*

In September 2005, Noven, Novogyne and Novartis were served with a summons and complaint from an individual plaintiff in Superior Court of New Jersey Law Division, Atlantic County in which the plaintiff claims personal injury allegedly arising from the use of HT products, including Vivelle®. The plaintiff claims compensatory, punitive and other damages in

**Table of Contents**

an unspecified amount. Noven does not expect any activity in this case in the near future, as the court has entered an order to stay proceedings in all its pending and future HT cases except for cases where Wyeth Pharmaceuticals and its affiliates and Pfizer, Inc. are the defendants.

In April 2006, an individual plaintiff and her husband filed a complaint in the United States District Court, District of Minnesota against Noven, Novogyne, Novartis, Wyeth Inc. and Wyeth Pharmaceuticals, Inc. alleging liability in connection with personal injury claims allegedly arising from the use of HT products, including Noven's CombiPatch® product. The plaintiffs claim compensatory and other damages in an unspecified amount.

In July 2006, four complaints were filed in the United States District Court, District of Minnesota against Noven and other pharmaceutical companies by four separate individual plaintiffs, each filing alone or with her husband. Three of the complaints also name Novartis as a defendant, and of these, two name Novogyne as a defendant as well. Each complaint alleges liability in connection with personal injury claims allegedly arising from the use of HT products, including Vivelle® in one case and CombiPatch® in two of the cases. The plaintiffs in each case claim compensatory and other damages in an unspecified amount. Noven has established an accrual for the expected legal fees related to the cases referenced above, although the amount is not material.

Novartis has advised Noven that Novartis has been named as a defendant in at least 25 lawsuits that include approximately 26 plaintiffs that allege liability in connection with personal injury claims allegedly arising from the use of HT patches distributed and sold by Novartis and Novogyne, including Noven's Vivelle-Do®, Vivelle®, and CombiPatch® products. Novogyne has been named as a defendant in one lawsuit in addition to the four lawsuits referenced above. Novartis has indicated that it will seek indemnification from Noven and Novogyne to the extent permitted by the agreements between and among Novartis, Novogyne and Noven. Novogyne's aggregate limit under its claims-made insurance policy as of September 30, 2007 was \$10.0 million. Novogyne has established reserves in the amount of \$10.1 million with an offsetting insurance recovery of \$7.8 million for expected defense and settlement expenses as well as for estimated future cases alleging use of Noven's HT products. This accrual represents Novartis management's best estimate as of September 30, 2007.

Noven intends to defend all of the foregoing lawsuits vigorously, but the outcome of these product liability lawsuits cannot ultimately be predicted.

In June 2007, Johnson-Matthey Inc. filed a complaint in the United States District Court, Eastern District of Texas against Noven alleging that Noven was infringing one of its patents through its manufacture and sale of Daytrana. The plaintiff is seeking injunctions from further infringement and claiming compensatory and other damages in an unspecified amount. Noven intends to vigorously defend this lawsuit. In July 2007, Johnson-Matthey added Shire as a defendant to this lawsuit after Shire filed a declaratory judgment against Johnson-Matthey in the United States District Court, Eastern District of Pennsylvania. In August 2007, Noven filed a motion for a transfer of venue of the case to the United States District Court, Eastern District of Pennsylvania. Noven's ultimate liability, if any, with respect to the lawsuit is presently not determinable.

Noven is a party to other pending legal proceedings arising in the normal course of business, none of which Noven believes is material to its financial position, results of operations or cash flows.

***JDS Segment commitments***

As part of the acquisition of JDS, Noven has certain commitments and contingencies related to contractual arrangements, primarily related to milestone payments for development, FDA submission, FDA approval and commercial sales of products under development. As of September 30, 2007, Noven was responsible for \$23.5 million in such contingent milestones, which may be payable over the next three to five years. As of September 30, 2007, \$11.5 million of these milestones were reflected in Noven's balance sheet. See Note 12 Contract and License Agreements for additional information.

**Table of Contents**

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

The following section addresses material aspects of our financial condition at September 30, 2007, and our results of operations for the three months ended September 30, 2007 (the 2007 Quarter ) and September 30, 2006 (the 2006 Quarter ), and the nine months ended September 30, 2007 (the 2007 Period ) and September 30, 2006 (the 2006 Period ). The contents of this section include:

An executive summary of our results of operations for the 2007 Quarter;

An overview of our transdermal business and our Novogyne joint venture;

An overview of our JDS Segment;

A review of certain items that may affect the historical or future comparability of our results of operations;

An analysis of our results of operations and our liquidity and capital resources;

A discussion of how we apply our critical accounting estimates;

A discussion of recently-issued accounting standards; and

An outlook that includes our current financial guidance.

This discussion should be read in conjunction with Noven's financial statements for the three and nine months ended September 30, 2007 and 2006 and the related notes included elsewhere in this Form 10-Q, as well as the section Management's Discussion and Analysis of Financial Condition and Results of Operations from our Form 10-K.

**Executive Summary**

*The following Executive Summary is qualified in its entirety by the more detailed discussion and analysis of our financial condition and results of operations appearing in this Item 2 as well as in our financial statements and related notes included in this Form 10-Q.*

Our financial results for the 2007 Quarter are the first results that we have reported following our acquisition of JDS Pharmaceuticals, LLC ( JDS ), a specialty pharmaceutical company focused in psychiatry and women's health. The JDS acquisition marked our transition from primarily a drug delivery company to a fully-integrated specialty pharmaceutical company. Our results include the results of operations for JDS from August 14, 2007 through September 30, 2007.

The 2007 Quarter also includes (i) a one-time \$100.2 million charge for the JDS purchase price allocated to in-process research and development, which is required under the accounting rules, and (ii) a net \$3.3 million charge related to reimbursements to Shire plc in connection with the voluntary withdrawal of a portion of Daytrana product in the trade channel.

Including the impact of these substantial charges, we reported a net loss of \$59.0 million (\$2.38 loss per share) for the 2007 Quarter, compared to net income of \$5.0 million (\$0.20 diluted earnings per share) for the 2006 Quarter.

Our net revenues in the 2007 Quarter were \$21.8 million, an increase of 39% compared to the \$15.7 million reported in the 2006 Quarter. This increase reflects the recognition of \$3.3 million in net revenues associated with our sales of Pexeva® and Lithobid® products. The increase also reflected higher sales of our Vivelle-Dot® estrogen patch and higher license revenues due to the amortization of additional Daytrana sales milestones.

**Table of Contents**

Our gross margin percentage in the 2007 Quarter was 41% compared to 30% in the 2006 Quarter. Gross margin in the 2007 Quarter benefited primarily from higher overall product revenues, greater transdermal facility utilization, and the continuing benefit of cost reductions implemented in the 2006 Quarter. The 2007 Quarter also benefited from a 76% gross margin percentage on JDS product sales.

Research and development expenses for the 2007 Quarter increased 44% to \$3.6 million, primarily attributable to a \$0.8 million increase in clinical research associated with our transdermal pipeline and to \$0.5 million in JDS-related research and development expenses.

Selling, general and administrative expenses for the 2007 Quarter increased \$5.9 million, or 98%, to \$11.9 million, reflecting the addition of \$3.5 million in JDS-related expenses and \$2.2 million in expenses associated with the voluntary market withdrawal of a portion of Daytrana product.

We recognized \$10.9 million in earnings from Novogyne in the 2007 Quarter, an increase of 33% compared to the 2006 Quarter. Net revenues at Novogyne increased 15% to \$38.7 million in the 2007 Quarter, primarily due to increased sales of Vivelles-Dot®. Novogyne's gross margin for the 2007 Quarter, at 79%, was consistent with the 2006 Quarter. Selling, general and administrative expenses decreased 12% due to the timing of samples expense. Novogyne's net income for the 2007 Quarter increased 32% to \$22.5 million, compared to \$17.0 million in the 2006 Quarter.

At September 30, 2007, we had an aggregate \$72.4 million in cash and cash equivalents and short-term investments, compared to \$153.6 million at December 31, 2006. This decrease reflects the payment of \$130.4 million in the JDS acquisition; tax payments of \$16.2 million; and \$5.1 million used to purchase shares under our recently-established share repurchase program, partially offset by the receipt of an aggregate \$50.0 million in milestone payments relating to Shire's sales of Daytrana, \$18.5 million in distributions received from Novogyne; and \$5.9 million received from Shire in connection with our amphetamine patch development program.

Total prescriptions for Vivelles-Dot® increased 4% in the 2007 Quarter compared to the 2006 Quarter, and total prescriptions for Novogyne's products, taken as a whole, increased 2%. By comparison, the overall U.S. HT market declined 8% for the same period. Total prescriptions for Daytrana (launched in June 2006) increased 64% in the 2007 Quarter compared to the 2006 Quarter, while prescriptions for ADHD stimulant therapies as a class increased 8% for the same period. Reflecting ongoing generic substitution, total prescriptions for Lithobid® decreased 39% in the 2007 Quarter compared to the 2006 Quarter. Total prescriptions for Pexeva® increased 21% in the 2007 Quarter compared to the 2006 Quarter, while for the same period prescriptions for the SSRI class of antidepressants were largely unchanged.

**Overview of Noven's Transdermal Business and Our Novogyne Joint Venture**

Our transdermal business is focused on developing advanced transdermal patches. We presently derive the majority of our transdermal revenues from sales of transdermal patches for use in menopausal HT. In the United States, our HT products are marketed and sold by Novogyne Pharmaceuticals, the joint venture that we formed with Novartis in 1998. Our business, financial position and results of operations are significantly dependent upon Novogyne and its marketing of our HT products in the United States. A discussion of Novogyne's results of operations and their impact on our results can be found under the caption "Results of Operations - Equity in Earnings of Novogyne."

In all countries other than the United States, Canada and Japan, we have licensed the marketing rights to these products to Novartis Pharma, which is an affiliate of Novartis. In most of

**Table of Contents**

these markets, Vivelle® is marketed under the brand name Menorest, Vivelle-Dot® is marketed under the brand name Estradot® and CombiPatch® is marketed under the brand name Estalis®.

We hold a 49% equity interest in Novogyne, and Novartis holds the remaining 51% equity interest. Under the terms of the joint venture agreements, we manufacture and supply our HT products to Novogyne, perform marketing, sales and promotional activities, and receive royalties from Novogyne based on Novogyne's sales of the estrogen therapy ( ET ) products. Novartis distributes Vivelle®, Vivelle-Dot® and CombiPatch® and provides certain other services to Novogyne, including financial and accounting functions.

Novartis is entitled to an annual \$6.1 million preferred return from Novogyne, which has the effect of reducing our share of Novogyne's income in the first quarter of each year. After the annual preferred return to Novartis, our share of Novogyne's income increases as product sales increase, subject to a maximum of 49%. Our share of Novogyne's income was \$10.9 million and \$8.2 million for the 2007 Quarter and the 2006 Quarter, respectively. The income we recognize from Novogyne is a non-cash item. Any cash we receive from Novogyne is in the form of cash distributions declared by Novogyne's Management Committee. Accordingly, the amount of cash that we receive from Novogyne in any period is typically not the same as the amount of income we recognize from Novogyne for that period. For the 2007 Period and the 2006 Period, we received \$18.5 million and \$17.6 million, respectively, in distributions from Novogyne, which, excluding the \$50.0 million Daytrana milestones received from Shire in 2007, accounted for a substantial portion of our net cash flows generated by operating activities for these periods. We expect that for the next several years a significant portion of our earnings will be generated through our interest in Novogyne and a significant portion of our cash flow will also be generated through our interest in Novogyne, as well as any additional milestone payments we may receive from Shire. Any failure by Novogyne to remain profitable or to continue to make distributions would have a material adverse effect on our results of operations and financial condition.

The market for HT products, including transdermals, significantly declined in the years following the July 2002 publication of the WHI study that found adverse health risks associated with HT, and in current periods the market continues to decline. Comparing the 2007 Quarter to the 2006 Quarter, total prescriptions dispensed in the HT market in the United States decreased 8%. Comparing the same periods, aggregate prescriptions for our United States HT products increased 2%. Total prescriptions in the estrogen segment of the HT market in the United States decreased 9% comparing the same periods, while prescriptions for our Vivelle® line of products increased 3%. Vivelle-Dot®, which represented 89% of our total United States HT prescriptions in the 2007 Quarter, increased 4% from the 2006 Quarter. We believe that Vivelle-Dot® patch prescriptions have benefited from patient conversions from the original Vivelle® product (the predecessor product to Vivelle-Dot®), which represented 3% of our total United States prescriptions in the 2007 Quarter. Vivelle® is in the process of being discontinued in several jurisdictions where our advanced Vivelle-Dot® ET patch has gained acceptance. We ceased manufacturing of Vivelle® for the United States market at the end of 2006.

United States prescriptions for our CombiPatch® product (which represented approximately 8% of our total United States HT prescriptions in the first quarter of 2007) decreased 9% from the 2006 Quarter to the 2007 Quarter, while prescriptions for the total United States market for fixed combination hormone therapy decreased 10%. The combination therapy arm of the WHI studies involved an oral combination estrogen/progestin product and, accordingly, the combination therapy segment of the HT market has experienced the most significant decline. Further decreases above expectations for our CombiPatch® product (whether as a result of the WHI studies, competition in the category or otherwise) could require Novogyne (which holds the CombiPatch® marketing rights) to record an impairment loss related to these marketing rights, which would adversely affect the results of operations of both Noven and Novogyne.

**Table of Contents**

**Overview of Noven's JDS Segment**

JDS, acquired by us in August 2007, is a specialty pharmaceutical company that is currently marketing two branded prescription psychiatry products and is advancing several developmental products in psychiatry and women's health. We will seek to leverage JDS's marketing and sales infrastructure with next-generation psychiatry products and with complementary products that we will seek to develop and/or acquire.

JDS's marketed and developmental products consist of:

Pexeva®, a selective serotonin re-uptake inhibitor (SSRI) antidepressant indicated for major depressive disorder, panic disorder, obsessive compulsive disorder and generalized anxiety disorder. It is one of only two remaining patented brands without a generic equivalent in the over \$6.0 billion U.S. SSRI market. Pexeva® is subject to a composition of matter patent that extends to 2017 and other patents extending to 2022.

Lithobid®, an extended release lithium product, is the only branded lithium product sold in the U.S. Lithobid® is indicated for the maintenance of bipolar disorder and the treatment of related manic episodes, and participates in an estimated annual market for lithium therapies that exceeds \$400 million (calculated at branded prices).

Lithium QD, a developmental once-daily form of lithium carbonate, is in clinical development. It is subject to U.S. patents that extend to 2022 and may benefit from three years of exclusivity under the Hatch-Waxman Act. Currently there are no once-daily lithium products on the market. A once-daily lithium product has the potential to improve compliance and reduce high serum level peaks common with products prescribed in multiple doses per day. In October 2007, a Phase 3 clinical trial of Lithium QD did not achieve its primary endpoint with statistical significance. Clinical data from that trial is currently under analysis. We believe that additional clinical studies will be required to complete development of this product, at substantial additional cost, and with no assurance that development will be completed or that the product will ultimately be approved.

Stavzor & Stavzor ER. Through JDS, we hold marketing rights to Stavzor (valproic acid delayed release) and Stavzor ER (valproic acid extended release) in a proprietary enteric-coated soft gelatin capsule delivery system pursuant to a license with Banner Pharmacaps. If approved, these products are expected to be indicated for bipolar disorder, migraine therapy and epilepsy, and would compete with Abbott Laboratories Depakote® and Depakote® ER products. In October 2007, an NDA for Stavzor received an approvable letter from the FDA, and although there can be no assurance, the product is expected to be launched in mid-2008. Stavzor ER is in pre-clinical development by Banner. There can be no assurance that Stavzor ER will be successfully formulated, developed, approved or commercialized.

Mesafem. The pipeline that we acquired in the JDS transaction also includes a women's health product called Mesafem that, if approved, would complement our expertise in the women's health area. Mesafem is a low-dose paroxetine mesylate capsule under development for the treatment of vasomotor symptoms associated with menopause, including hot flashes and night sweats. Published clinical data has demonstrated the efficacy of paroxetine for this indication. Mesafem is subject to the same patents as Pexeva®, as well as other pending patent applications, and may benefit from three years of exclusivity under the Hatch-Waxman Act. Although there can be no assurance, we expect that Mesafem will enter Phase 3 studies in the first half of 2008.

Our expectations for future JDS Segment results are addressed under "Outlook" below.

**Table of Contents****Certain Items that May Affect Historical or Future Comparability**

For a discussion of certain items that may affect the historical or future comparability of our results of operations and financial condition, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations of our Form 10-K as well as the following updated and/or supplemented items. Such disclosure is not intended to address every item that may affect the historical or future comparability of our results of operations or financial condition and such disclosure should be read in conjunction with the discussion and analysis of our results of operations, liquidity and capital resources and outlook appearing elsewhere in this Item 2.

*JDS Pharmaceuticals, LLC*

We acquired JDS on August 14, 2007. The total purchase price for the JDS acquisition consisted of \$125.0 million paid at closing, approximately \$5.4 million of transaction costs consisting primarily of fees paid for financial advisory, legal, valuation and accounting services, and approximately \$0.5 million in connection with non-competition agreements entered into with two executives of JDS in connection with the Merger. Noven funded the Merger from the sale of short-term investments. The acquisition of JDS was accounted for under the purchase method of accounting. The total purchase price for the acquisition has been preliminary allocated to tangible and intangible assets acquired and liabilities assumed based on their estimated fair values at the Closing Date, which increased our assets and liabilities on the Closing Date as follows (amounts in thousands):

Current assets, including cash of \$0.6 million	\$ 7,893
Property and equipment	362
Intangible assets	
Acquired in-process research and development expenses	100,150
Identifiable intangible assets	38,547
Goodwill	14,359
Other assets	163
Accrued expenses and other current liabilities	(15,344)
Long-term obligations assumed	(3,711)
Contingent milestones assumed	(11,500)
 Total purchase price	 \$ 130,919

As noted in the table above, \$100.2 million of the purchase price has been allocated IPR&D, which was expensed in the 2007 Quarter immediately following the completion of the Merger. The IPR&D expense resulted in our significant losses for the three and nine months ended September 30, 2007.

The \$38.5 million in Identifiable Intangible Assets relate to (i) intellectual property rights associated with JDS's products approved by the FDA; (ii) favorable lease intangible asset; and (iii) non-competition agreements with two executives of JDS. At September 30, 2007, the carrying amount of Noven's intangible assets (including certain patent development costs unrelated to the JDS acquisition) totaled \$40.3 million. Noven estimates that the annual amortization expense for intangible assets held at September 30, 2007 for each of the five years through 2012 are as follows (amounts in thousands):

**Table of Contents**

	Remainder of 2007	2008	2009	2010	2011	2012
Cost of goods sold:						
Intellectual property	\$ 792	\$ 3,335	\$ 3,297	\$ 3,452	\$ 3,670	\$ 3,983
Selling, general and administrative:						
Non-competition agreements	55	221	171	55		
Favorable lease	74	115				
	129	336	171	55		
Total	\$ 921	\$ 3,671	\$ 3,468	\$ 3,507	\$ 3,670	\$ 3,983

We are required to test our intangible assets, including our goodwill, for impairment on an annual basis or more frequently if events or changes in circumstances indicate that the asset might be impaired. If after testing the intangible assets and goodwill, we determine that these assets are impaired, then we would be required to write-down the impaired asset to fair value in the period when the determination is made.

Substantially all of the acquired long-term obligation of \$3.7 million was paid immediately after closing. The \$11.5 million contingent milestones assumed relates to contingent sales milestones related to JDS's acquisition of Pexeva® from Synthon Pharmaceuticals, Inc. which are payable upon the achievement of specified sales levels of the product.

*Daytrana*

In September 2007, Shire initiated a voluntary market withdrawal of a portion of Daytrana product on the market primarily in response to feedback from patients and caregivers who experienced difficulty removing the release liner from some Daytrana patches. We will reimburse Shire for certain costs related to the withdrawal, which are estimated to be approximately \$3.3 million. We recognized this amount in allowances and expenses associated with the withdrawal in the 2007 Quarter. Specifically, revenues for the 2007 Quarter are net of approximately \$0.8 million in allowances for returns related to the voluntary market withdrawal of Daytrana. In addition, our cost of products sold includes \$0.3 million of AMI and destruction costs and our selling, general and administrative expenses in the 2007 Quarter include \$2.2 million in costs associated with this voluntary market withdrawal. No assurance can be given that the actual amount of the costs related to the market withdrawal will not exceed Noven's estimate.

In the first quarter of 2007, Noven and Shire implemented enhancements to the Daytrana release liner intended to improve ease of use of the patch. Noven's results of operations and financial position could be adversely affected if the Daytrana product that was not subject to the market withdrawal does not improve Daytrana's ease of use.

In July 2007, we submitted a response to the list of observations on Form 483 received from the FDA following an on-site inspection of our manufacturing facilities. The majority of the observations in the Form 483 relate to the Daytrana patch and difficulties experienced by some patients in removing the release liner of the Daytrana patch, including certain product lots that utilize an enhanced release liner. No assurance can be given that our response will be acceptable to the FDA or satisfactorily address the FDA's concerns, and there can be no assurance that the FDA will not take regulatory action that could adversely affect our business, results of operations and financial position.

The DEA controls access to controlled substances, including methylphenidate, the active ingredient in Daytrana. Manufacturers of products containing controlled substances must annually apply to the DEA for procurement quota in order to obtain these substances for manufacturing. At this time, we have received sufficient methylphenidate quota to meet expected Daytrana product orders from Shire for the remainder of 2007. No assurance can be given that we will receive sufficient quota in 2008 or any other future period. Given the DEA's current approach to awarding controlled substance quota, we expect at any given time to have applications pending with the DEA for procurement quota

(either annual or supplemental) that are likely to be critical to continued Daytrana production. Production is also dependent on receiving timely shipments of methylphenidate from suppliers. Any shortage, delay or stoppage in the supply of the active methylphenidate ingredient could cause us to lose revenues or incur additional costs (including those related to expedited production), which could have an adverse effect on our results of operations in general and our gross margin in particular.

**Table of Contents*****Results of Operations*****Three and nine months ended September 30, 2007 compared to the three and nine months ended September 30, 2006.*****Revenues***

Total revenues for the three and nine months ended September 30, 2007 and 2006 are summarized as follows (dollar amounts in thousands):

	Three Months			Nine Months		
	2007	2006	% Change	2007	2006	% Change
Product revenues						
Novogyne:						
Product sales	\$ 5,801	\$ 5,273	10%	\$ 15,974	\$ 13,990	14%
Royalties	2,100	1,791	17%	5,764	5,138	12%
	7,901	7,064	12%	21,738	19,128	14%
Product revenues third parties:						
Product sales	8,697	5,671	53%	25,381	15,402	65%
Royalties	92	90	2%	239	246	(3%)
	8,789	5,761	53%	25,620	15,648	64%
Total product revenues	16,690	12,825	30%	47,358	34,776	36%
Contract and license revenues:						
Contract	280	44	536%	179	1,112	(84%)
License	4,845	2,839	71%	12,432	7,559	64%
	5,125	2,883	78%	12,611	8,671	45%
Net revenues	\$ 21,815	\$ 15,708	39%	\$ 59,969	\$ 43,447	38%

**Net Revenues**

As described in more detail below, the 39% increase in net revenues for the 2007 Quarter as compared to the 2006 Quarter was primarily attributable to the addition of \$3.3 million in Pexeva® and Lithobid® revenues to product revenues third parties due to the acquisition of JDS on August 14, 2007. In addition, there were increases in license revenues due to additional amortization of deferred revenue related to Daytrana milestones and increases in Vivelle-Dot® product revenues.

As described in more detail below, the 38% increase in net revenues for the 2007 Period as compared to the 2006 Period was primarily attributable to increased sales of Daytrana and an increase in license revenue associated with that product. In addition, aggregate international product sales increased due to the timing of orders and higher minimum price reconciliation payments as compared to the 2006 Period. Aggregate sales to Novogyne increased primarily due to increased sales of Vivelle-Dot®. In addition, revenues in the 2007 Period benefited from the inclusion of Pexeva® and Lithobid® sales beginning with our acquisition of JDS on August 14, 2007.

**Product Revenues Novogyne**

Product revenues Novogyne consists of our sales of Vivelle-Dot<sup>®</sup>/Estradot<sup>®</sup>, CombiPatch<sup>®</sup> and Vivelle<sup>®</sup> hormone therapy patches to Novogyne at a fixed price for product sampling and resale by Novogyne primarily in the United States as well as the royalties we receive as a result of Novogyne's sales of Vivelle-Dot<sup>®</sup> and Vivelle<sup>®</sup>.

The \$0.8 million increase in product revenues from Novogyne for the 2007 Quarter as compared to the 2006 Quarter primarily related to a \$0.8 million increase in sales of Vivelle-Dot<sup>®</sup>. The Vivelle-Dot<sup>®</sup> increase reflects a \$1.2 million increase in trade product sales primarily due to the timing of orders from Novogyne and a \$0.4 million increase due to pricing, partially offset by a \$0.8 million decrease in samples attributable to the timing of orders from Novogyne.

**Table of Contents**

The \$2.6 million increase in product revenues from Novogyne for the 2007 Period as compared to the 2006 Period primarily related to a \$2.6 million increase in Vivelle-Dot<sup>®</sup>, of which \$1.3 million related to trade product sales due to increased prescription trends, \$0.8 million related to the timing of orders from Novogyne for samples of Vivelle-Dot<sup>®</sup> and \$0.5 million related to price. Royalties increased \$0.6 million due to higher sales by Novogyne for the 2007 Period. These increases are partially offset by a \$0.4 million decline in Estradot<sup>®</sup> sales due to timing of orders.

As noted below under Novogyne Net Revenues, Novogyne sells its products to trade customers, including wholesalers, distributors and chain pharmacies and the timing of orders by trade customers is difficult to predict and can lead to significant variability in trade customers ordering patterns. As a result, there may be significant period-to-period variability in Novogyne's ordering patterns from Noven.

**Product Revenues – Third Parties**

Product revenues – third parties consists of (i) sales of Estradot<sup>®</sup>, Estalis<sup>®</sup> and Menorest hormone therapy patches to Novartis Pharma at a price based on a percentage of Novartis Pharma's net selling price (subject to certain minima) for resale primarily outside the United States and Japan, together with royalties generated from Novartis Pharma's sales of Vivelle<sup>®</sup> and Estradot<sup>®</sup> in Canada; (ii) sales of Daytrana to Shire for commercial resale in the United States; and (iii) beginning on August 14, 2007, Noven's commercial sales of Pexeva<sup>®</sup> and Lithobid<sup>®</sup> to trade customers, including wholesalers, distributors and chain pharmacies.

The \$3.0 million increase in product revenues – third parties for the 2007 Quarter as compared to the 2006 Quarter primarily related to the addition of \$3.3 million in Pexeva<sup>®</sup> and Lithobid<sup>®</sup> revenues, as well as to a \$0.3 million increase related to HT product revenue partially offset by a \$0.6 million decrease in sales of Daytrana. The increase related to HT product revenue was attributable to the recognition of a \$0.5 million higher price adjustment payment received from Novartis Pharma in the 2007 Quarter compared to the 2006 Quarter. This increase was partially offset by a \$0.2 million decline in unit sales. The decrease in Daytrana is primarily due to \$0.8 million in allowances for returns related to the voluntary market withdrawal of the product.

The \$10.0 million increase in product revenues – third parties for the 2007 Period as compared to the 2006 Period primarily related to \$5.4 million increase in unit sales of Daytrana, the addition of \$3.3 million in Pexeva<sup>®</sup> and Lithobid<sup>®</sup> revenues and a \$1.3 million increase related to HT product pricing with Novartis Pharma. Daytrana product sales in the 2007 Period were \$11.0 million compared to \$5.7 million in the 2006 Period. Sales of Daytrana commenced in the second quarter of 2006. The increase related to HT product pricing was primarily due to the recognition of a higher price adjustment payment received from Novartis Pharma in the 2007 Period compared to the 2006 Period.

**Contract and License Revenues**

Contract revenues consist of the recognition of payments received as work is performed on research and development projects. The payments received may take the form of non-refundable up-front payments, payments received upon the completion of certain phases of work and success milestone payments. License revenues consist of the recognition of non-refundable up-front, milestone and similar payments under license agreements.

Contract revenue increased \$0.2 million for the 2007 Quarter due to termination of a contract for which we have no further continuing involvement. Contract revenues declined \$0.9 million for the 2007 Period, primarily reflecting a decline in contract work performed.

**Table of Contents**

License revenues increased \$2.0 million for the 2007 Quarter compared to the 2006 Quarter, mostly attributable to a \$2.1 million increase in the recognition of deferred license revenues related to Daytrana due to the recognition of an additional \$50.0 million in sales milestones. License revenues increased \$4.9 million for the 2007 Period compared to the 2006 Period, mostly attributable to a \$6.0 million increase in the recognition of deferred license revenues due to the amortization of the \$50.0 million approval milestone for three quarters in comparison to two quarters in the 2006 Period, amortization of the \$25.0 million milestone triggered in the fourth quarter of 2006 as well as amortization of the \$25.0 million milestone triggered in the second quarter of 2007. The 2006 Period benefited from the recognition of \$1.0 million in deferred license revenues related to one-time non-refundable payment from a third party.

**Gross to Net Revenues**

We record revenues net of sales allowances for rebates, chargebacks, cash and other discounts, as well as sales returns allowances. The following table sets forth the reconciliation of our gross sales to net sales for both our Transdermal Segment as well as our JDS Segment:

	Three Months			Nine Months		
	2007	2006	% Change	2007	2006	% Change
Noven transdermal						
Gross revenues	\$ 19,332	\$ 15,708	23%	\$ 57,486	\$ 43,447	32%
Sales returns allowances	(842)		N/M	(842)		N/M
Net revenues	18,490	15,708	18%	56,644	43,447	30%
JDS						
Gross revenues	5,066		N/M	5,066		N/M
Sales allowances	(1,550)		N/M	(1,550)		N/M
Sales returns allowances	(191)		N/M	(191)		N/M
Net revenues	3,325		N/M	3,325		N/M
Total net revenues	\$ 21,815	\$ 15,708	39%	\$ 59,969	\$ 43,447	38%

**Gross Margin**

This section discusses our gross margin percentages relating to our product revenues (i) across all of our products ( Overall Gross Margin ), (ii) on our product revenues from Novogyne ( Gross Margin Novogyne ), which for accounting purposes is considered a related party, and (iii) on our product revenues from third parties ( Gross Margin Third Parties ). Product revenues from third parties include HT product sales to Novartis Pharma for resale primarily outside the U.S. and Japan, Daytrana product sales to Shire and, starting on August 14, 2007, JDS sales of Pexeva<sup>®</sup> and Lithobid<sup>®</sup> to trade customers.

The allocation of overhead costs impacts our calculation of gross margins for each of our transdermal products. Overhead costs, which were in excess of \$6.0 million and \$18.0 million in the 2007 Quarter and 2007 Period, respectively, consist of salaries and benefits, supplies and tools, equipment costs, depreciation, and insurance costs. Overhead costs represent a substantial portion of our inventory production costs and the allocation of overhead among our various products requires us to make significant estimates that involve subjective and often complex judgments. Using different estimates would likely result in materially different results for Gross Margin Novogyne and Gross Margin Third Parties than are presented in the gross margin table below.

**Table of Contents**

Our gross margins for the three and nine months ended September 30, 2007 and 2006 are summarized as follows (dollar amounts in thousands):

	Three Months		Nine Months	
	2007	2006	2007	2006
<b>Overall Gross Margin:</b>				
Product revenues	\$ 16,690	\$ 12,825	\$ 47,358	\$ 34,776
Cost of products sold	9,811	9,041	28,052	27,068
Gross profit (product revenues less cost of products sold)	6,879	3,784	19,306	7,708
Gross margin (gross profit as a percentage of product revenues)	41%	30%	41%	22%

	Three Months		Nine Months	
	2007	2006	2007	2006
<b>Gross Margin Novogyne:</b>				
Product revenues	\$ 7,901	\$ 7,064	\$ 21,738	\$ 19,128
Cost of products sold	4,286	3,702	10,530	10,304
Gross profit (product revenues less cost of products sold)	3,615	3,362	11,208	8,824
Gross margin (gross profit as a percentage of product revenues)	46%	48%	52%	46%

	Three Months		Nine Months	
	2007	2006	2007	2006
<b>Gross Margin Third Parties:</b>				
Product revenues	\$ 8,789	\$ 5,761	\$ 25,620	\$ 15,648
Cost of products sold	5,525	5,339	17,522	16,764
Gross profit/(loss) (product revenues less cost of products sold)	3,264	422	8,098	(1,116)
Gross margin/(loss) (gross profit (loss) as a percentage of product revenues)	37%	7%	32%	(7%)

In general, our sales of Pexeva® and Lithobid® have a higher gross margin than our other products because we sell these products to trade customers at wholesale and commercial prices. Our sales of HT products to Novogyne for

resale in the U.S. have a higher gross margin than our other transdermal products, reflecting favorable pricing, larger production orders and other factors. Our sales of HT products to Novartis Pharma for resale in international markets generally have a lower gross margin than sales of HT products sold to Novogyne due to, among other things, unfavorable pricing environments in foreign markets, and smaller production orders.

As noted in the tables above, Overall Gross Margin improved significantly in both the 2007 Quarter and in the 2007 Period as compared to the similar periods in 2006. During the 2006 Quarter, our Overall Gross Margin was materially and adversely affected by start-up expenses associated with commencing production of Daytrana, and production inefficiencies including lower than desired yields and increased costs associated with meeting critical launch timelines. To a lesser extent,

**Table of Contents**

Overall Gross Margin in the 2006 Quarter was also negatively affected by increased personnel and other resources dedicated to quality control in our HT operations and by lower production volume in our HT business due to the timing of orders.

Overall Gross Margin in the 2007 Quarter and the 2007 Period benefited from (i) the addition of our Pexeva<sup>®</sup> and Lithobid<sup>®</sup> products, which had net sales of \$3.3 million and related cost of products sold of \$0.8 million, resulting in a gross margin of 76% for those products; (ii) significantly higher product revenues; higher facility utilization for our transdermal products, which contributed to improved overhead absorption; and cost savings associated with our cost reduction program that we implemented in the third quarter of 2006 to reduce costs and improve operating efficiency; and (iii) a \$0.5 million and \$1.3 million increase in price reconciliation payments relating to international sales of our HT products for the 2007 Quarter and in the 2007 Period in comparison to the same periods in 2006, respectively. These payments increase product revenues without increasing costs.

Overall Gross Margin in the 2007 Quarter and 2007 Period was negatively affected by our gross margin on Daytrana product sales during the 2007 Quarter. We sell Daytrana finished product to Shire at a fixed cost, so our profit on product sales of Daytrana depends on our ability to manufacture the product efficiently and to fully utilize our facilities. For the 2007 Quarter, Daytrana product revenues were \$1.4 million, (which reflects a \$0.8 million adjustment in allowances for returns at Noven related to the Daytrana market withdrawal) and cost of products sold related to Daytrana was \$2.0 million (which reflects a \$0.3 million adjustment for AMI and destruction costs related to the withdrawal), resulting in a negative quarterly gross margin for the product.

Our expectations for future gross margin performance are addressed under *Outlook* below.

**Operating Expenses**

Operating expenses for the three and nine months ended September 30, 2007 and 2006 are summarized as follows (dollar amounts in thousands):

	Three Months			Nine Months		
	2007	2006	% Change	2007	2006	% Change
Research and development	\$ 3,649	\$ 2,527	44%	\$ 10,300	\$ 8,899	16%
Acquired in-process research and development	100,150		N/M	100,150		N/M
Selling, general and administrative	11,873	6,010	98%	23,003	16,386	40%

**Research and Development**

Research and development expenses include costs associated with, among other things, product formulation, pre-clinical testing, clinical research and studies, regulatory and medical affairs, production for clinical and regulatory purposes, production related development engineering for developmental products, and the personnel associated with each of these functions. The \$1.1 million increase in research and development expenses for the 2007 Quarter as compared to the 2006 Quarter was primarily attributable to the addition of \$0.5 million of JDS expenses since the Closing Date related to clinical studies and an increase in our transdermal clinical research cost of \$0.8 million, partially offset by \$0.1 million decline in development engineering related to Daytrana and other products. The \$1.4 million increase in research and development expenses for the 2007 Period as

**Table of Contents**

compared to the 2006 Period was primarily due to a \$1.6 million increase in clinical research costs, \$0.5 million in JDS expenses since August 14, 2007 related to clinical studies and a \$0.3 million increase in personnel costs, partially offset by a \$0.7 million decline in development engineering related to Daytrana and other products.

**Acquired In-Process Research and Development**

We immediately expensed \$100.2 million in the 2007 Quarter and the 2007 Period representing the portion of the purchase price allocated to IPR&D in our acquisition of JDS. This amount represents the value assigned to projects that have been initiated and achieved material progress but (i) have not yet reached technological feasibility or have not yet reached the appropriate regulatory approval; (ii) have no alternative future use; and (iii) the fair value is estimable with reasonable certainty.

**Selling, General and Administrative**

Selling, general and administrative expenses increased \$5.9 million for the 2007 Quarter as compared to the 2006 Quarter primarily due to the addition of \$3.5 million of JDS expenses since the Closing Date primarily related to sales and marketing expenses. In addition, Noven's transdermal selling, general and administrative expenses increased \$2.4 million, primarily due to a \$2.2 million in costs associated with the voluntary withdrawal of Daytrana, \$0.8 million increase in professional fees and a \$0.2 million increase in stock-based compensation, partially offset by a \$0.8 million decline in salary and related benefits.

Selling, general and administrative expenses increased \$6.6 million for the 2007 Period as compared to the 2006 Period primarily due to the addition of \$3.5 million of JDS expenses since the Closing Date. In addition, Noven's transdermal selling, general and administrative expenses had a \$3.1 million increase which was attributable to \$2.2 million in costs associated with the voluntary withdrawal of Daytrana, \$0.9 million increase in professional fees and a \$0.6 million increase in stock-based compensation. These increases were partially offset by a \$0.4 million decline in salary and related benefits.

**Other Income and Expenses**

*Interest Income*

Interest income increased \$0.1 million and \$1.9 million for the 2007 Quarter and the 2007 Period as compared to the 2006 Quarter and the 2006 Period, respectively. These increases were primarily attributable to an increase in cash available for investment due to our receipt from Shire of milestone payments of \$50.0 million in April 2006, \$25.0 million in March 2007 and \$25.0 million in August 2007, partially offset by the \$130.4 million in consideration related to the JDS acquisition, which decreased our cash available for investment in the 2007 Quarter.

*Income Taxes*

Our effective tax rate was approximately 35% and 33% for the 2007 Period and the 2006 Period, respectively. The increase in our effective tax rate for the 2007 Period as compared to the 2006 Period related primarily to a higher percentage of our income that was subject to state income taxes and lower tax-free interest income as a percentage of our total loss due to the sale of short-term investments for payments relating to the Merger and the immediate expensing of IPR&D related to the JDS acquisition.

The provision for income taxes is based on the Federal statutory and state income tax rates. Net deferred income tax assets are measured using the average graduated tax rate for the estimated

**Table of Contents**

amount of annual taxable income in the years that the liability is expected to be settled or the asset recovered. The effect of adjusting the expected tax rate related to the net deferred income tax assets is included in the provision for income taxes. The acquisition of JDS caused our deferred income tax assets to significantly increase, primarily due to the fact that the \$100.2 million IPR&D expense recognized in the 2007 Quarter and the 2007 Period is not immediately deductible for tax purposes. As of September 30, 2007, we had a net deferred tax asset of \$62.2 million compared to \$19.4 million at June 30, 2007. Realization of this deferred tax asset depends upon the generation of sufficient future taxable income. A valuation allowance is established if it is more likely than not that all or a portion of the deferred tax asset will not be realized. JDS files separate state income tax returns in states where JDS has determined that it is required to file state income taxes. As a result, state deferred tax assets relating to JDS are evaluated separately in determining whether the state deferred tax assets are realizable. We expect that JDS will incur taxable losses in the next few years due to future expected clinical trial expenditures related to product development. These expected taxable losses create negative evidence indicating the need for a valuation allowance at September 30, 2007. We recorded a valuation allowance of \$3.4 million during the quarter ended September 30, 2007, due to uncertainties in realizing these state deferred tax assets based on our projection of future state taxable income. If we determine, based on future JDS profitability that these state deferred tax assets are more likely than not to be realized, a release of all, or part, of the related valuation allowance could result in an immediate income tax benefit in the period the valuation allowance is released.

*Equity in Earnings of Novogyne*

We share in the earnings of Novogyne according to an established formula after satisfaction of an annual preferred return of \$6.1 million to Novartis. Our share of Novogyne's earnings (a non-cash item) increases as Novogyne's product sales increase, subject to a cap of 49%. Novogyne earned sufficient income in the first quarter of each of 2007 and 2006 to meet Novartis' annual preferred return for those periods and for us to recognize earnings from Novogyne under the formula. We report our share of Novogyne's earnings as Equity in earnings of Novogyne in our unaudited statements of operations.

The financial results of Novogyne for the three and nine months ended September 30, 2007 and 2006 are summarized as follows (dollar amounts in thousands):

	Three Months			Nine Months		
	2007	2006	% Change	2007	2006	% Change
Gross revenues <sup>1</sup>	\$ 45,224	\$ 39,204	15%	\$ 125,432	\$ 112,138	12%
Sales allowances	5,770	4,283	35%	16,769	11,622	44%
Sales returns allowances	781	1,193	(35%)	772	4,576	(83%)
Sales and returns allowances	6,551	5,476	20%	17,541	16,198	8%
Net revenues	38,673	33,728	15%	107,891	95,940	12%
Cost of sales	8,152	7,529	8%	22,994	22,212	4%
Gross profit	30,521	26,199	16%	84,897	73,728	15%
Gross margin percentage	79%	78%		79%	77%	
Selling, general and administrative expenses	8,278	9,419	(12%)	27,990	28,172	(1%)
Income from operations	22,243	16,780	33%	56,907	45,556	25%
Interest income	286	250	14%	783	564	39%

Net income	\$ 22,529	\$ 17,030	32%	\$ 57,690	\$ 46,120	25%
Noven's equity in earnings of Novogyne	\$ 10,948	\$ 8,234	33%	\$ 25,025	\$ 19,323	30%

<sup>1</sup> Novogyne's gross revenues, which are calculated by adding sales allowances and sales returns allowances to net revenues, are discussed in this section because Noven's management believes it is a useful measure to evaluate and compare Novogyne's sales period to period in light of the significant historic fluctuations in Novogyne's sales allowances and returns.

Novogyne Net Revenues

Novogyne sells its products to trade customers, including wholesalers, distributors and chain pharmacies. As has historically been the case, the timing of purchases by trade customers is driven by the inventory needs of each customer and other factors, and does not necessarily track underlying

**Table of Contents**

prescription trends in any given period or coincide with Novogyne's quarterly financial reporting periods. As a result, the timing of orders by trade customers is difficult to predict and can lead to significant variability in Novogyne's quarterly results.

Novogyne's gross revenues increased \$6.0 million for the 2007 Quarter as compared to the 2006 Quarter. By product, Vivelle-Dot® and CombiPatch® increased \$6.4 million and \$0.1 million, respectively, while Estradot® decreased \$0.5 million. The \$6.4 million Vivelle-Dot® increase consisted of a \$2.5 million increase related to pricing and a \$3.9 million increase in unit sales due to increased product demand and to the timing of orders. The decrease in Estradot® sales to an affiliate of Novartis Pharma in Canada was attributable to the timing of orders. The increase in CombiPatch® was attributable to a \$0.3 million increase related to pricing, partially offset by a \$0.2 million decline in unit sales as a result of the continuing decline in the market for combination therapies as well as the impact of a competitive product.

Novogyne's gross revenues increased \$13.3 million for the 2007 Period as compared to the 2006 Period. By product, Vivelle-Dot® increased \$14.4 million while Estradot® and CombiPatch® declined \$0.9 million and \$0.2 million, respectively. The \$14.4 million Vivelle-Dot® increase consisted of a \$8.4 million increase related to pricing and a \$5.9 million increase in unit sales due to increased product demand and to the timing of orders. The decline in Estradot® was attributable to the timing of orders. The decline in CombiPatch® was attributable to a \$1.2 million decline in unit sales as a result of the continuing decline in the market for combination therapies as well as the impact of a competitive product. This CombiPatch® decline was partially offset by a \$1.0 million increase related to pricing.

Sales allowances consist of chargebacks, Medicaid rebates, managed healthcare rebates, cash discounts and other allowances, which tend to fluctuate based on changes in gross revenues. These sales allowances were 13% and 11% of gross revenues for the 2007 Quarter and the 2006 Quarter, respectively. For the 2007 Period and the 2006 Period, these sales allowances were 13% and 10%, respectively. The increase in sales allowances was attributable to increases in actual managed healthcare rebates and cash discounts and allowances related to price increases that took effect in the 2007 Period.

Sales returns allowances consist of allowances for returns of expiring product. The activity for sales returns allowances for the three and nine months ended September 30, 2007 and 2006 was as follows:

	Three Months		Nine Months	
	2007	2006	2007	2006
Increases in allowances for returns primarily of expiring product	\$ 781	\$ 1,193	\$ 772	\$ 4,576
Actual returns primarily for expiring product	\$ (880)	\$ (862)	\$ (2,354)	\$ (3,135)

The decrease in allowances for returns of expiring product for the three and nine months ended September 30, 2007 was primarily related to lower actual returns of CombiPatch® as compared to the same period in the prior year. The higher returns of CombiPatch® in the prior period primarily related to returns of a superseded packaging configuration.

**Table of Contents****Novogyne Gross Margin**

Novogyne's gross margin was largely unchanged for the 2007 Quarter compared to the 2006 Quarter as higher pricing was partially offset by higher aggregate sales and returns allowances as a percentage of revenue.

The 2% gross margin increase for the 2007 Period as compared to the 2006 Period was primarily related to higher pricing, especially for Vivelle-Dot®, and to a lesser extent an aggregate decrease in sales returns allowances as a percentage of revenues.

**Novogyne Selling, General and Administrative Expenses**

Novogyne's selling, general and administrative expenses for the 2007 Quarter decreased \$1.1 million compared to the 2006 Quarter primarily due to lower sample expenses due to timing of orders. Novogyne's policy is to immediately expense samples when title transfers from Noven.

Novogyne's selling, general and administrative expenses decreased \$0.2 million for the 2007 Period as compared to the 2006 Period due to a \$0.9 million decline in HT litigation expenses and a \$0.1 million decline in sales, marketing and advertising expenses. These declines were partially offset by a \$0.9 million increase in sample expenses due to the timing of sample orders by Novogyne.

**Liquidity and Capital Resources**

As of September 30, 2007 and December 31, 2006, we had the following (amounts in thousands):

	September 30, 2007	December 31, 2006
Cash and cash equivalents	\$ 11,253	\$ 9,144
Short-term investments	61,100	144,455
Working capital	60,516	180,330

Cash provided by (used in) operating, investing and financing activities for the 2007 Period and 2006 Period is summarized as follows (amounts in thousands):

	Nine Months	
	2007	2006
Cash flows:		
Operating activities	\$ 57,801	\$ 51,199
Investing activities	(49,771)	(119,157)
Financing activities	(5,921)	9,670

**Operating Activities**

Net cash provided by operating activities for the 2007 Period primarily resulted from our receipt of \$50.0 million in milestone payments from Shire, our receipt of \$18.5 million in cash distributions from Novogyne, and our receipt of \$5.9 million in connection with the amphetamine transdermal system agreement with Shire. These amounts were partially offset by changes in working capital due to the timing of certain payments, including \$16.2 million in tax payments, \$2.9 million related to insurance and \$2.6 million in compensation and related liabilities.

**Table of Contents**

Net cash provided by operating activities for the 2006 Period primarily resulted from our receipt of \$50.0 million related to the Daytrana approval and \$17.6 million in cash distributions from Novogyne. These amounts were partially offset by changes in working capital due to the timing of certain payments, including those related to insurance, compensation and related liabilities and payments to Shire for clinical trial costs incurred in connection with obtaining Daytrana regulatory approval.

***Investing Activities***

We invest a portion of our cash in short-term investments, which primarily consist of investment grade, asset backed, variable rate debt obligations and municipal auction rate securities, which are categorized as available-for-sale under the provisions of SFAS No. 115 Accounting for Certain Investments in Debt and Equity Securities .

Net cash used in investing activities for the 2007 Period was primarily attributable to \$130.4 million in acquisition costs related to the acquisition of JDS in the 2007 Quarter, net of cash acquired, and \$2.3 million in equipment purchases to support operations and expansion of facilities, partially offset by \$83.4 million in net proceeds from the sale of short-term investments.

Net cash used in investing activities for the 2006 Period was primarily attributable to \$112.6 million in net purchases of short-term investments, as well as the purchase of \$5.8 million in fixed assets to expand production capacity for future products.

***Financing Activities***

Net cash used in financing activities for the 2007 Period was primarily attributable to the open-market purchase of \$5.1 million of shares of our common stock under the stock repurchase program established in the 2007 Quarter and the payment of \$3.7 million in long-term obligations assumed as part of the Merger with JDS. These payments were offset by \$2.5 million received in connection with the issuance of common stock from the exercise of stock options. In addition, the 2007 Period benefited from \$0.4 million in excess tax deductions from the exercise of stock options.

Net cash provided by financing activities for the 2006 Period was primarily attributable to \$8.1 million received in connection with the issuance of common stock from the exercise of stock options and \$1.6 million in excess tax deductions from the exercise of stock options.

***Short-Term and Long-Term Liquidity***

Our principal sources of short-term liquidity are existing cash, cash generated from product sales, milestones, fees and royalties under development and license agreements and distributions from Novogyne. For the 2007 Period, a significant portion of our income before income taxes was comprised of equity in earnings of Novogyne and the recognition of deferred license revenue, both of which are non-cash items. Accordingly, our net income may not be reflective of our cash flow.

Our short-term cash flow is dependent on distributions from Novogyne and sales, royalties and license fees associated with our products. Any decrease in sales of those products by us or our licensees or any increase in returns of products to us or to Novogyne (including any such changes resulting from the HT studies), the further decline of the HT market, or the inability or failure of Novogyne to pay distributions would have a material adverse effect on our short-term cash flow and require us to rely on our existing cash balances or on borrowings to support our operations and business.

As discussed above, we acquired JDS for approximately \$125.0 million in cash at closing plus approximately \$5.4 million in transaction related costs. In addition, we assumed approximately

**Table of Contents**

\$15.3 million of accrued expenses and other current liabilities and assumed certain contractual arrangements whereby we may be required to pay to third parties up to \$23.5 million in product development and sales milestones that could become due over the next five years. We funded the purchase price and related transaction expenses from our sale of short-term investments. In addition, we expect to increase our research and development expense in the remaining 2007-2009 timeframe by up to an aggregate \$35 million related to the development of JDS products. These amounts are in addition to our expected research and development expense for our transdermal programs during the same periods. We expect to fund the additional research and development expenses from our existing cash and short-term investments as well as the sources of funds described above.

We currently have no long-term debt. To the extent the sources of funds described above together with our existing cash and short-term investments are insufficient to fund our operations, including our anticipated increased research and development expenses, we would expect to undertake a debt and/or equity financing as a source of liquidity.

Our liquidity is also dependent on our receipt from Shire of the third milestone payment related to our Daytrana patch. In the second quarter of 2006, we received a \$50.0 million Daytrana approval milestone. In the 2007 first quarter, we received the first of three potential Daytrana sales milestones. In the 2007 third quarter, we received the second \$25.0 million sales milestone. We cannot assure that we will achieve the third \$25.0 million sales milestone, which is triggered upon Shire's achievement of \$75.0 million in annual net sales of Daytrana. For the 2007 Period, we paid an aggregate \$16.2 million in taxes, the majority of which relate to the \$50.0 million Daytrana approval milestone. We expect to continue to make tax payments on the \$50.0 million milestone for the remainder of 2007 and into early 2008. The majority of the income taxes related to the first and second milestones are expected to be paid in 2008 and into early 2009.

In July 2007, the FDA completed an on-site inspection of our manufacturing facilities. At the completion of the inspection, we received a list of observations on Form 483. The majority of the observations in the Form 483 relate to the Daytrana patch and difficulties experienced by some patients in removing the release liner of the Daytrana patch, including certain product lots that utilize an enhanced release liner. We have submitted our written response to the observations to the FDA. No assurance can be given that our response will be acceptable to the FDA or satisfactorily address the FDA's concerns, and there can be no assurance that the FDA will not take regulatory action that could adversely affect our business, results of operations and financial position.

In September 2007, Shire initiated a voluntary market withdrawal of a limited portion of Daytrana product. Shire took this action primarily in response to feedback from patients and caregivers who had experienced difficulty removing the release liner from some Daytrana patches. We recognized an aggregate \$3.3 million in allowances and expenses associated with the withdrawal in the 2007 Quarter.

In the first quarter of 2007, Noven and Shire implemented enhancements to the Daytrana release liner intended to improve ease of use of the patch. Noven's results of operations and financial position could be adversely affected if the Daytrana product that was not subject to the market withdrawal does not improve Daytrana's ease of use.

Our liquidity for the 2007 Period benefited from \$2.5 million received as the exercise price paid by option holders in connection with their exercise of employee stock options. We expect this

**Table of Contents**

amount to fluctuate from period to period depending on the performance of Noven's stock and equity award exercises. Beginning in 2006, we began granting SSARs to employees and restricted stock to non-employee directors in lieu of stock options. These types of awards do not provide cash to us upon their exercise.

A portion of our cash and short-term investments in the 2007 Quarter was used to repurchase our common stock under our stock repurchase program. As of September 30, 2007, Noven had repurchased 322,345 shares of its common stock at an aggregate price of approximately \$5.1 million.

Capital expenditures were \$2.3 million for the 2007 Period. We expect to fund our foreseeable capital expenditures from our existing cash and short-term investments. As a general matter, we believe that we have sufficient liquidity available to meet our operating needs and anticipated short-term capital requirements.

If our products under development are successful, we expect that our cash requirements will increase to fund plant and equipment purchases to expand production capacity. For our long-term operating needs, we intend to utilize funds derived from the above sources, as well as funds generated through sales of products under development or products that we may license or acquire from others, including those acquired as part of our acquisition of JDS. We expect that such funds will be comprised of payments received pursuant to future development and licensing arrangements, as well as direct sales of our own products. If such funds are not sufficient to fund plant and equipment purchases to expand production capacity, we may rely on debt and/or equity financing to fund such expansion.

We cannot assure that we will successfully complete the development of such products, that we will obtain regulatory approval for any such products, that any approved product will be produced in commercial quantities, at reasonable costs, and be successfully marketed, or that we will successfully negotiate future licensing or product acquisition arrangements. Because much of the cost associated with product development and expansion of manufacturing facilities is incurred prior to product launch, if we are unsuccessful in out-licensing, or if we are unable to launch additional commercially-viable products that we develop or that we license or acquire from others, we will have incurred the up-front costs associated with product development or acquisition without the benefit of the liquidity generated by sales of those products, which could adversely affect our long-term liquidity needs. Factors that could impact our ability to develop or acquire and launch additional commercially-viable products are discussed in Part I Item 1A of our Form 10-K, as supplemented by Part II Item 1A Risk Factors of the quarterly reports on Form 10-Q filed in 2007, as well as other reports filed from time to time with the Securities and Exchange Commission.

In addition to the acquisition of JDS, our strategic plan includes the acquisition of one or more products, technologies or businesses that we believe may be complementary to our business. We expect to draw upon our existing cash and short-term investments to fund all or a portion of these potential strategic acquisitions. To the extent our existing cash and short-term investments are insufficient to fund any potential acquisitions, we may be required to seek debt financing or to issue equity or debt securities. If we ultimately elect to finance all or any portion of an acquisition through debt financing or debt securities, we would be required to devote funds to service and ultimately repay such debt and could be subject to financial or operational covenants that could limit or hinder our ability to conduct our business.

To the extent that we seek debt or equity financing, no assurance can be given that such financing will be available, if at all, in a timely manner, or on favorable terms. If we are unable to obtain satisfactory alternative financing, we may be required to delay or reduce our proposed expenditures, including expenditures for research and development, plant and equipment and strategic acquisitions, in order to meet our future cash requirements.

**Table of Contents**

**Outlook**

A summary of our current financial guidance is provided below. Our guidance includes certain items related to the impact on our financial results of our acquisition of JDS, which closed on August 14, 2007. The forward-looking information contained in this section is based on our current assumptions and expectations, many of which are beyond our control to achieve. In particular, for purposes of this guidance we have assumed, among other things, that during the remainder of 2007 and into 2008/2009 there will not be any material:

acquisitions of products, companies, or technologies or other transactions;

changes in Noven's or Novogyne's accounting or accounting principles or any of the estimates or judgments underlying our critical accounting policies;

regulatory or technological developments;

changes in the supply of, demand for, or distribution of our products (including any changes resulting from competitive products, product recalls/withdrawals, or new study results);

negative actions with respect to our applications for methylphenidate quota or other disruptions in supplies of raw materials;

changes in our business relationships/collaborations; or

changes in the economy or the health care sector generally.

Financial guidance is inherently uncertain. Accordingly, we cannot assure that we will achieve results consistent with this guidance, and our actual financial results could differ materially from the expected results discussed below. For a discussion of certain factors that may impact our actual financial results for the periods referenced, including additional risks and uncertainties related to JDS, readers should carefully consider the risks, uncertainties and cautionary factors discussed in Part I Item 1A of our Form 10-K, as supplemented by Part II Item 1A Risk Factors of the quarterly reports on Form 10-Q filed in 2007, as well as other reports filed from time to time with the Securities and Exchange Commission.

*Daytrana.* We expect our product sales of Daytrana to Shire for full-year 2007 to be in the \$15 million range, subject to the availability of sufficient methylphenidate raw material supply. During 2006, we received a \$50.0 million milestone payment from Shire relating to the final marketing approval of Daytrana by the FDA. In the first quarter of 2007, we received the first of three potential \$25.0 million sales milestones. In the 2007 Quarter, we received the second \$25.0 million sales milestone. The third \$25.0 million sales milestone may be achieved in 2008. We expect to continue to defer and recognize the approval milestone and all sales milestones as license revenues on a straight-line basis, beginning on the date the milestone is achieved through the first quarter of 2013, which is our current best estimate of the end of the useful economic life of the product. Reflecting the impact of this recognition schedule, license revenues in 2007 will substantially exceed 2006 levels.

*HT Product Sales.* We expect Noven's global HT product revenues for full-year 2007 to increase in the 10% range compared to 2006 levels, largely reflecting expected increases in our Vivelle-Dot® product sales to Novogyne.

*JDS Product Sales.* We expect to report aggregate product revenues from sales of JDS's Pexeva® and Lithobid® products from the Closing Date through December 31, 2007 in the \$9 million to \$10 million range.

*Gross Margin.* We expect our overall gross margin percentage for full year 2007 to be in the low 40% range, reflecting a gross margin percentage associated with the Transdermal Segment in the 35% range, and an estimated gross margin percentage associated with the JDS Segment in the 80%

**Table of Contents**

range. We expect our cost of goods will include roughly \$800,000 per quarter for ongoing amortization associated with JDS's commercialized products, subject to adjustment in future periods depending on sales forecasts and other factors.

*Research and Development Expense.* We estimate our consolidated research and development expense for full year 2007 to be in the \$15 million range, increasing to mid-\$30 million range in 2008, and decreasing to the low-to-mid \$30 million range in 2009. Estimates of research and development expenses for future periods are subject to substantial adjustment as each product advances through various stages of development.

*Selling, General and Administrative Expense.* We expect our consolidated selling, general and administrative expense for full year 2007 to be in the \$37.0 million range, including costs associated with Shire's voluntary withdrawal of a portion of Daytrana product, and certain costs associated with the expected commercial launch of Stavzor in 2008. We expect our consolidated selling, general and administrative expense for full year 2008 to be in the mid-to-upper \$40.0 million range, subject to adjustment depending on the timing of the possible launch of Stavzor in 2008.

*Novogyne.* We expect Novogyne's full year 2007 net revenues to increase in the 10% range compared to 2006 levels, and we expect Novogyne's net income to increase in the 18% range compared to 2006 levels.

*Interest Income.* Interest income is expected to decrease for periods after the acquisition of JDS, reflecting lower cash and short-term investment balances following payment of the JDS purchase price.

*Effective Tax Rate.* We estimate that our effective tax rate for full-year 2007 will be in the 35% to 36% range.

**Aggregate Contractual Obligations**

As a result of the JDS acquisition, the aggregate contractual obligations disclosed in our Form 10-K as of December 31, 2006 have materially changed. We may be required to pay to third parties up to \$23.5 million in sales and product development milestones for commercialized and developmental products, as follows:

Pexeva<sup>®</sup> Sales Milestones \$11.5 million in contingent sales milestones, which amount was recorded as a liability on our balance sheet upon closing of the JDS acquisition, may be payable to Synthon Pharmaceuticals upon Pexeva<sup>®</sup>'s achievement of the following sales thresholds:

\$2.0 million milestone payable when annual net sales exceed \$8.0 million in each of 2007 and 2008. Pexeva<sup>®</sup> net sales exceeded this threshold for the 2007 Period.

\$1.25 million milestone payable for each of the first two years in which annual net sales of Pexeva<sup>®</sup> equal or exceed \$10.0 million from 2007 to 2017. Pexeva<sup>®</sup> net sales exceeded this threshold for the 2007 Period.

\$5.0 million milestone payable in the first year that annual net sales of Pexeva<sup>®</sup> (or any paroxetine mesylate product) exceed \$30.0 million from 2007 through 2017.

Lithium QD Development Milestones \$4.0 million in contingent development and sales milestones may be payable to a third party related to the Lithium QD product, and an additional \$2.0 million in contingent payments may be payable to the manufacturer under the Lithium QD supply agreement, in each case depending on future product development and other events.

**Table of Contents**

Stavzor and Stavzor ER Development Milestones \$6.0 million in contingent development and sales milestones may be payable to Banner over the course of development of Stavzor and Stavzor ER, depending on the achievement of specified development and sales milestones.

All these milestones are dependent on the achievement of different development and sales milestones and there is no assurance that such milestones will be achieved and paid. In addition to the contingent milestones, as part of the JDS acquisition, we assumed the operating lease of office space that JDS uses for their operations in New York, New York. Total rental expense for this operating lease was \$0.1 million for the 2007 Quarter and the 2007 Period. The minimum rental payments over the remaining lease term are \$0.1 million for the remainder of 2007 and \$0.2 million in 2008.

**Critical Accounting Estimates**

For a discussion of our critical accounting estimates, see Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Estimates, which is included in our Form 10-K, as updated and supplemented by the following:

*Revenue Recognition*

Revenues, primarily for Pexeva® and Lithobid® products, are reduced at the time of sale to reflect expected returns that are estimated based on historical experience. Additionally, provisions are made at the time of sale for all discounts, rebates and estimated sales allowances based on historical experience updated for changes in facts and circumstances, as appropriate. Such provisions are recorded as a reduction of revenue.

These deductions represent estimates of the related obligations, requiring the use of judgment when estimating the impact of these sales deductions on gross sales for a reporting period. These estimates for revenue deductions are derived utilizing a combination of information received from third parties, including market data, inventory reports from its major wholesale customers, historical information and other analysis. Our management believes that it is able to reasonably estimate these sales deductions.

The following briefly describes the nature of each revenue deduction and how we estimate the related accruals:

The United States Medicaid program is a state-government-administered program that uses state and federal funds to provide assistance to certain vulnerable and needy individuals and families. In 1990, the Medicaid Drug Rebate Program was established to reduce state and federal expenditures for prescription drugs. Under the rebate program, rebates are paid to states based on drugs paid for by those states. Provisions for estimating Medicaid rebates are calculated using a combination of historical experience, product and population growth, price increases, the impact of contracting strategies and specific terms in the individual state agreements. These provisions are then adjusted based upon the established re-filing process with individual states. For Medicaid, the calculation of rebates involves interpretation of relevant regulations, which are subject to challenge or change in interpretative guidance by government authorities. Since Medicaid rebates are typically billed up to six months after the product is dispensed, any rebate adjustments may involve revisions of accruals for several quarters.

The products also participate in prescription drug savings programs that offer savings to patients that are eligible participants under United States Medicare programs. These savings vary

**Table of Contents**

based on a patient's current drug coverage and personal income levels. Provisions for the obligations under these programs are based on historical experience, trend analysis and current program terms.

On January 1, 2006, an additional prescription drug benefit was added to the United States Medicare program which funds healthcare benefits to individuals over the age of 65. Individuals that previously had dual Medicaid/Medicare drug benefit eligibility had their Medicaid prescription drug coverage replaced on January 1, 2006, by the new Medicare Part D coverage provided through private prescription drug plans. The change led to a significant shift of plan participants between programs in which products participate. Provisions for Medicare Part D rebates are estimated using a combination of specific terms of individual plan agreements, product and population growth, price increases and the impact of contracting strategies.

Wholesaler chargebacks relate to contractual arrangements with certain indirect customers to sell products at prices that are lower than the list price charged to wholesalers. A wholesaler chargeback represents the difference between the invoice price charged to the wholesaler and the indirect customer's contract discount price. Provisions for estimating chargebacks are calculated using a combination of historical experience, product growth rates and the specific terms in each agreement. Wholesaler chargebacks are generally settled within a few weeks of incurring the liability.

Managed health care rebates are offered to key managed health care, group purchasing organizations and other direct and indirect customers to sustain and increase product market share. These rebate programs provide that the customer receive a rebate after attaining certain performance parameters relating to product purchases, formulary status and/or pre-established market share milestones relative to competitors. Since rebates are contractually agreed upon, rebates are estimated based on the specific terms in each agreement, historical experience and product growth rates. The sales performance of products subject to managed health care rebates and other contract discounts and levels of inventory in the distribution channel are tracked, and adjustments to the accrual are made periodically to reflect actual experience.

In order to evaluate adequacy of ending accrual balances, we use both internal and external estimates of the level of inventory in the distribution channel and the rebate claims processing lag time. External data sources include periodic reports of wholesalers and purchased third party market data. Management internally estimates the inventory level in the retail channel and in transit.

It is customary in the pharmaceutical industry to allow returns of unused stocks with remaining shelf lives of six months or less. Generally, our policy is that no product will be shipped to customers with less than nine months of remaining shelf-life and we generally will accept returns due to expiration within twelve months after the product has expired. These policies cause a significant lag time between when a product is sold and the latest date on which a return could occur. An allowance for estimated sales returns is recorded based on (i) the historical experience of actual product returns and (ii) the estimated lag time between when an actual sale takes place in relation to when the products are physically returned by a customer. The historical actual returns rate is then applied to product sales during the estimated lag period to develop the returns estimate. We also consider trends and expectations for future demand and trade inventory levels. We believe this is a reasonable basis on which to estimate returns exposure and incorporates the key factors that contribute to returns. These estimates are based on currently available information, and the ultimate outcome may be different than the amounts estimated given the subjective nature and complexities inherent in this area and in the pharmaceutical industry.

Our product supply policy is to maintain inventories on a consistent level from year to year based on the pattern of consumption. Wholesaler inventory levels are monitored monthly based on gross sales volume, prescription volumes based on third party data and information received from key wholesalers. Based on this information, the inventories on hand at wholesalers and other

**Table of Contents**

distribution channels are estimated to be approximately one to one and one-half month at September 30, 2007 for Pexeva® and Lithobid® products. We believe the third party data sources are sufficiently reliable; however, its accuracy cannot be independently verified.

Cash discounts are offered to customers to encourage prompt payment. Cash discounts, which are typically 2% of gross sales, are accrued at the time of sale.

Other sales discounts, such as consumer coupons and discount cards, are also offered. These discounts are recorded at the time of sale and estimated utilizing historical experience and the specific terms for each program.

*Goodwill*

As of September 30, 2007, Noven recorded goodwill of \$14.4 million. SFAS 142 addresses financial accounting and reporting for acquired goodwill and other intangible assets. SFAS No. 142 requires that goodwill and intangible assets with indefinite lives be measured for impairment at least annually or whenever events indicate that there may be an impairment. In order to determine if an impairment exists, Noven compares the reporting unit's carrying value to the reporting unit's fair value. If it is determined that the full carrying amount of an asset is not recoverable, an impairment loss is recorded in the amount by which the carrying amount of the asset exceeds its fair value. For purposes of this test, the JDS Segment is considered the reporting unit. Determining the reporting unit's fair value requires Noven to make estimates on market conditions and operational performance. Any resulting impairment loss could have a material adverse impact on Noven's financial condition and results of operations. See Note 8 Goodwill and Intangible Assets for additional information.

*Deferred Income Taxes*

Accounting principles generally accepted in the United States require that we not record a valuation allowance against our net deferred tax asset if it is more likely than not that we will be able to generate sufficient future taxable income to utilize our net deferred tax asset, which due to the JDS acquisition increased to \$62.2 million as of September 30, 2007 primarily related to the non-deductibility of the immediately expensed IPR&D of \$100.2 million. Estimates of future taxable income requires us to make significant estimates that involve subjective and often complex judgments, the most significant of which relates to future cash flows of approved products and products in IPR&D. The forecast of future IPR&D cash flows required various assumptions to be made including:

revenue that is likely to result from the approved products or IPR&D projects, including estimated number of units to be sold, estimated selling prices, estimated market penetration, estimated market share, year-over-year growth rates over the product life cycles and estimated sales allowances;

contract and license revenues generated by approved products or IPR&D projects;

cost of sales for the potential product using historical data, industry data or other sources of market data;

sales and marketing expenses using historical data, industry data or other market data;

general and administrative expenses;

research and development expenses; and

future equity in earnings of Novogyne.

Additional considerations for IPR&D projects include:

the project's stage of completion;

the costs incurred to date;

**Table of Contents**

- the projected costs to complete IPR&D projects;
- the contribution, if any, of the acquired identifiable intangible assets;
- the projected launch date of the products under development;
- the estimated life of the products under development; and
- the probability of success of launching a commercially viable product.

Realization of this deferred tax asset depends upon the generation of sufficient future taxable income. A valuation allowance is established if it is more likely than not that all or a portion of the deferred tax asset will not be realized. JDS files separate state income tax returns in states where JDS has determined that it is required to file state income taxes. As a result, state deferred tax assets relating to JDS are evaluated separately in determining whether the state deferred tax assets are realizable. We expect that JDS will incur taxable losses in the next few years due to future expected clinical trial expenditures related to product development. These expected taxable losses create negative evidence indicating the need for a valuation allowance at September 30, 2007. We recorded a valuation allowance of \$3.4 million during the quarter ended September 30, 2007, due to uncertainties in realizing these state deferred tax assets based on our projection of future state taxable income. If we determine, based on future JDS profitability that these state deferred tax assets are more likely than not to be realized, a release of all, or part, of the related valuation allowance could result in an immediate income tax benefit in the period the valuation allowance is released.

*Accounting for Uncertainty in Income Taxes*

On January 1, 2007, we adopted the provisions of and began accounting for uncertainty in income taxes in accordance with FIN 48. This interpretation requires companies to determine whether it is more likely than not that a tax position will be sustained upon examination by the appropriate taxing authorities before any part of the benefit can be recorded in the financial statements. Under FIN 48 an enterprise cannot recognize a tax benefit for a tax position that is not likely to be sustained. The application of income tax law is inherently complex. Laws and regulations in this area are voluminous and are often ambiguous. As such, we are required to make many subjective assumptions and judgments regarding our income tax exposures. Interpretations and guidance surrounding income tax laws and regulations change over time. As a result, changes in our subjective assumptions, estimates and judgments can materially affect amounts recognized in our financial statements. See Note 10 to the condensed consolidated financial statements, *Income Taxes* for additional information on our uncertain tax positions.

**Recent Accounting Pronouncements**

In February 2007, the FASB issued SFAS 159. This Statement permits entities to choose to measure many financial instruments and certain other items at fair value and applies to all entities, including not-for-profit organizations. Most of the provisions of this statement apply only to entities that elect the fair value option. However, the amendment to FASB Statement No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, applies to all entities with available-for-sale and trading securities. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. Early adoption is permitted as of the beginning of a fiscal year that begins on or before November 15, 2007, provided the entity also elects to apply the provisions of FASB Statement No. 157, *Fair Value Measurements*. We are assessing the impact of adopting SFAS 159 and the impact it may have on Noven's results of operations and financial condition.

In June 2007, the FASB's Emerging Issue Task Force (EITF) issued EITF Issue No. 07-03, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* (EITF 07-03). This EITF requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the related services are performed. Entities should continue to evaluate whether they expect the good to be delivered or services to be rendered. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. EITF 07-03 is effective for financial statements issued for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. Earlier adoption is permitted. We are currently assessing the impact of

adopting EITF 07-03 and the impact it may have on Noven's results of operations and financial condition.

**Table of Contents**

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

Not Applicable.

**Item 4. Controls and Procedures**

*Disclosure Controls and Procedures*

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15 promulgated under the Securities Exchange Act of 1934. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective in timely alerting them to material information relating to Noven required to be included in our periodic Securities and Exchange Commission filings. However, that conclusion should be considered in light of the various limitations described below on the effectiveness of those controls and procedures, some of which pertain to most if not all business enterprises, and some of which arise as a result of the nature of our business. Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures will prevent all error and all improper conduct. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of improper conduct, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Further, the design of any system of controls also is based in part upon assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. Furthermore, our level of historical and current equity participation in Novogyne may substantially impact the effectiveness of our disclosure controls and procedures. Because we do not control Novogyne, and Novogyne's financial, accounting, inventory, sales and sales deductions functions are performed by Novartis, our disclosure controls and procedures with respect to our equity investment in Novogyne are necessarily more limited than those we maintain with respect to ourself.

*Changes in Internal Control over Financial Reporting*

For purposes of Management's evaluation of our internal control over financial reporting as of September 30, 2007, we have elected to exclude JDS from the scope of management's assessment as permitted by guidance provided by the Securities and Exchange Commission (SEC). JDS represented approximately 21% of our consolidated assets at September 30, 2007 and contributed approximately 6% of total revenues for the 2007 period. The JDS business will be included in management's assessment of the effectiveness of our internal controls over financial reporting in fiscal year 2008.

Other than the acquisition of JDS, no changes were made in our internal control over financial reporting subsequent to the date of our Chief Executive Officer's and Chief Financial

**Table of Contents**

Officer's evaluation that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

*Certificates*

Provided with this quarterly report on Form 10-Q are certificates of our Chief Executive Officer and Chief Financial Officer. We are required to provide those certifications by Section 302 of the Sarbanes-Oxley Act of 2002 and the SEC's implementing regulations. This Item 4 of this quarterly report is the information concerning the evaluation referred to in those certifications, and you should read this information in conjunction with those certifications for a more complete understanding of the topics presented.

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

Certain lawsuits and legal proceedings in which we are involved are described in Part I, Item 3 Legal Proceedings of our Form 10-K. The following is a description of material developments related to our legal proceedings during the period covered by this Form 10-Q, and through the filing of this Form 10-Q, and should be read in conjunction with the report referenced above. Unless otherwise indicated, all proceedings discussed in the reports referenced above remain outstanding.

In addition to the HT cases previously disclosed in our filings with the Securities and Exchange Commission, Novartis has advised us that Novartis has been named as a defendant in at least 25 lawsuits that include approximately 26 plaintiffs that allege liability in connection with personal injury claims allegedly arising from the use of HT patches distributed and sold by Novartis and Novogyne, including our Vivelle-Dot<sup>®</sup>, Vivelle<sup>®</sup>, and CombiPatch<sup>®</sup> products. Novartis has indicated that it will seek indemnification from Noven and Novogyne to the extent permitted by the agreements between and among Novartis, Novogyne and Noven.

We intend to defend all of the foregoing lawsuits vigorously, but the outcome of these product liability lawsuits cannot ultimately be predicted.

In June 2007, Johnson-Matthey Inc. filed a complaint in the United States District Court, Eastern District of Texas against us alleging that we were infringing one of its patents through our manufacture and sale of Daytrana<sup>®</sup>. The plaintiff is seeking injunctions from further infringement and claiming compensatory and other damages in an unspecified amount. We intend to vigorously defend this lawsuit. In July 2007, Johnson-Matthey added Shire as a defendant to this lawsuit after Shire filed a declaratory judgment against Johnson-Matthey in the United States District Court, Eastern District of Pennsylvania. In August 2007, we filed a motion for a transfer of venue of the case to the United States District Court, Eastern District of Pennsylvania.

We are a party to other pending legal proceedings arising in the normal course of business, none of which we believe is material to our financial position or results of operations.

**Item 1A. Risk Factors**

Except as described below, there have been no material changes to the risk factors previously disclosed in our Form 10-K or in our quarterly reports on Form 10-Q filed during 2007. Readers are urged to carefully review our risk factors because they may cause our results to differ from the forward-looking statements made in this report or otherwise made by or on our behalf. The risk factors are not listed in order of priority and are not the only ones we face. If any of these risks actually occurs, our business, financial condition and results of operations would suffer. Additional risks not presently known to us or other factors not perceived by us to present significant

**Table of Contents**

risks to our business at this time also may impair our business operation. We do not undertake to update any of these forward-looking statements or to announce the results of any revisions to these forward-looking statements except as required by law.

**We may not realize the expected benefits of our acquisition of JDS.**

We may be unable to take advantage of the opportunities that we expect to obtain from the JDS acquisition. We cannot be certain of the future success of JDS's current products and, more importantly, those in its pipeline. The potential success of a new pharmaceutical product is subject to many risks, including but not limited to:

the failure of ongoing and planned clinical trials and the risk that results from early-stage clinical trials may not be indicative of results in later-stage trials;

the unproven safety and efficacy of products under development;

the difficulty of predicting FDA approvals, including the timing of approval and that approval may not be granted at all;

while FDA approval may be granted, the possibility that any expected period of exclusivity may not be realized and that we may not be able to produce commercially viable quantities;

the difficulty of predicting acceptance and demand for new pharmaceutical products;

the impact of competitive products, pricing and managed care and formulary status;

the possibility that any product launch may be delayed or that product acceptance may be less than anticipated;

the possibility that patent applications may not result in issued patents, and that issued patents may not be enforceable or could be invalidated;

the commercial markets that we intend to enter with new products may not develop in the manner or to the extent that we anticipate; and

the potential negative impact of competitive responses to our sales, marketing and strategic efforts.

Any of the above factors may have a material adverse effect on our business, financial position and results of operations. As previously announced, a Phase III clinical study of Lithium QD, a developmental once-daily form of lithium carbonate acquired in connection with the JDS acquisition, did not achieve its primary endpoint with statistical significance. While we intend to continue development of this product, there is no assurance that it will be successful.

**Our acquisition of JDS is expected to dilute our earnings for an undetermined period of time.**

Following the closing of the JDS transaction, our financial results will reflect significant amortization and other ongoing integration-related expenses associated with the acquisition. In addition, we will have significant increases in our research and development expenses for an extended period of time as we continue development of the products in JDS's pipeline. No assurance can be given as to the future success of the products in JDS's pipeline and as to whether we will be able to recover our initial and ongoing investment in JDS and its products.

**Our acquisition of JDS may expose us to unexpected costs and liabilities.**

Our acquisition of JDS entails an inherent risk that we could become subject to contingent or other liabilities, including liabilities arising from events or conduct pre-dating the acquisition. While the owners of JDS have agreed in the merger agreement to indemnify us for certain breaches of

**Table of Contents**

covenants, warranties and representations, our right to indemnity is limited to a maximum of \$10 million and subject to time and other restrictions. These indemnification obligations may be inadequate to fully address any costs or damages we may incur, and any such costs or damages may have a material adverse effect on our business, financial position and results of operations. We may also incur significantly greater expenditures in integrating JDS than we had anticipated.

**Our acquisition of JDS has resulted in a substantial increase in our intangible assets, which will subject us to the risk of impairment charges.**

Intangible assets in the form of patent development costs and goodwill from the acquisition of JDS form a significant portion of our total assets. We are required to test our intangible assets, including our goodwill, for impairment on an annual basis or more frequently if events or changes in circumstances indicate that the asset might be impaired. If after testing the intangible assets and goodwill, we determine that these assets are impaired, then we would be required to write-down the impaired asset to fair value in the period when the determination is made. Such a write-down could have a material adverse effect on our results of operations.

**We may not successfully integrate JDS into our existing business, or such integration may be more costly or more difficult than expected.**

The JDS acquisition involves the integration of companies that have previously operated independently, which is a complex, costly and time-consuming process. In addition, this is the first time that we have undertaken an acquisition of this size. The difficulties of combining the companies' operations include, among other things:

retaining key customer and vendor relationships;

the necessity of coordinating geographically disparate organizations, systems and facilities;

consolidating corporate and administrative functions and eliminating redundancies;

limiting the diversion of management resources necessary to facilitate the integration;

implementing compatible information and communication systems, as well as common operating procedures;

creating compatible financial controls and comparable human resource management practices;

expenses of any undisclosed or potential legal liabilities;

preserving, and preventing disruption of, the important contractual and other relationships of each company;  
and

assimilating and retaining employees with diverse business backgrounds.

The successful integration of JDS's business will require us to take on new functions (such as commercial distribution and managed care) with which we do not have significant experience. Consistent with JDS's practice prior to the acquisition, we intend to outsource many of these functions to third parties. No assurance can be given that we will be successful in our efforts to develop or oversee these new capabilities in our business.

The process of integrating operations could cause an interruption of the activities of our business (including the operations of JDS's business) and the loss of key personnel. The diversion of management's attention, any delays or difficulties encountered in connection with the business combination and the integration of the companies' operations or the costs associated with these activities could have a material adverse effect on our business, financial position and results of

**Table of Contents**

operations. There is no assurance that we can successfully integrate JDS's business with our operations, that we will otherwise succeed in operating JDS's business and continue the development of its products or that the financial results of the combined companies will meet or exceed the financial results that we would have achieved without the acquisition.

**The voluntary market withdrawal of certain Daytrana product could have a material adverse effect on our results of operations and/or financial position.**

The voluntary market withdrawal of certain Daytrana product could have a significant financial impact on us in several ways. In addition to our costs directly relating to the withdrawal, we could be further affected if product not subject to the withdrawal does not continue to improve ease of use of the product. We may also face supply interruptions resulting from delays or inability to obtain DEA methylphenidate quota to replace withdrawn product. Additionally, we face the risk that the market withdrawal will affect sales of Daytrana to an extent that would inhibit or delay achievement of the third Daytrana milestone payment under our agreement with Shire.

**There are inherent uncertainties involved in the estimates, judgments and assumptions used in the preparation of our financial statements, and any changes in those estimates, judgments and assumptions could have a material adverse effect on our financial position and results of operations.**

The consolidated and condensed consolidated financial statements that we file with the SEC are prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP). The preparation of financial statements in accordance with U.S. GAAP involves making estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities. The most significant estimates we are required to make under U.S. GAAP include, but are not limited to, those related to revenue recognition, sales allowances, inventories and cost of goods sold, determining the useful life or impairment of goodwill and other long-lived assets, litigation settlements and related liabilities, and income taxes. We periodically evaluate estimates used in the preparation of the consolidated financial statements for reasonableness, including estimates provided by third parties. Appropriate adjustments to the estimates will be made prospectively, as necessary, based on such periodic evaluations. We base our estimates on, among other things, currently available information, market conditions, historical experience and various assumptions, which together form the basis of making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Although we believe that our assumptions are reasonable under the circumstances, estimates would differ if different assumptions were utilized and these estimates may prove in the future to have been inaccurate.

**Table of Contents****We are subject to chargebacks and rebates when our products are resold to or reimbursed by governmental agencies and managed care buying groups, which may reduce our net revenues and impact our operating results.**

Chargebacks and rebates are the difference between the prices at which we sell our products to wholesalers and the price that third party payors, such as governmental agencies and managed care buying groups, ultimately pay pursuant to fixed price contracts. Medicare, Medicaid and reimbursement legislation or programs regulate drug coverage and reimbursement levels for most of the population in the United States. Federal law requires all pharmaceutical manufacturers to rebate a percentage of their revenue arising from Medicaid-reimbursed drug sales to individual states. We record an estimate of the amount either to be charged back to us or rebated to the end-users at the time of sale to the wholesaler. Managed care organizations use these chargebacks and rebates as a method to reduce overall costs in drug procurement. We record an accrual for chargebacks and rebates based upon factors including current contract prices, historical chargeback and rebate rates and actual chargebacks and rebates claimed. The amount of actual chargebacks claimed could, however, be higher than the amounts we accrue, and could reduce our net revenues during the period in which claims are made. If we over or under estimate the level of chargebacks and rebates, there may be a material impact to our operating results.

**If our estimates for returned products are incorrect, there may be a materially adverse impact on our net sales as well as an impact on our operating results.**

In the pharmaceutical industry, customers are normally granted the right to return product for a refund if the product has not been used by its expiration date. Management is required to estimate the level of sales that will ultimately be returned pursuant to our return policy and to record a related reserve at the time of sale. These amounts are deducted from our gross sales to determine our net sales. We believe that we have sufficient data to estimate future returns at the time of sale. Management periodically reviews the allowances for returns and adjusts them based on actual experience. In order to reasonably estimate future returns, we analyze both quantitative and qualitative information including, but not limited to, actual return rates by product, the level of product in the distribution channel, expected shelf life of the product, product demand, the introduction of competitive or generic products that may erode current demand, our new product launches and general economic and industry wide indicators. There are inherent limitations in estimating future product returns due to the time lapse between sale and actual return of the product. If we over or under estimate the level of sales that will ultimately be returned, there may be a material impact to our operating results.

**Because we rely on independent manufacturers for some of our products, any production or regulatory problems these third parties experience could be disruptive to our inventory supply.**

Pexeva® and Lithobid® are manufactured and supplied to us by independent companies. Any production issues experienced by our independent manufacturers or delays in shipping products to us may affect our product supply and ultimately have a negative impact on our sales and profitability. All manufacturers of pharmaceutical products sold in the United States must comply with cGMP requirements and manufacturing operations and processes are subject to FDA inspection. Failure to comply with cGMP requirements can lead to the shutdown of a facility, the seizure of product distributed by that facility and other sanctions. Any regulatory issues experienced by our independent manufacturers could interrupt our ability to sell our products and adversely affect our present and future sales margins and market share, as well as harm our overall business.

**State pharmaceutical marketing compliance and reporting requirements may expose us to regulatory and legal action by state governments or other government authorities.**

In recent years, several states and localities, including California, the District of Columbia, Maine, Massachusetts, Michigan, Minnesota, New Mexico, Ohio, Rhode Island, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. We are currently in the process of developing a formal compliance infrastructure and standard operating procedures to comply with such laws. Unless we are in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive

adverse publicity.

**Table of Contents**

**If we market products in a manner that violates health care fraud and abuse laws, we may be subject to civil or criminal penalties.**

Federal health care program anti-kickback statutes prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally financed health care programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, patients, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing, or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, or off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated best price information to the Medicaid Rebate Program.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

**Table of Contents****Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

The following table provides information with respect to our stock repurchases during the third quarter of 2007:

	Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Program	Approximate Dollar Value That May Yet be Purchased under the Program <sup>(1)</sup>
July 1, 2007 to July 31, 2007				
August 1, 2007 to August 31, 2007				
September 1, 2007 to September 30, 2007	322,345	\$ 15.90	322,345	\$ 19,876,238
Totals	322,345	\$ 15.90	322,345	\$ 19,876,238

(1) In September 2007, we announced a stock repurchase program authorizing the repurchase of up to \$25.0 million of our common stock. There is no expiration date specified for this program.

**Item 5. Other Information**

The following executive officers have currently effective trading plans intended to comply with the guidelines specified in Rule 10b5-1 under the Securities Exchange Act of 1934: Eduardo A. Abrao, Diane M. Barrett, Jeffrey F. Eisenberg and W. Neil Jones. Other Noven executive officers (as well as Noven employees) may adopt Rule 10b5-1 trading plans from time to time. These plans generally provide for the exercise of stock options and the subsequent sale of the acquired shares on the open market, subject to specified limitations and minimum price thresholds. Under these plans, the executive officers do not control the specific timing of any option exercise or sale. Rule 10b5-1 permits corporate officers and directors to adopt written, pre-arranged stock trading plans when they are not in possession of material, non-public information. Public disclosure of the transactions under these plans is required to be made by the executive officers through Form 144 and Form 4 filings with the SEC.

Noven is in the process of negotiating a new employment agreement with Robert C. Strauss, Noven's President and Chief Executive Officer. The term of the existing employment agreement between Noven and Mr. Strauss, dated November 5, 2003, was not extended an additional year by Noven and, accordingly, the existing agreement will expire on December 31, 2007.



**Table of Contents**

**Item 6. Exhibits**

- 2.1 Agreement and Plan of Merger, dated as of July 9, 2007, by and among Noven Pharmaceuticals, Inc., Noven Acquisition, LLC, JDS Pharmaceuticals, LLC, and Satow Associates, LLC (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K of Noven Pharmaceuticals, Inc. filed on July 10, 2007).\*
  
- 10.1 Non-Competition Agreement between Noven Pharmaceuticals, Inc. and Phillip Satow, dated as of August 14, 2007 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K of Noven Pharmaceuticals, Inc. filed on August 20, 2007).
  
- 10.2 Consulting Agreement between JDS Pharmaceuticals, LLC and Phillip Satow, dated as of August 14, 2007 (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K of Noven Pharmaceuticals, Inc. filed on August 20, 2007).
  
- 10.3 Asset Purchase Agreement by and between Synthon Pharmaceuticals, Inc. and JDS Pharmaceuticals, LLC dated October 17, 2005 (with certain provisions omitted pursuant to Rule 24b-2).\*
  
- 10.4 Development, License and Supply Agreement by and between Banner Pharmacaps Inc. and JDS Pharmaceuticals, LLC dated April 26, 2007 (with certain provisions omitted pursuant to Rule 24b-2).\*
  
- 10.5 Contract Manufacturing Agreement between OSG Norwich Pharmaceuticals, Inc. and JDS Pharmaceuticals, LLC dated November 1, 2005 (with certain provisions omitted pursuant to Rule 24b-2).\*
  
- 10.6 Manufacturing and Supply Agreement between Solvay Pharmaceuticals, Inc. and JDS Pharmaceuticals, LLC dated August 25, 2004 (with certain provisions omitted pursuant to Rule 24b-2).\*
  
- 31.1 Certification of Robert C. Strauss, President, Chief Executive Officer and Chairman of the Board, pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
  
- 31.2 Certification of Diane M. Barrett, Vice President and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
  
- 32.1 Certification of Robert C. Strauss, President, Chief Executive Officer and Chairman of the Board, 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 Diane M. Barrett, Vice President and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.\*\*

\* Certain exhibits and schedules to this document have not been filed. The Registrant agrees to furnish a copy of any

omitted schedule  
or exhibit to the  
Securities and  
Exchange  
Commission  
upon request.

\*\* Pursuant to  
Item 601(b)(32)  
of  
Regulation S-K,  
this exhibit is  
furnished rather  
than filed with  
this Form 10-Q.

**Table of Contents**

**Signatures**

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

NOVEN PHARMACEUTICALS, INC.

Date: November 9, 2007

By: /s/ Diane M. Barrett  
Diane M. Barrett  
Vice President and Chief Financial  
Officer

59