NOVEN PHARMACEUTICALS INC
Form 10-Q
November 10, 2008

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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, 2008
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 þ No o

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

Large accelerated filer o Accelerated filer þ Non-accelerated filer o Smaller reporting company o
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No þ

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

Class	Outstanding at October 31, 2008
Common stock $.0001 par value	24,897,085

NOVEN PHARMACEUTICALS, INC.
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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, 2007 as supplemented by Part II Item 1A Risk Factors of this quarterly report on Form 10-Q, as well as other reports filed from time to time with the Securities and Exchange Commission.

Trademark Information: Lithobid®, Pexeva® and Stavzor® are registered trademarks, and Mesafem is a trademark of Noven Therapeutics, LLC; Vivelle® is a registered trademark of Novartis Pharmaceuticals Corporation; Estradot® (foreign) and Vivelle-Dot® are registered trademarks, and Menorest is a trademark, of Novartis AG; CombiPatch® and Estalis® (United States) are registered trademarks of Vivelle Ventures LLC; and Daytrana® is a registered trademark of Shire Pharmaceuticals Ireland Limited.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

NOVEN PHARMACEUTICALS, INC. AND SUBSIDIARIES

Condensed Consolidated Balance Sheets

(in thousands, except share data) (unaudited)

	September 30, 2008	December 31, 2007
Assets		
Current Assets:		
Cash and cash equivalents	$ 65,288	$ 13,973
Short-term investments available-for-sale, at fair value		21,565
Accounts receivable (less allowances of $477 at 2008 and $252 at 2007)	7,511	6,956
Accounts receivable Novogyne, net	6,156	8,683
Inventories	15,162	12,136
Net deferred income tax asset, current portion	10,703	7,614
Prepaid income taxes	5,374	4,925
Prepaid and other current assets	3,362	5,251
	113,556	81,103
Non-current Assets:		
Property, plant and equipment, net	34,921	36,213
Investments in auction rate securities	15,460	32,835
Investment in Novogyne	27,173	24,310
Net deferred income tax asset, non-current portion	63,172	58,053
Intangible assets, net	37,607	38,773
Goodwill	14,407	14,734
Deposits and other non-current assets	887	677
	193,627	205,595
	$ 307,183	$ 286,698
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable and accrued expenses	$ 9,285	$ 8,399
Accrued compensation and related liabilities	5,718	9,801
Other accrued liabilities	21,727	15,270
Current portion of long-term obligations	3,420	3,421
Deferred product revenue Stavzor®	1,432	
Deferred license and contract revenues, current portion	32,451	20,188
	74,033	57,079

Non-current Liabilities:		
Long-term obligations, less current portion	47	8,438
Deferred license and contract revenues, non-current portion	82,621	85,056
Other non-current liabilities	1,109	1,831
	83,777	95,325
Total Liabilities	157,810	152,404
Commitments and Contingencies (Note 14)		
Stockholders Equity:		
Preferred stock authorized 100,000 shares par value $.01 per share; no shares issued or outstanding		
Common stock authorized 80,000,000 shares, par value $.0001 per share; 25,219,370 and 24,881,867 issued at September 30, 2008 and December 31, 2007	3	2
Additional paid-in capital	121,848	118,561
Retained earnings	33,161	20,855
Accumulated other comprehensive loss	(515)	
Treasury stock, at cost - 322,345 shares at September 30, 2008 and December 31, 2007	(5,124)	(5,124)
Common stock held in trust	(1,412)	(950)
Deferred compensation obligation	1,412	950
	149,373	134,294
	$ 307,183	$ 286,698

The accompanying notes to unaudited condensed consolidated financial statements are an integral part of these financial statements.

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NOVEN PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Revenues:				
Product revenues Novogyne:				
Product sales, net	$ 5,945	$ 5,801	$ 13,929	$ 15,974
Royalties	2,258	2,100	6,787	5,764
Total net product revenues Novogyne	8,203	7,901	20,716	21,738
Product revenues, net third parties	11,131	8,789	34,357	25,620
Total net product revenues	19,334	16,690	55,073	47,358
License and contract revenues	6,371	5,125	16,717	12,611
Total net revenues	25,705	21,815	71,790	59,969
Costs and Expenses:				
Cost of products sold Novogyne	3,994	4,286	10,783	10,530
Cost of products sold third parties	10,933	5,525	28,236	17,522
Total cost of products sold	14,927	9,811	39,019	28,052
Acquired in-process research and development		100,150		100,150
Research and development	4,041	3,649	10,653	10,300
Selling and marketing	7,326	3,103	17,485	3,564
General and administrative	11,147	8,770	27,075	19,439
Total costs and expenses	37,441	125,483	94,232	161,505
Reversal of contingent milestone liability	5,000		5,000	
Loss from operations	(6,736)	(103,668)	(17,442)	(101,536)
Equity in earnings of Novogyne	13,849	10,948	34,545	25,025
Interest income, net	344	1,306	1,466	4,751
Income (loss) before income taxes	7,457	(91,414)	18,569	(71,760)
Provision (benefit) for income taxes	2,253	(32,377)	6,263	(25,335)

Net income (loss)	$ 5,204	$ (59,037)	$ 12,306	$ (46,425)
Basic earnings (loss) per share	$ 0.21	$ (2.38)	$ 0.50	$ (1.87)
Diluted earnings (loss) per share	$ 0.21	$ (2.38)	$ 0.50	$ (1.87)
Weighted average number of common shares outstanding:				
Basic	24,638	24,792	24,600	24,787
Diluted	24,766	24,792	24,703	24,787

The accompanying notes to unaudited condensed consolidated financial statements are an integral part of these financial statements.

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NOVEN PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Statement of Changes in Stockholders Equity and Comprehensive Income
(in thousands, except share amounts)
(unaudited)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock	Other	Total
Balance at December 31, 2007	24,560	$ 2	$ 118,561	$ 20,855	$	$ (5,124)	$	$ 134,294
Issuance of shares pursuant to employee equity plan	3	1	29					30
Stock-based compensation expense and issuance of shares to officers and outside directors	334		3,258					3,258
Common stock held in trust	(32)						(462)	(462)
Deferred compensation obligation	32						462	462
Comprehensive income:								
Net income				12,306				12,306
Other comprehensive income:								
Unrealized loss on investments in auction rate securities					(515)			(515)
Comprehensive income								$ 11,791
Balance at September 30, 2008	24,897	$ 3	$ 121,848	$ 33,161	$ (515)	$ (5,124)	$	$ 149,373

The accompanying notes to unaudited condensed consolidated financial statements are an integral part of these financial statements.

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NOVEN PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Nine Months ended September 30,	
	2008	2007
Cash flows from operating activities:		
Net income (loss)	$ 12,306	$ (46,425)
Adjustments to reconcile net income (loss) to net cash flows provided by operating activities:		
Depreciation, amortization and certain other noncash items	6,665	4,422
Disposal of property, plant and equipment	656	46
Inventory write-offs	5,022	1,068
Reversal of contingent milestone liability	(5,000)	
Stock-based compensation expense	3,258	3,118
Acquired in-process research and development expense		100,150
Income tax benefits on exercise of stock options		461
Excess tax benefit from exercise of stock options		(390)
Deferred income tax benefit	(8,208)	(49,464)
Recognition of deferred license and contract revenues	(16,717)	(12,611)
Equity in earnings of Novogyne	(34,545)	(25,025)
Distributions from Novogyne	28,982	18,465
Changes in operating assets and liabilities:		
Increase in accounts receivable trade, net	(555)	(375)
Decrease in milestone payment receivable Shire		25,000
Decrease in accounts receivable Novogyne, net	2,527	790
Increase in inventories	(8,048)	(2,813)
Decrease in prepaid income taxes	2,251	4,505
Decrease (increase) in prepaid and other current assets	1,109	(910)
Increase in deposits and other assets	(176)	(2)
Increase (decrease) in accounts payable and accrued expenses	1,258	(4,983)
Decrease in accrued compensation and related liabilities	(4,046)	(509)
Increase in other accrued liabilities	6,457	11,244
Increase in deferred license and contract revenues	26,545	31,620
Increase in deferred product revenue Stavzor®	1,432	
Increase in other liabilities	145	419
Cash flows provided by operating activities	21,318	57,801
Cash flows from investing activities:		
Purchases of property, plant and equipment	(2,997)	(2,257)
Payments for intangible assets	(1,734)	(256)
Acquisition of JDS, net of cash acquired		(130,353)
Purchase of company-owned life insurance	(335)	(260)
Purchases of investments	(62,800)	(1,276,473)
Proceeds from sale of investments	101,225	1,359,828

Cash flows provided by (used in) investing activities	33,359	(49,771)
Cash flows from financing activities:		
Issuance of common stock from exercise of stock options	30	2,531
Purchase of treasury stock		(5,124)
Excess tax benefit from exercise of stock options		390
Payments of long-term obligations	(3,392)	(3,718)
Cash flows used in financing activities	(3,362)	(5,921)
Net increase in cash and cash equivalents	51,315	2,109
Cash and cash equivalents, beginning of period	13,973	9,144
Cash and cash equivalents, end of period	$ 65,288	$ 11,253

The accompanying notes to unaudited condensed consolidated financial statements are an integral part of these financial statements.

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NOVEN PHARMACEUTICALS, INC. AND SUBSIDIARIES

Notes to Unaudited Condensed Consolidated Financial Statements

1. DESCRIPTION OF BUSINESS AND BASIS OF PRESENTATION:

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

Noven and Novartis Pharmaceuticals Corporation (Novartis) established 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 hormone therapy product delivery systems marketed under the brand names 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.

On August 14, 2007 (the Closing Date), Noven acquired JDS Pharmaceuticals, LLC (JDS), a privately-held specialty pharmaceutical company that currently markets and sells three branded prescription psychiatry products through a targeted sales force, and is advancing the clinical development of Mesafem, our developmental non-hormonal product for vasomotor symptoms (hot flashes). Effective January 8, 2008, JDS s name was changed to Noven Therapeutics, LLC (Noven Therapeutics). With the acquisition of Noven Therapeutics, Noven now operates in two segments distinguished along product categories: (i) the Noven Transdermals segment, which currently engages in the research, development, manufacturing and licensing to partners of transdermal drug delivery technologies and prescription transdermal products; and (ii) the Noven Therapeutics segment, which currently engages in the development, marketing and sales of pharmaceutical products. See Note 15 Segment Data for Noven s segment reporting.

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 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, 2007 (Form 10-K), and as supplemented by Part II Item 1A Risk Factors of this quarterly report on Form 10-Q. 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 2008 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 (GAAP) have been condensed or omitted. The unaudited condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and the notes to the consolidated 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 consolidated financial statements included in Noven s Form 10-K.

In July 2008, the United States Food and Drug Administration (FDA) granted final approval for Stavzor® (valproic acid delayed release capsules) in the treatment of manic episodes associated with bipolar disorder, adjunctive therapy in multiple seizure types (including epilepsy), and prophylaxis of migraine headaches. During the three months ended September 30, 2008, Noven made a $1.5 million milestone payment to Banner Pharmacaps Inc. (Banner) upon receiving FDA approval for Stavzor®. Upfront and

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milestone payments made to third parties in connection with research and development collaborations prior to regulatory approval are expensed as incurred. Payments made to third parties subsequent to regulatory approval are capitalized and amortized through cost of products sold over the shorter of the period over which the economic benefit is expected to be realized or their remaining legal lives. Noven Therapeutics commercially launched Stavzor® in August 2008. Noven sells Stavzor® to pharmaceutical wholesalers and chain drug stores. These companies have the right to return Stavzor® for up to one year after product expiration. As a result of the commercial launch of Stavzor® in the third quarter of 2008, Noven does not have sufficient sales history to reasonably estimate product returns. Under Statement of Financial Accounting Standards (SFAS) No. 48, Revenue Recognition When Right of Return Exists (SFAS No. 48), Noven cannot recognize revenue on product shipments until it can reasonably estimate returns relating to these shipments. In accordance with SFAS No. 48, Noven defers recognition of revenue and the associated costs on product shipments of Stavzor® to Noven s customers until such time as Stavzor® units are dispensed through patient prescriptions, since Noven s customers are no longer permitted to return the product after it has been dispensed. Noven estimates the volume of prescription units dispensed at pharmacies based on data provided by external sources. These sources poll pharmacies, hospitals, mail order and other retail outlets for Stavzor® prescriptions and project this sample on a national level. Noven will recognize revenue based on prescription units dispensed until Noven has sufficient history to reasonably estimate its product returns. No net revenues were recognized for Stavzor® during the third quarter of 2008.

Certain reclassifications have been made to the prior period s statements of operations and statement of cash flows to conform to the current period s presentation.

2. RECENT ACCOUNTING PRONOUNCEMENTS:

The following information updates the discussion of recent accounting pronouncements in Note 2 of the consolidated financial statements included in Noven s Form 10-K.

In May 2008, the Financial Accounting Standards Board (FASB) issued SFAS No. 162, The Hierarchy of Generally Accepted Accounting Principles (SFAS No. 162). SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with GAAP. This statement will be effective 60 days following the Securities Exchange and Commission s approval of the Public Company Accounting Oversight Board amendments to AU Section 411, The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles. Noven does not expect adoption of SFAS No. 162 to have a material impact on its consolidated financial condition, results of operations or cash flows.

In April 2008, the FASB issued FASB Staff Position (FSP) No. 142-3, Determination of the Useful Life of Intangible Assets (FSP 142-3). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, Goodwill and Other Intangible Assets . The intent of FSP 142-3 is to improve the consistency between the useful life of a recognized intangible asset under SFAS No. 142 and the period of expected cash flows used to measure the fair value of the asset under GAAP and SFAS No. 141(R), Business Combinations. For a recognized intangible asset, an entity shall disclose information that enables users of financial statements to assess the extent to which the expected future cash flows associated with the asset are affected by the entity s intent and/or ability to renew or extend the arrangement. FSP 142-3 is effective for financial statements issued for fiscal years and interim periods beginning after December 15, 2008, with early adoption prohibited. FSP 142-3 requires the guidance for determining the useful life of a recognized intangible asset to be applied prospectively to intangible assets acquired after the effective date. The disclosure requirements shall be applied prospectively to all intangible assets recognized as of, and subsequent to, the effective date. Noven does not expect adoption of FSP 142-3 to have a material impact on its consolidated financial condition, results of operations or cash flows.

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In March 2008, the FASB issued SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities an amendment of FASB Statement No. 133 (SFAS No. 161). SFAS No. 161 changes the disclosure requirements for derivative instruments and hedging activities. Entities are required to provide enhanced disclosures about: (i) how and why an entity uses derivative instruments; (ii) how derivative instruments and related hedged items are accounted for under SFAS No. 133 and its related interpretations; and (iii) how derivative instruments and related hedged items affect an entity s financial position, financial performance, and cash flows. SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early adoption encouraged. SFAS No. 161 encourages, but does not require, comparative disclosures for earlier periods at initial adoption. Noven does not expect adoption of SFAS No. 161 to have a material impact on its consolidated financial condition, results of operations or cash flows.

In June 2007, the Emerging Issues 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 be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the related services are performed or upon a determination that the entity does not expect the goods to be delivered or services to be rendered. EITF 07-03 is effective for financial statements issued for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. Consistent with this EITF, beginning January 1, 2008 Noven capitalizes non-refundable advance payments for goods and services to be used in future research and development. Such payments are expensed at the time the related goods and services are received or when management determines that the goods and services will not be received. No material advance payments were made during the nine months ended September 30, 2008, thus adoption did not materially impact Noven s consolidated financial condition, results of operations or cash flows.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of SFAS No. 115 (SFAS No. 159). SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value and applies to all entities. Most of the provisions of SFAS No. 159 apply only to entities that elect the fair value option. However, the amendment to SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities, applies to all entities with available-for-sale and trading securities. SFAS No. 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. Noven did not elect the fair value option for its available-for-sale investments. Consequently, Noven continues to account for these instruments in accordance with SFAS No. 115 wherein unrealized gains and losses are recognized in equity as a component of other comprehensive income unless a decline in value is judged to be other than temporary, in which case the loss would be immediately charged to operations.

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements (SFAS No. 157). SFAS No. 157 defines fair value, establishes a framework for measuring fair value in GAAP, and expands disclosure about fair value measurements. SFAS No. 157 applies under other accounting pronouncements that require or permit fair value measurements, but does not require any new fair value measurements. In February 2008 the FASB issued FSP 157-2, Effective Date of FASB Statement No. 157 (FSP 157-2). Under FSP 157-2, the provisions of SFAS No. 157 will be adopted for financial instruments in 2008 and, when required, for nonfinancial assets and nonfinancial liabilities in 2009 (except for those that are recognized or disclosed at fair value in the financial statements on a recurring basis). Adoption of SFAS No. 157 did not affect Noven s consolidated financial condition, results of operations or cash flows. However, as a result of illiquid conditions in the market for auction rate securities, Noven was required to employ financial models and valuation techniques to value its investments in auction rate securities. SFAS No. 157 requires disclosure about the inputs used to determine the fair value of Noven s investments. These disclosures are provided in Note 5.

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3. CASH FLOW INFORMATION:

Income Tax and Interest Payments

Cash payments for income taxes were $13.2 million and $16.2 million for the nine months ended September 30, 2008 and 2007, respectively. 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. For the nine months ended September 30, 2008 and 2007, Novogyne paid $2.7 million and $5.2 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 distributions to Noven from Novogyne. Noven received tax refunds directly from the State of New Jersey of $2.7 million and $2.4 million during the nine months ended September 30, 2008 and 2007, respectively, related to these state income tax payments made on Noven s behalf. Cash payments for interest were not material for the nine months ended September 30, 2008 and 2007.

Non-cash Operating Activities

Noven recorded a $0.5 million income tax benefit as additional paid-in capital derived from the exercise of non-qualified stock options and disqualifying dispositions of incentive stock options for the nine months ended September 30, 2007.

Non-cash Investing Activities

Noven recorded $0.5 million in unrealized losses on its investments in auction rate securities for the nine months ended September 30, 2008. The unrealized losses were recorded as a reduction of stockholders equity through other comprehensive income.

4. INVESTMENTS AVAILABLE-FOR-SALE:

At September 30, 2008, Noven held investments in auction rate securities (classified as available-for-sale) with a par value and fair value of $16.0 and $15.5 million, respectively. Auction rate securities are floating rate debt securities with long-term nominal maturities, the interest rates of which are reset periodically (typically every seven to thirty-five days) through a Dutch auction process. These periodic auctions have historically provided a liquid market for auction rate securities, as this mechanism generally allowed existing investors to rollover their holdings and continue to own their respective securities at then-existing market rates or to liquidate their holdings by selling their securities at par value. Beginning in February 2008, as part of the ongoing credit market crisis, several auction rate securities from various issuers have failed to receive sufficient order interest from potential investors to clear successfully, resulting in auction failures. Historically, when investor demand was insufficient, the banks running the auctions would step in and purchase the remaining securities in order to prevent an auction failure. However, since early 2008, the banks have been allowing these auctions to fail. As a result of failed auctions, these investments now pay interest at a rate defined by the governing documents or indenture.

Noven liquidated $39.0 million of auction rate securities at par value during the nine months ended September 30, 2008. During the three months ended March 31, 2008, Noven recorded an unrealized loss of $0.5 million to reduce the investments to fair value. From March 31, 2008 through September 30, 2008, Noven determined that no additional loss was required to be recorded. The unrealized loss has been recorded as a reduction of stockholders equity through other comprehensive income. Because the investments are tax-exempt, there is no related tax effect.

Noven s auction rate security investments are collateralized primarily by tax-exempt municipal bonds and, to a lesser extent, guaranteed student loans. Noven does not hold any auction rate securities collateralized by mortgages or collateralized debt obligations. Noven believes its investments are of high

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credit quality, as all are investment grade and the majority are rated AA or higher. Furthermore, management currently has the intent and believes it has the ability to hold these investments until the anticipated recovery in fair value occurs. Based on these factors, Noven believes the decline in fair value of these investments is due to general market conditions and is temporary in nature. Noven will continue to monitor the market for its auction rate security investments. If management determines in a future period that a decline in fair value is other than temporary, then in accordance with SFAS No. 115, Noven would be required to recognize a realized loss in operations in the period when such determination is made.

5. FAIR VALUE MEASUREMENTS:

Noven adopted SFAS No. 157, Fair Value Measurements in 2008. SFAS No. 157, among other things, defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. SFAS No. 157 clarifies that fair value is an exit price, representing the amount expected to be received to sell an asset, or paid to transfer a liability, in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. To increase consistency and comparability in fair value measurements and related disclosures, SFAS No. 157 sets forth a three-tier hierarchy for the inputs used to measure fair value based on the degree to which such inputs are observable in the marketplace, as follows:

(i) Level 1 observable inputs such as quoted prices in active markets;

(ii) Level 2 inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

(iii) Level 3 unobservable inputs for which there is little or no market data, which require the reporting entity to develop its own assumptions.

During the nine months ended September 30, 2008, Noven recorded a $0.5 million unrealized loss on its investments in auction rate securities which are classified as available-for-sale under SFAS No. 115. As of September 30, 2008, the total par value and fair value of Noven s investments were $16.0 million and $15.5 million, respectively. Due to continuing auction failures beginning in February 2008, Noven utilized valuation models to determine the fair values of its investments in auction rate securities. The fair values of the investments were calculated based on the following: (i) the underlying structure of each security; (ii) the present value of future principal and interest payments discounted at rates considered to reflect current market conditions; (iii) consideration of the probabilities of default, auction failure, or repurchase at par for each period; and (iv) consideration of third party credit enhancement. These estimated fair values could change significantly based on future market conditions.

Changes to investments measured at fair value on a recurring basis using unobservable inputs (Level 3) during the nine months ended September 30, 2008 were as follows (in thousands):

Balance at December 31, 2007	$ 54,400
Purchases of investments	550
Sales of investments at par	(38,975)
Unrealized losses recorded as other comprehensive loss	(515)
Balance at September 30, 2008	$ 15,460

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6. INVENTORIES:

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

	September 30, 2008	December 31, 2007
Finished goods	$ 3,452	$ 3,171
Work in process	2,216	1,532
Raw materials	9,494	7,433
Total	$ 15,162	$ 12,136

During the nine months ended September 30, 2008, Noven recorded a $5.0 million charge to cost of products sold related to the write-off of inventories. These write-offs were primarily related to an equipment failure in transdermal manufacturing during the three months ended March 31, 2008 which resulted in $1.8 million of Novogyne product write-offs and $1.0 million of third party HT product write-offs, as well as inventory write-offs during the nine months ended September 30, 2008 of approximately $1.4 million due to Daytrana® product that exhibited high peel force characteristics and $0.8 million related to scrap and expired material in the ordinary course of business.

Shire plc (Shire) retains title to the active methylphenidate ingredient (AMI) in Daytrana®. The value of the AMI is neither included in Daytrana® product revenues nor 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 minimum yields of the finished product. Shire has a reciprocal obligation to pay Noven if the yield requirements are exceeded. Noven slightly exceeded the yield requirements for the nine months ended September 30, 2008 for product shipped to Shire, resulting in an immaterial payment from Shire to Noven. During the nine months ended September 30, 2008, Noven used $4.2 million of AMI in the finished product. Noven had $3.7 million and $2.6 million of consignment AMI inventory on hand at September 30, 2008 and December 31, 2007, respectively, which is not reflected in the inventory table above. Noven owed Shire approximately $1.6 million and $0.5 million as of September 30, 2008 and December 31, 2007, respectively, primarily as a result of product that did not meet the product s release liner removal specification.

7. GOODWILL AND INTANGIBLE ASSETS:

All of Noven s goodwill arose from the JDS acquisition in August 2007 and, thus, relates to the Noven Therapeutics segment. The carrying amount of goodwill is $14.4 million and $14.7 million at September 30, 2008 and December 31, 2007, respectively. Goodwill is tested for impairment annually in the fourth quarter or more frequently, when events or other changes in circumstances indicate that the carrying value of goodwill may not be recoverable. If after testing the intangible assets and goodwill, Noven determines that these assets are impaired, then Noven would be required to write-down the impaired asset to fair value and record a corresponding expense in the period when the determination is made. Such a write-down and corresponding expense could have a material adverse effect on Noven s results of operations.

During the nine months ended September 30, 2008, certain events occurred related to the JDS acquisition, resulting in a $0.3 million net reduction in goodwill as follows:

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As part of the JDS acquisition, a portion of the purchase price was placed in escrow to be distributed upon final determination of the amount of net working capital purchased by Noven. In June 2008, Noven reached a final agreement with the prior owners of JDS with respect to the net working capital adjustment, which agreement resulted in a $1.1 million payment to Noven from the escrow account. As a result of the working capital adjustment, Noven adjusted the amount due from escrow by $1.0 million and recorded a corresponding increase of $1.0 million to goodwill.

Also as part of the JDS acquisition, Noven recognized a favorable lease asset related to office space in New York and a liability for employee relocation costs, based on a tentative determination that Noven would exit the New York location by May 2008. During the second quarter of 2008, management decided to retain the New York office space through its remaining contractual term and not to require relocation of the remaining personnel based in New York. As a result of these decisions, Noven revised the value of the acquired favorable lease asset and reversed the unused relocation liability, resulting in a $1.3 million reduction in goodwill.

Noven s intangible assets, all of which are subject to amortization, are summarized in the table below as of September 30, 2008 and December 31, 2007 (amounts in thousands):

	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Weighted-Average Remaining Life (years)
As of September 30, 2008				
Patent development costs	$ 4,777	$ (2,938)	$ 1,839	7.2
Acquired product intangibles	39,290	(4,286)	35,004	9.0
Non-competition agreements	530	(249)	281	1.6
Favorable lease	790	(307)	483	2.0
	$ 45,387	$ (7,780)	$ 37,607	8.8
As of December 31, 2007				
Patent development costs	$ 4,542	$ (2,573)	$ 1,969	8.1
Acquired product intangibles	37,790	(1,549)	36,241	10.0
Non-competition agreements	530	(82)	448	2.4
Favorable lease	227	(112)	115	0.8
	$ 43,089	$ (4,316)	$ 38,773	9.8

The intangible assets for acquired products, non-competition agreements and favorable lease included in the tables above resulted primarily from the JDS acquisition. In addition, during the three months ended September 30, 2008, Noven made a $1.5 million milestone payment to Banner upon FDA approval for Stavzor®. The payment was included in acquired product intangibles and is being amortized over the estimated life of the product. Amortization expense totaled $1.2 million and $0.5 million for the three months ended September 30, 2008 and 2007, respectively. Amortization expense totaled $3.5 million and $0.8 million for the nine months ended September 30, 2008 and 2007, respectively.

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Noven estimates that the annual amortization expense for intangible assets held at September 30, 2008 for each of the five years through 2013 is as follows (amounts in thousands):

	Remainder of 2008	Years Ending December 31, 2009	2010	2011	2012	2013
Cost of goods sold:						
Intellectual property	$ 1,065	$ 4,192	$ 4,146	$ 4,085	$ 4,069	$ 4,008
General and administrative:						
Non-compete and favorable lease agreements	116	413	236			
Total	$ 1,181	$ 4,605	$ 4,382	$ 4,085	$ 4,069	$ 4,008

8. OTHER ACCRUED LIABILITIES:

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

	September 30, 2008	December 31, 2007
Income taxes payable	$ 4,063	$ 2,414
Accrued medicaid and other rebates	2,759	4,065
Accrued market withdrawal costs	7,287	3,300
Allowance for product returns	3,135	1,875
Other accrued liabilities	4,483	3,616
Total other accrued liabilities	$ 21,727	$ 15,270

9. 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) and nonvested shares of common stock (restricted stock). Noven accounts for these awards in accordance with SFAS No. 123 (revised 2004), Share-Based Payment . At September 30, 2008, there were 1,967,083 stock options and 1,586,213 SSARs issued and outstanding under the 1999 Plan.

Noven has granted a total of 388,780 shares of restricted stock under the 1999 Plan. The following table summarizes the information regarding Noven s restricted stock at September 30, 2008 (share amounts in thousands):

	Shares	Weighted Average Grant-Date Fair Value
Nonvested at December 31, 2007	6	$ 22.86
Granted	328	9.90
Vested	(94)	11.40
Nonvested at		

September 30, 2008	240	$	9.67

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Noven granted 70,847 and 26,244 shares of restricted stock to Noven s non-employee directors in June 2008 and May 2007, respectively, as compensation for Board services. 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 EITF Issue No. 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 consolidated balance sheets. At September 30, 2008 and December 31, 2007 there were a total of 80,167 and 48,300 shares of common stock in the rabbi trust, respectively. Restricted stock grants during the nine months ended September 30, 2008 include an aggregate 257,345 shares of restricted stock granted to certain executive officers in 2008.

Noven has granted a total of 50,000 restricted stock units under the 1999 Plan. These restricted stock units were awarded to Noven s former Chief Executive Officer in January 2008 as part of a separation agreement. The fair value of this award (approximately $0.7 million) was charged to operations in 2007.

The assumptions used to value the SSARs for the three months ended September 30, 2008 and 2007 were as follows:

	2008	2007
Volatility	51.3%	41.8%
Risk free interest rate	3.08%	4.50%
Expected life (years)	4.8	4.0
Dividend yield	0.0%	0.0%

Total stock-based compensation recognized in Noven s consolidated statements of operations for the three and nine months ended September 30, 2008 and 2007 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Selling and marketing	$ 6	$ 111	$ 329	$ 333
General and administrative	726	783	2,353	2,039
Research and development	113	127	289	381
Total cost of products sold	68	121	287	365
	$ 913	$ 1,142	$ 3,258	$ 3,118
Tax benefit recognized related to compensation expense	$ 279	$ 359	$ 1,083	$ 1,020

Stock-based compensation costs of $0.1 million for each of the three months ended September 30, 2008 and 2007, and $0.3 million and $0.4 million for the nine months ended September 30, 2008 and 2007, respectively, were included in manufacturing expenses, which are included in the determination of inventory costs. In any given period, the amount of stock-based compensation costs included in ending inventory is immaterial. There were no stock-based compensation costs capitalized as part of fixed assets for the three and nine months ended September 30, 2008 or 2007.

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Cash received from options exercised under all share-based payment arrangements for the nine months ended September 30, 2008 and 2007 was $30,000 and $2.5 million, respectively. The tax benefit from option exercises under stock-based compensation arrangements for the nine months ended September 30, 2008 was immaterial due to the small number of exercises during the period. The tax benefit realized on the tax deductions from option exercises under stock-based compensation arrangements was $0.5 million for the nine months ended September 30, 2007, of which $0.4 million was reported as cash flow from financing activities for the nine months ended September 30, 2007.

Stock option and SSAR transactions under the 1999 Plan are summarized as follows for the nine months ended September 30, 2008 (options/SSARs and aggregate intrinsic value in thousands):

	Options/ SSARs	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Term
Outstanding at December 31, 2007	3,511	$ 16.83		
Granted	593	10.11		
Exercised	(3)	10.60	$ 3	
Canceled and expired	(548)	18.08		
Outstanding at September 30, 2008	3,553	$ 15.64	$ 1,337	3.9
Outstanding and exercisable at end of the period	2,209	$ 17.24	$ 294	2.6

As of September 30, 2008, 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 $10.5 million in the aggregate before the effect of income taxes, of which $1.2 million, $4.1 million, $3.0 million, $1.9 million and $0.3 million is expected to be incurred in the remainder of 2008 and in 2009, 2010, 2011 and 2012, respectively. The weighted-average period over which this compensation cost is expected to be recognized is 2.7 years. As of September 30, 2008, approximately 3,354,964 outstanding options/SSARs are vested or expected to vest. Such options have a weighted average exercise price of $15.79, $1.2 million aggregate intrinsic value and a weighted average remaining life of 3.74 years as of September 30, 2008.

10. 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. (FIN) 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

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1, 2007, was $0.9 million. If the $0.9 million were ultimately recognized, approximately $0.6 million would affect the effective tax rate due to approximately $0.3 million in related federal tax benefit. As of September 30, 2008 the gross amount of unrecognized tax benefits was approximately $1.2 million. If the $1.2 million is ultimately recognized, approximately $0.8 million would affect the effective tax rate due to approximately $0.4 million in related federal tax benefit. Interest and penalties related to income taxes are classified as a component of income tax expense. Approximately $0.4 million and $0.5 million were accrued for interest and penalties as of September 30, 2008 and December 31, 2007, respectively. Noven does not expect the gross amount of unrecognized tax benefits to significantly increase or decrease within twelve months after September 30, 2008. All of Noven s unrecognized tax benefits pertain to state tax positions.

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. The accruals are determined based upon Noven s best estimate of possible assessments by the Internal Revenue Service (IRS) or other taxing authorities and are adjusted, from time to time, based upon changing facts and circumstances. Federal returns for years 2004 through 2007 remain open and subject to examination by the IRS. During the third quarter of 2008, the IRS initiated an examination of Noven s federal income tax return for the year ended December 31, 2006. Noven does not expect the outcome of the examination to materially impact its tax liabilities. Noven files and remits state income taxes in various states where Noven has determined it is required to file state income taxes. Noven s filings with those states remain open for audit for the years 2003 through 2007. Other than the examination of Noven s 2006 federal income tax return and routine state tax inquiries, there are no other examinations currently taking place related to 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 can materially change the amount of unrecognized income tax benefits for tax positions taken, which may increase Noven s income tax liabilities or decrease the amount of deferred tax assets.

At September 30, 2008 and December 31, 2007, net deferred tax assets were $73.9 million and $65.7 million, respectively. Realization of these deferred tax assets 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. Noven Therapeutics files separate state income tax returns in states where Noven Therapeutics has determined that it is required to file state income taxes. As a result, state deferred tax assets relating to Noven Therapeutics are evaluated separately in determining whether the state deferred tax assets are realizable. Noven expects that Noven Therapeutics will incur taxable losses in the next few years due to future expected clinical trial expenditures related to product development and selling and marketing costs required to commercialize its products. These expected taxable losses create negative evidence indicating the need for a valuation allowance at September 30, 2008 and December 31, 2007. Noven s valuation allowance for state deferred tax assets was $4.1 million and $3.2 million as of September 30, 2008 and December 31, 2007, respectively, due to uncertainties in realizing these state deferred tax assets based on Noven s projection of future state taxable income relating to Noven Therapeutics. If Noven determines, based on future Noven Therapeutics profitability that these state deferred tax assets will more likely than not 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.

11. CONTRACT AND LICENSE AGREEMENTS:

SHIRE COLLABORATION

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 payable upon Shire s achievement of

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$25.0 million, $50.0 million and $75.0 million in annual Daytrana® net sales, respectively. Noven received the first $25.0 million sales milestone in the first quarter of 2007, the second $25.0 million sales milestone in the third quarter of 2007 and the third $25.0 million sales milestone in the third quarter of 2008. 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.

SYNTHON PHARMACEUTICALS COLLABORATION

In November 2005, JDS, now Noven Therapeutics, entered into an asset purchase agreement with Synthon Pharmaceuticals, Inc. (Synthon) 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 Noven s acquisition of JDS, Noven became responsible for possible future contingent milestone payments of up to $11.5 million in the event sales of Pexeva® achieve certain levels under the asset purchase agreement with Synthon, as further described as follows:

- $1.0 million milestone payable if 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 payment 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 $8.0 million threshold for 2007 and are expected to exceed such thresholds in 2008.

- $1.25 million milestone payable for each of the first two years if annual net sales of Pexeva® equal or exceed $10.0 million from 2007 to 2017. Pexeva® net sales exceeded this threshold for 2007 and are expected to exceed such thresholds in 2008.

- $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.

Noven accrued for these contingent milestone payments at the time of closing of the JDS acquisition based on projected future sales of Pexeva® which indicated that the achievement of each of the specified sales levels was probable at the time. In the third quarter of 2008, Noven determined that the achievement of $30.0 million in annual net sales for Pexeva® was no longer probable, resulting in a change in accounting estimate. The change results from lower forecasted long-term prescription growth than originally expected, as well as a redistribution of selling effort to support Stavzor®, which was commercially launched in August 2008. In the third quarter of 2008, Noven recognized $5.0 million in operating income as a result of the reversal of the accrued liability for the final contingent milestone payment upon a determination that the achievement of the milestone was no longer probable. The change in accounting estimate resulted in a positive net income impact of $3.2 million after taxes ($0.13 diluted earnings per share) for the three and nine months ended September 30, 2008, respectively. Noven does not expect the impact of this change in accounting estimate to have a material impact on future periods.

In April 2008, Noven made a milestone payment of $3.3 million to Synthon as a result of annual net sales of Pexeva® exceeding $8.0 million in 2007. As of September 30, 2008 and December 31, 2007, $3.3 million and $11.5 million, respectively, of these milestones were reflected as liabilities on Noven s consolidated balance sheets. In addition, Noven expects to trigger a $3.3 million milestone payment to Synthon based on 2008 sales.

BANNER PHARMACAPS COLLABORATION

In April 2007, JDS entered into a development, license and supply agreement with 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 potential development milestone payments. The agreement also provides that Banner will be the exclusive supplier of the products licensed under the agreement.

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In September 2008, Noven made a $1.5 million milestone payment to Banner upon FDA approval for Stavzor®. The remaining potential development milestone payments of up to $4.5 million are contingent upon the satisfaction of certain conditions related to the development of an extended release valproic acid product.

PROCTER & GAMBLE PHARMACEUTICALS COLLABORATION

In August 2008, Noven entered into global license and supply agreements with Procter & Gamble Pharmaceuticals, Inc. (P&GP) relating to the development and commercialization of prescription transdermal patches for the treatment of Hypoactive Sexual Desire Disorder (HSDD) in women. The global license agreement supersedes and replaces the prior development letter agreement entered into between Noven and P&GP on April 28, 2003. Under the agreements, Noven granted P&GP an exclusive worldwide license to a testosterone patch for the treatment of HSDD in women, as well as potential next-generation patches in the same therapeutic category, and P&GP granted Noven exclusive supplier rights with respect to such licensed products. If the testosterone patch is ultimately approved and commercially launched, Noven would receive royalties and manufacturing fees under the agreements. Noven may also receive additional development and sales milestone payments related to the licensed products. The royalty payments are to be determined based on a percentage of P&GP s quarterly sales of the licensed products. The milestone payments are contingent upon the achievement of certain sales milestones. Pursuant to the agreements, P&GP will fund any clinical development costs and will be responsible for any regulatory filings and marketing applications associated with any licensed products developed under the agreements.

12. 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 2008 and 2007 to meet Novartis annual preferred return for those periods and for Noven to recognize earnings from Novogyne under the formula.

During the three and nine months ended September 30, 2008 and 2007, Noven had the following transactions with Novogyne (in thousands):

	Three Months		Nine Months	
	2008	2007	2008	2007
Revenues:				
Product sales	$ 5,945	$ 5,801	$ 13,929	$ 15,974
Royalties	2,258	2,100	6,787	5,764
	$ 8,203	$ 7,901	$ 20,716	$ 21,738
Reimbursed expenses	$ 6,770	$ 6,940	$ 21,424	$ 21,046

Reimbursed expenses are primarily comprised of selling and marketing expenses paid by Noven on behalf of Novogyne. As of September 30, 2008 and December 31, 2007, Noven had amounts due from Novogyne of $6.2 million and $8.7 million, respectively.

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The unaudited condensed statements of operations of Novogyne for the three and nine months ended September 30, 2008 and 2007 are as follows (in thousands):

	Three Months		Nine Months	
	2008	2007	2008	2007
Gross revenues	$ 53,281	$ 45,224	$ 148,629	$ 125,432
Sales allowances	7,024	5,770	18,579	16,769
Sales return allowances	432	781	931	772
Sales allowances and returns	7,456	6,551	19,510	17,541
Net revenues	45,825	38,673	129,119	107,891
Cost of sales	8,893	8,152	25,489	22,994
Selling, general and administrative expenses	9,013	8,278	27,823	27,990
Income from operations	27,919	22,243	75,807	56,907
Interest income	341	286	782	783
Net income	$ 28,260	$ 22,529	$ 76,589	$ 57,690
Noven s equity in earnings of Novogyne	$ 13,849	$ 10,948	$ 34,545	$ 25,025

The activity in the Investment in Novogyne account for the nine months ended September 30, 2008 is as follows (in thousands):

Investment in Novogyne, beginning of period	$ 24,310
Equity in earnings of Novogyne	34,545
Cash distributions from Novogyne	(28,982)
Deemed distribution by Novogyne for state income tax payment	(2,700)
Investment in Novogyne, end of period	$ 27,173

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, 2008, Noven received cash distributions representing return on investment of $11.7 million and $29.0 million, respectively, from Novogyne. 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, respectively, from Novogyne. In addition, as discussed in Note 3, tax payments of $2.7 million and $5.2 million were made by Novogyne on Noven s behalf to the New Jersey Department of Revenue during the nine months ended September 30, 2008 and 2007, respectively. These amounts were recorded as reductions in the investment in Novogyne when received (or in the case of tax payments, when paid).

13. SHARE REPURCHASE PROGRAM:

In September 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 December 31, 2007, Noven had repurchased 322,345 shares of its common stock at an aggregate price of approximately $5.1 million. These shares remained in treasury as of September 30, 2008 and December 31, 2007. No shares were repurchased under the program during the nine months

ended September 30, 2008.

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14. COMMITMENTS AND CONTINGENCIES:

HORMONE THERAPY (HT) STUDIES:

Since 2002, several studies, including the Women s Health Initiative (WHI) study performed by the National Institutes of Health (NIH) and a study performed by the National Cancer Institute (NCI), have identified increased risks from the use of HT, including increased risks of invasive breast cancer, ovarian cancer, stroke, heart attacks and blood clots. As a result of the findings from these and other studies, the FDA has required that black box labeling be included on all 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. Since the July 2002 publication of the WHI and NCI study data, total United States prescriptions have declined for substantially all HT products, including our HT products in the aggregate. Researchers continue to analyze data from the WHI study and other studies. Other studies evaluating HT are currently underway or in the planning stage. In particular, a private foundation has commenced a clinical study aimed at determining whether estrogen therapy (ET) use, by women aged 42 to 58, reduces the risk of heart disease. The study also seeks to determine if transdermal estrogen patches are more or less beneficial than an oral HT product. While Noven s HT products are not being used in the study, the market for Noven s HT products could be adversely affected if this study finds 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 s products have been named in lawsuits filed against Noven, Novogyne and Novartis.

SUPPLY AGREEMENTS:

Noven s supply agreement with Novogyne for Vivelle-Dot® products expired in January 2003. 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. In connection with a transition to Vivelle-Dot®, effective December 2006, Noven ceased supplying Vivelle® product to Novogyne.

Noven and Shire are parties to a long-term supply agreement under which Noven manufactures and supplies Daytrana® to Shire at a fixed price. During the three months ended September 30, 2008 and 2007, Noven s net product sales of Daytrana® to Shire were $1.8 million and $1.4 million, respectively. During the nine months ended September 30, 2008 and 2007, Noven s net product sales of Daytrana® to Shire were $7.5 million and $11.0 million, respectively. The supply agreement gives Shire the right to qualify a second manufacturing source and purchase a portion of its requirements from that source. If Shire were to exercise this right, Noven s financial results from sales of Daytrana® would be adversely affected.

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 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.

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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.

In July 2008, one additional complaint was filed in the United States District Court, District of Minnesota against Wyeth Inc. and other named pharmaceutical companies, including Noven, Novogyne and Novartis. The complaint alleges liability in connection with personal injury claims allegedly arising from the use of HT products, including Vivelle-Dot®. The plaintiffs claim compensatory and other damages in an unspecified amount.

Each of the aforementioned federal court cases has been, or is expected to be, transferred to the federal multi-district litigation proceedings that are pending in the United States District Court, Eastern District of Arkansas.

Novartis has advised Noven that Novartis is currently named as a defendant in at least 30 additional lawsuits that include approximately 31 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-Dot®, 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, 2008 was $10.0 million. Novogyne has established reserves in the amount of $9.2 million with an offsetting insurance recovery of $6.9 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, 2008.

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 Noven s manufacture and sale of Daytrana®. The plaintiff is seeking injunctions from further infringement and claiming compensatory and other damages in an unspecified amount. In July 2007, Johnson-Matthey added Shire as a defendant in this lawsuit. The parties have completed initial discovery and the case has been scheduled for trial in late 2009.

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

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 consolidated financial condition, results of operations or cash flows.

FDA WARNING LETTER:

Daytrana® is Noven s transdermal methylphenidate system for the treatment of ADHD, which Noven has licensed globally to Shire. Noven and Shire have received reports from some consumers concerning the difficulty of removing the release liner from Daytrana® patches. In the first quarter of 2007, Noven, together with Shire, implemented enhancements to the Daytrana® release liner. While the enhanced release liner has reduced the level of consumer reports, some patients and caregivers continue to have difficulty in removing the release liner from some Daytrana® patches.

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In July 2007, Noven received from the FDA a list of observations on Form 483 following an on-site inspection of its manufacturing facilities. The majority of the observations in the Form 483 related to the Daytrana® patch and difficulties experienced by some patients in removing the release liner, including certain product lots that utilize the enhanced release liner. In July 2007, Noven submitted to the FDA its response to the Form 483.

In the third quarter of 2007, Shire initiated two voluntary market withdrawals of a portion of the 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 paid Shire $3.3 million in February 2008 related to the withdrawals. These costs were charged to operations in 2007.

In January 2008, Noven received a warning letter from the FDA in connection with the FDA s July 2007 inspection of its manufacturing facilities. In the warning letter, which is posted at the FDA s website, the FDA cited Current Good Manufacturing Practice deficiencies related to: (i) peel force specifications for removal of Daytrana® release liner; and (ii) data supporting the peel force characteristics of Daytrana® enhanced release liner throughout the product s shelf life. Noven submitted its response to the warning letter on January 30, 2008. In March 2008, the Florida District Office of the FDA indicated that Noven s response appears to be satisfactory and stated that Noven s response had been forwarded to the FDA s Center for Drug Evaluation and Research for further review. In April 2008, a Noven stability protocol identified certain Daytrana® lots exhibiting high peel force characteristics. In June 2008, Shire initiated the voluntary recall of two lots of Daytrana® that did not meet the product s release liner removal specification. Noven has agreed to pay Shire $1.95 million related to Shire s June 2008 recall, of which $0.25 million and $1.7 million were charged to operations in the first and second quarters of 2008, respectively. In August 2008, Shire initiated the voluntary recall of two additional lots of Daytrana® that did not meet the product s release liner removal specification. Noven has agreed to pay Shire $1.7 million related to Shire s August 2008 recall, of which approximately $1.4 million has been charged to general and administrative expenses, $0.2 million was recorded as a reduction in revenues and $0.1 million was charged to cost of products sold in the three months ended September 30, 2008. For each of the recalls described above, the amounts reflected as reductions of revenue represent the amounts recognized for product which is expected to be returned. The charge to cost of products sold represents the value of AMI included in such product for which Noven is required to reimburse Shire. The amount charged to general and administrative expenses represents amounts Noven is obligated to reimburse Shire for direct costs of the recalls.

Noven is in the process of implementing new product release testing intended to predict which Daytrana® lots are at risk of developing peel force issues during the product s shelf life. Product that fails to meet this test will be destroyed, which will result in increased Daytrana® manufacturing costs, including reimbursements to Shire for the AMI for destroyed product. For the nine months ended September 30, 2008, Daytrana® cost of products sold exceeded Noven s Daytrana® net revenues by $6.5 million. As a result of this new release testing, Noven s cost of product sold for future Daytrana® production is expected to increase materially to reflect Daytrana® lots that fail to meet the new release testing standard, which will result in a continuing significantly negative gross margin for the product unless and until the peel force issue is resolved.

In accordance with SFAS No. 5, Accounting for Contingencies (SFAS No. 5), Noven has determined that certain previously-manufactured lots that would not have met the new release testing standard are probable of being voluntarily withdrawn or recalled from the market prior to the expiration of their shelf life. Consequently, during the quarter ended September 30, 2008, Noven established a reserve of $4.3 million related to these affected lots. This reserve includes $1.7 million of estimated recall costs that Noven will be required to reimburse Shire if there are voluntary withdrawals or recalls. Of the $4.3 million reserve, approximately $1.7 million has been charged to general and administrative expenses, $1.1 million was recorded as a reduction in revenues and $1.5 million was charged to cost of products sold (of which $0.8 million relates to the cost of AMI as discussed in Note 6). Noven cannot assure that its costs related to this issue will not exceed the $4.3 million reserved amount. Although the new release testing is designed to reduce the likelihood that newly-manufactured product will be withdrawn or recalled in the future, Noven cannot assure that its testing procedures will detect all production issues or that there will not be future Daytrana® market withdrawals or recalls.

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Noven believes it has identified the root cause of, and has identified potential solutions related to, this issue, although it will take time to test the effectiveness of the potential solutions and to determine whether such solutions satisfactorily resolve the issue. Noven cannot assure that there will be a satisfactory resolution of the peel force issue. Failure to adequately address the issues raised by the FDA in the warning letter as well as the production and other issues involving Daytrana® could result in additional regulatory action, including fines, recalls of products, injunctions, seizures, suspension of production or withdrawal of the approval of products. Any such regulatory action would be expected to have a material adverse effect on Noven, including the potential for litigation related to this matter, harm to Noven s reputation and various costs associated with the foregoing.

CONTRACT AND LICENSE AGREEMENTS:

Noven is obligated to perform under its contract and license agreements. In certain circumstances, Noven is required to indemnify its licensees from damages caused by the products Noven manufactures as well as claims or losses related to patent infringement.

NOVEN THERAPEUTICS COMMITMENTS:

Noven Therapeutics has certain commitments and contingencies related to contractual arrangements, primarily related to milestone payments for development, FDA submission, FDA approval and commercial sales of current and developmental products. As of September 30, 2008 and December 31, 2007, Noven Therapeutics was responsible for up to $18.7 million and $23.5 million in such contingent milestones, respectively. As of September 30, 2008 and December 31, 2007, $3.3 million and $11.5 million of these milestones, respectively, were reflected as liabilities in Noven s consolidated balance sheets. As discussed in Note 11, in April 2008, Noven made a $3.3 million milestone payment to Synthon and, in September 2008, Noven made a $1.5 million milestone payment to Banner. In addition, as further discussed in Note 11, in the third quarter of 2008, Noven recognized $5.0 million in operating income as a result of the reversal of an accrued liability for the final contingent milestone payment upon a determination that the achievement of $30.0 million in annual net sales for Pexeva® was no longer probable.

EMPLOYMENT AGREEMENT AND BONUS PLAN:

In connection with the appointment of Noven s President and Chief Executive Officer, Noven entered into an employment agreement, dated April 29, 2008 (the Agreement). The initial two-year term of the Agreement expires on April 28, 2010 and will continue for consecutive one-year terms unless it is terminated by either party under certain conditions. The President and Chief Executive Officer s base salary under the Agreement is approximately $0.7 million, subject to increases at the discretion of the Board of Directors. The President and Chief Executive Officer s annual target incentive bonus under Noven s annual incentive plan during the term will be at least 75% of his base salary. In connection with the Agreement, the President and Chief Executive Officer was granted the following equity awards under the 1999 Plan: (i) SSARs with an aggregate fair value of $1.3 million to acquire 311,529 shares of Noven s common stock at an exercise price of $9.10 per share (the market price on the grant date) which vest at a rate of 25% per year on each anniversary of the grant date; and (ii) 250,000 shares of restricted stock. The shares of restricted stock vest as follows: (a) 50,000 shares were immediately vested upon grant; (b) 50,000 shares vest ratably over three years; and (c) 150,000 shares vest in three equal parts upon Noven s achievement of specified performance targets based on Noven s pre-tax income.

Noven has a formula bonus plan that includes company and individual performance goals. Under the plan, a fixed percentage of each eligible employee s base salary is established as a target incentive bonus award for such employee. To the extent that actual company performance is equal to, exceeds or is less than

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the company performance targets, an employee s bonus award may be equal to, greater than or less than his or her target award. An employee s non-financial goals are then considered in determining his or her final bonus award. Management s estimate of the bonus accrual is expensed over the year in which it is earned.

CREDIT FACILITY:

In July 2008, Noven entered into an agreement for a $15.0 million credit facility. In connection with the credit facility and in lieu of granting a security interest in Noven s assets, Noven granted a negative pledge in favor of the lender, whereby Noven agreed not to pledge, grant any security interest in, or allow any lien or encumbrance in or on, certain of Noven s financial assets. As of September 30, 2008, no borrowings were outstanding under this facility.

15. SEGMENT DATA:

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. The table below presents segment information for the periods identified and reconciles segment information to the applicable consolidated amounts. There are no inter-segment revenues. The results of the Noven Therapeutics segment are included in Noven s consolidated results beginning on the date of acquisition (August 14, 2007). Consequently, Noven s results for the three and nine months ended September 30, 2007 do not include the results of the Noven Therapeutics segment for the period prior to the Closing Date.

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(in thousands):	Three Months Ended September 30, 2008	2007	Nine Months Ended September 30, 2008	2007
Noven Transdermals:				
Product revenues	$ 14,527	$ 13,365	$ 37,986	$ 44,033
License and contract revenues	6,371	5,125	16,717	12,611
Net revenues	20,898	18,490	54,703	56,644
Cost of products sold	(13,024)	(8,998)	(33,058)	(27,239)
Selling and marketing	(48)	(332)	(455)	(793)
Equity in earnings of Novogyne	13,849	10,948	34,545	25,025
Segment contribution	21,675	20,108	55,735	53,637
Noven Therapeutics:				
Product revenues	4,807	3,325	17,087	3,325
Cost of products sold	(1,903)	(813)	(5,961)	(813)
Acquired in-process research and development		(100,150)		(100,150)
Selling and marketing	(7,278)	(2,771)	(17,030)	(2,771)
Reversal of contingent milestone liability	5,000		5,000	
Segment contribution	626	(100,409)	(904)	(100,409)
Unallocated income (expense):				
Research and development	(4,041)	(3,649)	(10,653)	(10,300)
General and administrative	(11,147)	(8,770)	(27,075)	(19,439)
Interest income, net	344	1,306	1,466	4,751
Income (loss) before income taxes	$ 7,457	$ (91,414)	$ 18,569	$ (71,760)

Segment assets consisted of the following as of September 30, 2008 and December 31, 2007 (in thousands):

	September 30, 2008	December 31, 2007
Noven Transdermals	$ 86,635	$ 83,912
Noven Therapeutics	56,302	57,893
Assets not allocated to segments[1]	164,246	144,893
Total Assets	$ 307,183	$ 286,698

[1] Assets not allocated to segments

consist primarily of cash and cash equivalents, investments in auction rate securities and deferred income taxes.

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16. SUBSEQUENT EVENT TERMINATION AGREEMENT:

On November 5, 2008, Noven entered into a letter agreement (the Termination Agreement) with Shire terminating Noven s agreements with Shire for the development of an amphetamine patch. The Termination Agreement terminates the amphetamine letter agreements dated as of (i) June 15, 2004, (ii) May 4, 2007, and (iii) June 4, 2007. Under the Termination Agreement, rights to the developmental amphetamine patch were returned to Noven. Noven intends to pursue the further development and commercialization of the product. Shire will be entitled to a modest royalty if Noven elects to commercialize a product that incorporates intellectual property arising from the development project with Shire. As of September 30, 2008, Noven s consolidated balance sheet reflected deferred license and contract revenue of $7.2 million related to this project. As a result of the termination of this project with Shire, Noven expects to recognize the $7.2 million as license and contract revenues in the fourth quarter of 2008.

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

The following section addresses material aspects of our consolidated financial condition as of September 30, 2008, and our consolidated results of operations for the three months ended September 30, 2008 (the 2008 Quarter) and September 30, 2007 (the 2007 Quarter), and the nine months ended September 30, 2008 (the 2008 Period) and September 30, 2007 (the 2007 Period). The contents of this section include:

An executive summary of our consolidated results of operations for the 2008 Quarter;

An overview of Noven and our Novogyne joint venture;

An overview of Noven Therapeutics;

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

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

An outlook that includes our current financial guidance.

This discussion should be read in conjunction with Noven s unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2008 and 2007 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 unaudited condensed consolidated financial statements and related notes included in this Form 10-Q.

Our financial results for the 2008 Quarter included the results of operations of Noven Therapeutics (previously known as JDS Pharmaceuticals), a specialty pharmaceutical company that we acquired on August 14, 2007. The 2008 Quarter also included the recognition of $5.0 million in operating income due to the reversal of a $5.0 million accrued liability related to a future Pexeva® contingent sales milestone. In addition, results for the 2008 Quarter included (i) a $1.7 million charge for reimbursements due to Shire for a voluntary recall of certain Daytrana® product initiated by Shire in the 2008 Quarter, and (ii) a $4.3 million reserve related to previously-manufactured Daytrana® product at risk of exceeding the product s peel force specification during its shelf life (together, the Daytrana® Charges).

The 2007 Quarter included (i) a $100.2 million charge for the portion of the JDS Pharmaceuticals purchase price allocated to in-process research and development (the IPR&D Charge), and (ii) a $3.3 million charge related to reimbursements to Shire in connection with their voluntary withdrawal of certain lots of Daytrana® product.

For the 2008 Quarter, we reported net income of $5.2 million ($0.21 diluted earnings per share), compared to a net loss of $59.0 million ($2.38 loss per share) for the 2007 Quarter. Our net revenues in the 2008 Quarter were $25.7 million, an 18% increase over the 2007 Quarter. This increase reflects a full quarter of sales of Noven Therapeutics Pexeva® and Lithobid® products, as well as increased license and contract revenues, primarily due to amortization of deferred revenue from additional Daytrana® sales milestone payments. The increase in net revenues was partially offset by a $1.3 million reduction in third quarter revenues, representing a portion of the Daytrana® Charges.

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Gross margin, as a percentage of net product revenues, was 23% in the 2008 Quarter compared to 41% in the 2007 Quarter. Cost of products sold in the 2008 Quarter included $1.6 million of the Daytrana® Charges, as well as increased quality assurance activities and expenses, primarily related to Daytrana® production. Due to new product release testing intended to identify and screen product at risk of exceeding the product s peel force specification during the product s shelf life, our cost of products sold for future Daytrana® production is expected to increase materially to reflect Daytrana® lots that fail to meet the new release testing standard, which is expected to result in a continuing significantly negative gross margin for the product unless and until the peel force issue affecting the product is resolved.

The 2007 Quarter included the $100.2 million IPR&D Charge. Excluding the IPR&D Charge, research and development expenses in the 2008 Quarter increased $0.4 million to $4.0 million compared to the 2007 Quarter. Selling and marketing expenses increased to $7.3 million from $3.1 million in the 2007 Quarter, reflecting a full quarter of selling and marketing expenses at Noven Therapeutics as well as $3.3 million related to the August 2008 commercial launch of Stavzor®. In the 2008 Quarter, general and administrative expenses increased $2.4 million, or 27%, reflecting $3.1 million of the Daytrana® Charges and a full quarter of expenses at Noven Therapeutics.

We recognized $13.8 million in earnings from Novogyne in the 2008 Quarter, an increase of 26% compared to the 2007 Quarter. Net revenues at Novogyne increased 18% to $45.8 million in the 2008 Quarter, primarily due to increased sales of Vivelle-Dot®. Novogyne s gross margin percentage for the 2008 Quarter increased slightly to 81%. Novogyne s selling, general and administrative expenses for the 2008 Quarter were $9.0 million, a 9% increase over the 2007 Quarter. Novogyne s net income for the 2008 Quarter increased 25% to $28.3 million compared to $22.5 million in the 2007 Quarter.

At September 30, 2008, we had $65.3 million in cash and cash equivalents and $15.5 million in investments in auction rate securities, representing an aggregate $80.7 million in cash, cash equivalents and investments in auction rate securities. This compares with $14.0 million in cash and cash equivalents and $54.4 million in investments in auction rate securities at December 31, 2007, representing an aggregate $68.4 million in cash, cash equivalents and investments in auction rate securities. In the 2008 Quarter, we received the third and final $25.0 million milestone payment related to Shire s sales of Daytrana®. Also in the 2008 Quarter, we obtained a $15.0 million revolving credit facility; no amounts were borrowed under this facility as of September 30, 2008.

Our investments in auction rate securities at September 30, 2008 had a fair value of $15.5 million and all were classified as non-current on our balance sheet following failed auctions occurring since February 2008. We liquidated $2.1 million and $39.0 million of these investments at par value in the 2008 Quarter and 2008 Period, respectively. The auction rate securities that we hold are collateralized primarily by tax-exempt municipal bonds and, to a much lesser extent, guaranteed student loans. We had recorded a temporary change in fair value of $0.5 million relating to our investments in auction rate securities in the first quarter of 2008; we did not record any additional change in fair value in either the second or third quarters of 2008.

Total prescriptions for Vivelle-Dot® increased 7% in the 2008 Quarter compared to the 2007 Quarter, and total prescriptions for Novogyne s HT products, taken as a whole, increased 3%. By comparison, the U.S. HT market declined 5% for the same period. Total prescriptions for Daytrana® decreased 14% in the 2008 Quarter compared to the 2007 Quarter, while prescriptions for ADHD stimulant therapies as a class increased 9% over the same period. Total prescriptions for Pexeva® decreased 11% in the 2008 Quarter compared to the 2007 Quarter, while for the same period prescriptions for the selective serotonin re-uptake inhibitor (SSRI) class increased 2%. Reflecting ongoing generic substitution, total prescriptions for Lithobid® decreased 30% in the 2008 Quarter compared to the 2007 Quarter.

In July 2008, the FDA granted final approval for Stavzor® (valproic acid delayed release capsules) in the treatment of manic episodes associated with bipolar disorder, adjunctive therapy in multiple seizure types (including epilepsy), and prophylaxis of migraine headaches. Noven Therapeutics commercially launched Stavzor® in August 2008.

In August 2008, we entered into global license and supply agreements with Procter & Gamble Pharmaceuticals, Inc. (P&GP) relating to the development and commercialization of prescription transdermal patches for the treatment of Hypoactive Sexual Desire Disorder (HSDD) in women. Under the agreements, we granted P&GP an exclusive worldwide license to a testosterone patch for the treatment of HSDD in women, as well as potential next-generation

patches in the same therapeutic category. The agreements provide for payment to us of royalties and manufacturing fees, as well as development and sales milestones, relating to the licensed products. P&GP will fund any clinical development costs and will be responsible for any regulatory filings and marketing applications associated with the licensed products, as applicable.

During the 2008 Quarter, we advanced preparations for a Phase 2 study of Mesafem, our developmental non-hormonal product for vasomotor symptoms (hot flashes), and patient screening for the study began in October 2008. Following an internal review and prioritization of projects in our drug development pipeline, we announced in November 2008 that we no longer intend to fund development of our Lithium QD and Stavzor® ER projects. Also in November 2008, we announced that we had reacquired rights to our developmental amphetamine patch for ADHD upon termination of a prior collaborative development arrangement.

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Overview of Noven 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 condition 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.

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 HT products. Novartis distributes 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 $13.8 million and $10.9 million for the 2008 Quarter and the 2007 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 2008 Period and the 2007 Period, we received $29.0 million and $18.5 million, respectively, in distributions from Novogyne, which accounted for a substantial portion of our net operating cash flows for these periods. We expect that for the next several years a substantial portion of our earnings will be generated through our interest in Novogyne and a substantial portion of our cash flow will also be generated through our interest in Novogyne. Any failure by Novogyne to remain profitable or to continue to make distributions would have a material adverse effect on our consolidated results of operations and financial condition.

Overview of Noven Therapeutics

Noven Therapeutics is a specialty pharmaceutical company that currently markets three branded prescription psychiatry products (Stavzor®, Pexeva® and Lithobid®) and is advancing the development of Mesafem , a non-hormonal therapy for the treatment of vasomotor symptoms associated with menopause. We will seek to leverage Noven Therapeutics marketing and sales infrastructure with next-generation psychiatry/CNS products, and with complementary products that we will seek to develop or acquire. We plan to increase our research and development expenses significantly over the next several years.

Certain Items that May Affect Historical or Future Comparability

Set forth below are certain items that may affect the historical or future comparability of our consolidated results of operations and financial condition. Such disclosure is not intended to address every item that may affect the historical or future comparability of our consolidated results of operations or financial condition and such disclosure should be read in conjunction with the discussion and analysis of our consolidated results of operations, liquidity and capital resources and outlook appearing elsewhere in this Item 2.

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Acquisition of JDS Pharmaceuticals, LLC in 2007

We acquired JDS (now Noven Therapeutics) on August 14, 2007. We accounted for the acquisition of JDS using the purchase method of accounting. The purchase price exceeded the amounts allocated to the tangible and intangible assets acquired and liabilities assumed by approximately $14.4 million, which has been recorded as goodwill, all of which is deductible for tax purposes.

We acquired $39.1 million in identifiable intangible assets in the JDS acquisition, which relate to: (i) intellectual property rights associated with Noven Therapeutics products approved by the FDA; (ii) a favorable lease intangible asset; and (iii) non-competition agreements with two former executives of JDS. At September 30, 2008, the carrying amount of Noven s intangible assets (excluding goodwill, but including certain intangibles unrelated to the JDS acquisition) totaled $37.6 million. Noven estimates that the annual amortization expense for intangible assets held at September 30, 2008 for each of the five years through 2013 will be as follows (amounts in thousands):

	Remainder of 2008	Years Ending December 31, 2009	2010	2011	2012	2013
Cost of goods sold:						
Intellectual property	$ 1,065	$ 4,192	$ 4,146	$ 4,085	$ 4,069	$ 4,008
General and administrative:						
Non-compete and favorable lease agreements	116	413	236			
Total	$ 1,181	$ 4,605	$ 4,382	$ 4,085	$ 4,069	$ 4,008

We test our goodwill acquired as a result of the JDS acquisition for impairment annually in the fourth quarter, or more frequently if indicators of impairment arise. Although we have not experienced any indicators which would call for an earlier impairment test, we cannot assure that goodwill will not be impaired when we perform our annual test in the fourth quarter. We are required to test our intangible assets with finite lives if events or changes in circumstances indicate that such assets might be impaired. If after testing our intangible assets and goodwill, we determine that these assets are impaired, then we would be required to write-down the impaired assets to fair value and record a corresponding expense in the period when the determination is made. Such a write-down and corresponding expense could have a material adverse effect on our results of operations.

Following the acquisition of JDS, we became responsible for contingent milestone payments in the event that sales of Pexeva® achieved certain levels specified under the asset purchase agreement with Synthon. At the closing date, we recorded a liability related to contingent milestone payments for which we determined it was probable that we would achieve the specified targets. In the third quarter of 2008, we concluded that it was no longer probable that we would achieve the final sales milestone. As a result, we recognized $5.0 million in operating income as a result of reversing the liability for this contingent milestone payment.

Daytrana®

Daytrana® is our transdermal methylphenidate system for the treatment of ADHD, which we have licensed globally to Shire. We and Shire have received reports from some consumers concerning the difficulty of removing the release liner from certain Daytrana® patches. In the first quarter of 2007, we, together with Shire, implemented enhancements to the Daytrana® release liner. While the enhanced release liner has reduced the level of consumer reports, some patients and caregivers continue to have difficulty in removing the release liner from some Daytrana® patches.

In July 2007, we received from the FDA a list of observations on Form 483 following an on-site inspection of our manufacturing facilities. The majority of the observations in the Form 483 related to the Daytrana® patch and difficulties experienced by some patients in removing the release liner, including certain product lots that utilize the enhanced release liner. In July 2007, we submitted to the FDA our response to the Form 483.

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In the third quarter of 2007, Shire initiated two voluntary market withdrawals of a portion of the 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 paid Shire $3.3 million in February 2008 related to those withdrawals. This payment was charged to operations in 2007.

In January 2008, we received a warning letter from the FDA in connection with the FDA s July 2007 inspection of our manufacturing facilities. In the warning letter, which is posted at the FDA s website, the FDA cited Current Good Manufacturing Practice deficiencies related to: (i) peel force specifications for removal of Daytrana ® release liner; and (ii) data supporting the peel force characteristics of Daytrana ® enhanced release liner throughout the product s shelf life. We submitted our response to the warning letter on January 30, 2008. In March 2008, the Florida District Office of the FDA indicated that our response appears to be satisfactory and stated that our response had been forwarded to the FDA s Center for Drug Evaluation and Research for further review. In April 2008, a Noven stability protocol identified certain Daytrana® lots exhibiting high peel force characteristics. In June 2008, Shire initiated the voluntary recall of two lots of Daytrana® that did not meet the product s release liner removal specification. We have agreed to pay Shire $1.95 million related to their June 2008 recall, of which $0.25 million and $1.7 million were charged to operations in the first and second quarters of 2008, respectively. In August 2008, Shire initiated the voluntary recall of two additional lots of Daytrana® that did not meet the product s release liner removal specification. We have agreed to pay Shire $1.7 million related to their August 2008 recall, of which approximately $1.4 million has been charged to general and administrative expenses, $0.2 million was recorded as a reduction in revenues and $0.1 million was charged to cost of products sold in the 2008 Quarter. For each of the recalls described above, the amounts reflected as reductions of revenue represent the amounts recognized for product which is expected to be returned. The charge to cost of product sold represents the value of AMI included in such product for which we are required to reimburse Shire. The amount charged to general and administrative expenses represents amounts we are obligated to reimburse Shire for direct costs of the recalls.

We are in the process of implementing new product release testing intended to predict which Daytrana® lots are at risk of developing peel force issues during the product s shelf life. Product that fails to meet this test will be destroyed, which will result in increased Daytrana® manufacturing costs, including reimbursements to Shire for the AMI for destroyed product. For the 2008 Period, Daytrana® cost of products sold exceeded our Daytrana® net revenues by $6.5 million. As a result of this new release testing, our cost of product sold for future Daytrana® production is expected to increase materially to reflect Daytrana® lots that fail to meet the new release testing standard, which will result in a continuing significantly negative gross margin for the product unless and until the peel force issue is resolved.

In accordance with SFAS No. 5, we have determined that certain previously-manufactured lots that would not have met the new release testing standard are probable of being voluntarily withdrawn or recalled from the market prior to the expiration of their shelf life. Consequently, during the quarter ended September 30, 2008, we established a reserve of $4.3 million related to these affected lots. This reserve includes $1.7 million of estimated recall costs that we will be required to reimburse Shire if there are voluntary withdrawals or recalls. Of the $4.3 million reserve, approximately $1.7 million has been charged to general and administrative expenses, $1.1 million was recorded as a reduction in revenues and $1.5 million was charged to cost of products sold. We cannot assure that our costs related to this issue will not exceed the $4.3 million reserved amount. Although the new release testing is designed to reduce the likelihood that newly-manufactured product will be withdrawn or recalled in the future, we cannot assure that our testing procedures will detect all production issues or that there will not be future Daytrana® market withdrawals or recalls.

We believe we have identified the root cause of, and have identified potential solutions related to, this issue, although it will take time to test the effectiveness of the potential solutions and to determine whether such solutions satisfactorily resolve the issue. We cannot assure that there

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will be a satisfactory resolution of the peel force issue. Failure to adequately address the issues raised by the FDA in the warning letter as well as the production and other issues involving Daytrana® could result in additional regulatory action, including fines, recalls of products, injunctions, seizures, suspension of production or withdrawal of the approval of products. Any such regulatory action would be expected to have a material adverse effect on us, including the potential for litigation related to this matter, harm to our reputation and various costs associated with the foregoing.

Results of Operations

Our business is comprised of two reportable segments distinguished along product categories: (i) Noven Transdermals, which currently engages in the research, development, manufacturing and licensing to partners of transdermal drug delivery technologies and prescription transdermal products, including product sales to Shire, Novartis Pharma and Novogyne as well as our equity in earnings of Novogyne; and (ii) Noven Therapeutics, which currently engages in the development, marketing, sales and distribution of pharmaceutical products.

We evaluate segment performance based on segment contribution, which consists of segment gross margin less direct selling and marketing expenses, plus (in the case of Noven Transdermals) our equity in earnings of Novogyne. Research and development expenses, general and administrative expenses and interest income are not allocated to our operating segments. The contribution of our Noven Transdermals segment includes $13.8 million and $34.5 million of equity in earnings of Novogyne recognized in the 2008 Quarter and Period, respectively. We acquired the Noven Therapeutics business on August 14, 2007. Consequently, the results of the Noven Therapeutics segment are included in the 2007 Quarter and Period beginning on August 14, 2007. The negative contribution of our Noven Therapeutics segment in the 2008 Quarter (before the benefit from reversal of the contingent milestone liability) and Period reflects the impact of $7.3 million and $17.0 million, respectively, in selling and marketing expenses in support of Noven Therapeutics currently marketed products, including approximately $3.3 million of expenses in the 2008 Period related to the commercial launch of Stavzor®. The negative contribution of our Noven Therapeutics segment during the 2007 Quarter and 2007 Period includes $100.2 million related to the immediate write-off of acquired IPR&D.

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(in thousands):	Three Months Ended September 30, 2008	2007	Nine Months Ended September 30, 2008	2007
Noven Transdermals:				
Product revenues	$ 14,527	$ 13,365	$ 37,986	$ 44,033
License and contract revenues	6,371	5,125	16,717	12,611
Net revenues	20,898	18,490	54,703	56,644
Cost of products sold	(13,024)	(8,998)	(33,058)	(27,239)
Selling and marketing	(48)	(332)	(455)	(793)
Equity in earnings of Novogyne	13,849	10,948	34,545	25,025
Segment contribution	21,675	20,108	55,735	53,637
Noven Therapeutics:				
Product revenues	4,807	3,325	17,087	3,325
Cost of products sold	(1,903)	(813)	(5,961)	(813)
Acquired in-process research and development		(100,150)		(100,150)
Selling and marketing	(7,278)	(2,771)	(17,030)	(2,771)
Reversal of contingent milestone liability	5,000		5,000	
Segment contribution	626	(100,409)	(904)	(100,409)
Unallocated income (expense):				
Research and development	(4,041)	(3,649)	(10,653)	(10,300)
General and administrative	(11,147)	(8,770)	(27,075)	(19,439)
Interest income, net	344	1,306	1,466	4,751
Income (loss) before income taxes	$ 7,457	$ (91,414)	$ 18,569	$ (71,760)

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Three and nine months ended September 30, 2008 compared to the three and nine months ended September 30, 2007

Revenues

Total revenues for the three and nine months ended September 30, 2008 and 2007 are summarized as follows (dollar amounts in thousands):

	Three Months Ended September 30,		%	Nine Months Ended September 30,		%
	2008	2007	Change	2008	2007	Change
Noven Transdermals						
Novogyne:						
Product sales	$ 5,945	$ 5,801	2%	$ 13,929	$ 15,974	-13%
Royalties	2,258	2,100	8%	6,787	5,764	18%
Product revenues Novogyne	8,203	7,901	4%	20,716	21,738	-5%
Third Parties:						
Product sales	6,236	5,372	16%	17,015	22,056	-23%
Royalties	88	92	-4%	255	239	7%
Product revenues third parties	6,324	5,464	16%	17,270	22,295	-23%
Total product revenues	14,527	13,365	9%	37,986	44,033	-14%
License and contract revenues	6,371	5,125	24%	16,717	12,611	33%
Total Transdermals	20,898	18,490	13%	54,703	56,644	-3%
Noven Therapeutics						
Third Parties:						
Product sales	4,807	3,325	45%	17,087	3,325	414%
Net Revenues	$ 25,705	$ 21,815	18%	$ 71,790	$ 59,969	20%

Net Revenues

As described in more detail below, our net revenues in the 2008 Quarter were $25.7 million, an increase of 18% compared to $21.8 million reported in the 2007 Quarter. This increase reflects the addition of $1.5 million in net revenues primarily associated with our sales of Pexeva® and Lithobid® products through Noven Therapeutics, which was acquired in August 2007. We also realized a $1.2 million, or 24%, increase in license and contract revenues compared to the 2007 Quarter. In addition, the 2008 Quarter benefited from the fulfillment of backorders that resulted from production issues related to our Noven Transdermals segment in the first quarter. The 2008 Quarter was adversely affected by an aggregate $1.3 million reduction in revenues related to certain previously-manufactured lots at risk of not meeting the peel force specification during the product s shelf life.

As described in more detail below, our net revenues in the 2008 Period were $71.8 million, an increase of 20% compared to $60.0 million reported in the 2007 Period. This increase reflects the addition of $13.8 million in net revenues primarily associated with our sales of Pexeva® and Lithobid® products through Noven Therapeutics. We also realized a $4.1 million, or 33%, increase in license and contract revenues compared to the 2007 Period. These increases were offset by a $6.0 million decrease in product revenues from our Noven Transdermals segment

comprised primarily of a $3.6 million decrease in sales of Daytrana® and a $2.4 million decrease in the sale of HT products in the 2008 Period.

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Product Revenues Novogyne

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

The $0.3 million increase in Novogyne product revenues for the 2008 Quarter primarily resulted from the timing of orders from Novogyne. By product, Vivelle-Dot® increased $0.5 million, Combipatch® decreased $0.4 million, and royalties increased $0.2 million due to increased sales by Novogyne to its customers for the 2008 Quarter.

The $1.0 million decrease in Novogyne product revenues for the 2008 Period primarily resulted from a $2.1 million decline of Vivelle-Dot® product revenues, partially offset by a $0.2 million increase in unit sales of CombiPatch® due to the timing of orders from Novogyne, as well as an increase of $1.0 million in royalties due to increased sales by Novogyne to their customers for the 2008 Period. The decline in Vivelle-Dot® product revenues is attributable to the timing of orders as prescriptions have increased period to period. The previously disclosed backlog of orders due to the first quarter production issues were substantially filled as of September 30, 2008.

Product Revenues Third Parties

Product revenues third parties consist of: (i) sales of Estradot®, Estalis® 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 Estradot® in Canada; (ii) sales of Daytrana® to Shire for commercial resale in the United States; (iii) beginning on August 14, 2007, Noven s commercial sales of Pexeva® and Lithobid® to trade customers, including wholesalers, distributors and chain pharmacies; and (iv) beginning in August 2008, sales of Stavzor® to trade customers, including wholesalers, distributors and chain pharmacies.

The $0.9 million increase in product revenues third parties in our Noven Transdermals segment for the 2008 Quarter compared to the 2007 Quarter consisted of a $0.4 million increase in sales of Daytrana®, a $0.3 million increase in sales of Estradot® and a $0.3 million increase in sales of Estalis®, partially offset by a $0.2 million decline related to pricing. The increase in Daytrana® sales was primarily due to the timing of orders. The 2008 Quarter was adversely affected by an aggregate $1.3 million reduction in revenues related to expected Daytrana® product returns due to Shire s August 2008 voluntary recall as well as certain previously-manufactured lots that would not have met the new release testing standard and are probable of being recalled or withdrawn during the product s shelf life. The increase in Estradot® and Estalis® sales relates to the timing of orders from Novartis Pharma. With respect to pricing, we recognize the benefit from price increases for our third party HT product through periodic price reconciliation payments received from Novartis Pharma. We receive such payments from time to time upon Novartis Pharma s determination that its actual sales price of our product entitles us to receive amounts in excess of the minimum transfer price at which we initially sold the product to Novartis Pharma. We recognized $1.3 million and $1.5 million of such payments in the 2008 Quarter and 2007 Quarter, respectively.

The $5.0 million decrease in product revenues third parties in our Noven Transdermals segment for the 2008 Period compared to the 2007 Period consisted of a $3.6 million decline in sales of Daytrana®, a $0.8 million decline in third-party revenues from our HT products and a $0.6 million decline due to pricing. The decrease in Daytrana® product revenues was largely attributable to delays in the release of product at the end of the 2008 Quarter, an aggregate $1.5 million reduction in revenues related to expected Daytrana® product returns due to Shire s voluntary recalls and certain previously-manufactured lots that would not have met the new release testing standard and are probable of being recalled or withdrawn during the product s shelf life, the timing of orders and, to a lesser extent, decreased demand. The decline in third-party HT product revenues is attributable to the timing of orders and shipments. In addition, Noven realized a lower benefit from price increases for our third party HT product through periodic price reconciliation payments

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received from Novartis as discussed above. We recognized $2.4 million and $3.1 million of such payments in the 2008 Period and 2007 Period, respectively.

Noven Therapeutics, which was acquired in August 2007, generated $4.8 million and $17.1 million of net revenues in the 2008 Quarter and 2008 Period, respectively, from sales of Pexeva® and Lithobid® compared to $3.3 million in net revenues for the 2007 Quarter and 2007 Period from sales of Pexeva® and Lithobid®.

We sell Stavzor® to pharmaceutical wholesalers and chain drug stores. These companies have the right to return Stavzor® for up to one year after product expiration. As a result of the commercial launch of Stavzor® in the 2008 Quarter, we do not have sufficient sales history to reasonably estimate product returns. Under SFAS No. 48, we cannot recognize revenue on product shipments until we can reasonably estimate returns relating to these shipments. In accordance with SFAS No. 48, we defer recognition of revenue on product shipments of Stavzor® to our customers until such time as Stavzor® units are dispensed through patient prescriptions, since our customers are no longer permitted to return the product once it has been dispensed. We estimate the volume of prescription units dispensed at pharmacies based on data provided by external, independent sources. These sources poll pharmacies, hospitals, mail order and other retail outlets for Stavzor® prescriptions and project this sample on a national level. We will recognize revenue based on prescription units dispensed until we have sufficient history to reasonably estimate product returns. No net revenues were recognized for Stavzor® during the 2008 Quarter.

License and Contract Revenues

License revenues consist of the recognition of non-refundable up-front, milestone and similar payments under license agreements. 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 development work and success milestone payments.

License and contract revenues increased $1.2 million for the 2008 Quarter compared to the 2007 Quarter, primarily attributable to an increase in license revenues due to an increase in amortization of milestone payments received from Shire related to the license of Daytrana®.

License and contract revenues increased $4.1 million for the 2008 Period compared to the 2007 Period, attributable to a $3.4 million increase in license revenues primarily due to an increase in amortization of milestone payments received from Shire related to the license of Daytrana®. In addition, contract revenues increased $0.7 million due to additional work performed on developmental products.

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Gross to Net Revenues

We record revenues net of sales allowances for rebates, chargebacks, cash and other discounts, as well as sales returns allowances. Sales returns allowances for the Noven Transdermals segment consist of changes in allowances for returns for product recalls and/or products voluntarily withdrawn from the market, and, for the Noven Therapeutics segment, consist of changes in allowances for returns. The following table sets forth the reconciliation of our gross revenues to net revenues for the three and nine months ended September 30, 2008 and 2007, respectively (dollar amounts in thousands):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2008	% of gross revenues	2007	% of gross revenues	2008	% of gross revenues	2007	% of gross revenues
Noven Transdermals:								
Gross revenues	$ 22,147	100%	$ 19,332	100%	$ 56,546	100%	$ 57,486	100%
Sales returns allowances	(1,249)	-6%	(842)	-4%	(1,843)	-3%	(842)	-1%
Net revenues	$ 20,898	94%	$ 18,490	96%	$ 54,703	97%	$ 56,644	99%
Noven Therapeutics:								
Gross revenues	$ 9,208	100%	$ 5,066	100%	$ 28,849	100%	$ 5,066	100%
Cash discounts	(190)	-2%	(99)	-2%	(575)	-2%	(99)	-2%
Medicaid, Medicare & State program rebates and credits including redemption offers	(2,168)	-24%	(1,164)	-23%	(5,746)	-20%	(1,164)	-23%
Chargebacks	(307)	-3%	(89)	-2%	(939)	-3%	(89)	-2%
Wholesaler fees	(90)	-1%	(198)	-4%	(1,292)	-4%	(198)	-4%
Sales returns allowances	(1,646)	-18%	(191)	-4%	(3,210)	-11%	(191)	-4%
Sales and returns allowances	(4,401)	-48%	(1,741)	-34%	(11,762)	-41%	(1,741)	-34%
Net revenues	$ 4,807	52%	$ 3,325	66%	$ 17,087	59%	$ 3,325	66%

Gross Margin

This section discusses gross margins relating to our product revenues: (i) across all of our products (Overall Gross Margin); (ii) on our transdermal product revenues from Novogyne (Gross Margin Novogyne), which for accounting purposes is considered a related party; (iii) on our transdermal product revenues from third parties (Gross Margin Third Parties); and (iv) on our Noven Therapeutics products. Product revenues from third parties include HT product sales to Novartis Pharma for resale primarily outside the United States and Japan, as well as Daytrana® product sales to Shire. Noven Therapeutics product revenues include sales of Pexeva® and Lithobid® to trade customers.

For our Noven Transdermals segment, the allocation of manufacturing expenses impacts our determination of inventory costs and, consequently, gross margins for each of our products. Manufacturing expenses, which totaled $7.5 million and $24.0 million in the 2008 Quarter and the 2008 Period, respectively, include compensation and benefits, supplies and tools, equipment costs, depreciation and amortization, and insurance costs and represent a substantial portion of our inventory production costs. Manufacturing expenses for the 2007 Quarter and the 2007 Period were $6.4 million and $19.5 million, respectively. The allocation of manufacturing expenses among manufactured 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.

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Our gross margins are summarized as follows (dollar amounts in thousands):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2008		2007		2008		2007	
Noven Transdermals								
Novogyne:								
Product revenues	$ 8,203		$ 7,901		$ 20,716		$ 21,738	
Cost of products sold	3,994		4,286		10,783		10,530	
Gross profit	4,209	51%	3,615	46%	9,933	48%	11,208	52%
Third Parties:								
Product revenues	6,324		5,464		17,270		22,295	
Cost of products sold	9,030		4,712		22,275		16,709	
Gross profit (loss)	(2,706)	-43%	752	14%	(5,005)	-29%	5,586	25%
Total Noven Transdermals:								
Product revenues	14,527		13,365		37,986		44,033	
Cost of products sold	13,024		8,998		33,058		27,239	
Gross profit	1,503	10%	4,367	33%	4,928	13%	16,794	38%
Noven Therapeutics								
Product revenues	4,807		3,325		17,087		3,325	
Cost of products sold	1,903		813		5,961		813	
Gross profit	2,904	60%	2,512	76%	11,126	65%	2,512	76%
Total Company								
Product revenues	19,334		16,690		55,073		47,358	
Cost of products sold	14,927		9,811		39,019		28,052	
Gross profit	$ 4,407	23%	$ 6,879	41%	$ 16,054	29%	$ 19,306	41%

In general, Noven Therapeutics products have higher gross margins than our transdermal products because we sell Noven Therapeutics products directly to trade customers at wholesale and commercial prices. Our sales of HT products to Novogyne for resale in the United States 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 lower gross margins than sales of HT products sold to Novogyne due to, among other things, unfavorable pricing environments in foreign markets, and smaller production orders. Our gross margin on product sales of Daytrana® to Shire has been negatively affected by the factors described below.

As noted in the tables above, Overall Gross Margin declined in the 2008 Quarter compared to the 2007 Quarter. Overall Gross Margin in the 2008 Quarter was negatively affected by: (i) the addition of $1.1 million in

manufacturing costs in our Noven Transdermals segment over the 2007 Quarter, primarily in the quality assurance/control area, of which $0.2 million related to costs associated with the Daytrana® peel force issue; and (ii) cost of products sold in the 2008 quarter included $1.6 million of the Daytrana® Charges. Overall Gross Margin in the 2008 Quarter benefited from the addition of our Pexeva® and Lithobid® products, which had net sales of $4.8 million and related cost of products sold of $1.9 million, resulting in a gross margin of 60% for those products.

As noted in the tables above, Overall Gross Margin declined in the 2008 Period compared to the 2007 Period. Overall Gross Margin in the 2008 Period was negatively affected by: (i) inventory write-offs of $2.8 million, primarily related to an equipment failure in transdermal manufacturing (comprised of $1.8 million of Novogyne product write-offs and $1.0 million of third party HT product write-offs), as well as

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additional manufacturing costs incurred in the 2008 Period to address this issue; (ii) cost of products sold in the 2008 period included $1.7 million of the Daytrana® Charges; (iii) inventory write-offs of approximately $0.8 million due to Daytrana® product exhibiting high peel force characteristics; (iv) the addition of approximately $4.5 million in manufacturing costs in our Noven Transdermals segment over the 2007 Period, primarily in the quality assurance area, of which approximately $1.4 million related to costs associated with the Daytrana® peel force issue; and (v) significantly lower product revenues in our Noven Transdermals segment, primarily related to the timing of shipments and delays in the release of Daytrana® product at the end of the 2008 Quarter. Overall Gross Margin in the 2008 Period benefited from the addition of our Pexeva® and Lithobid® products, which together had net sales of $17.1 million and related cost of products sold of $6.0 million, resulting in a gross margin of 65% for those products and a decrease in product inventory at Novogyne which resulted in approximately $0.7 million of recognized deferred profit on product sold to Novogyne.

We sell Daytrana® finished product to Shire at a fixed cost, and consequently, our profit on product sales of Daytrana® depends on our ability to manufacture the product efficiently and to fully utilize our facilities. For the 2008 Quarter, Daytrana® net product revenues were $1.8 million and cost of products sold related to Daytrana® was $5.6 million, resulting in negative gross margin for the product. This compares with Daytrana® product revenues of $1.4 million and cost of products sold related to Daytrana® of $2.0 million for the 2007 Quarter. For the 2008 Period, Daytrana® net product revenues were $7.5 million and cost of products sold related to Daytrana® was $14.0 million, resulting in negative gross margin for the product. This compares with Daytrana® product revenues of $11.0 million and cost of products sold related to Daytrana® of $9.5 million for the 2007 Period. Daytrana® gross margin was negatively affected in the 2008 Quarter and the 2008 Period by the Daytrana® charges as well as increased manufacturing and quality assurance related expenditures, including, as discussed above, approximately $1.4 million related to costs associated with the Daytrana® peel force issue. We expect the peel force issue to continue to negatively affect margins as a result of increased Daytrana® manufacturing costs, including reimbursements to Shire for the AMI for destroyed product. We expect that higher manufacturing and quality costs, including reimbursements to Shire for AMI on discarded product, will continue to result in significantly negative gross margin for the product unless and until the peel force issue is resolved.

For the remainder of 2008, we expect to continue to incur increased quality assurance costs related to our continued efforts to improve our quality assurance systems and to address the issues raised by the FDA in the July 2007 Form 483 and January 2008 warning letter, and a significant portion of these continuing costs will be allocated to Daytrana®, which will negatively affect the gross margin on sales of this product in the remainder of 2008 and beyond.

Our expectations for gross margins for all of 2008 are addressed under Outlook below.

Operating Expenses

Operating expenses for the three and nine months ended September 30, 2008 and 2007 are summarized as follows (dollar amounts in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	2007	% Change	2008	2007	% Change
Research and development	$ 4,041	$ 3,649	11%	$10,653	$ 10,300	3%
Acquired in-process research and development		100,150	N/M		100,150	N/M
Selling and marketing	7,326	3,103	136%	17,485	3,564	391%

General and administrative	11,147	8,770	27%	27,075	19,439	39%

N/M Not Meaningful

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Research and Development

Research and development expenses include costs associated with, among other things, product formulation, pre-clinical testing, clinical 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 $0.4 million increase in research and development expenses for the 2008 Quarter, compared to the 2007 Quarter, was primarily attributable to a $0.2 million increase in pre-clinical testing and clinical research costs in our Noven Transdermals segment and a $0.2 million increase in Noven Therapeutics expenses. The $0.4 million increase in research and development expenses for the 2008 Period, compared to the 2007 Period, was primarily attributable to the $2.0 million increase in Noven Therapeutics expenses, primarily related to regulatory and medical affairs expenses and clinical research, partially offset by a $1.6 million decrease in pre-clinical testing and clinical research costs in our Noven Transdermals segment.

Acquired In-Process Research and Development

Immediately following the closing of the JDS acquisition, we expensed $100.2 million in the 2007 Quarter and the 2007 Period representing the portion of the purchase price allocated to in-process research and development 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 and Marketing

The $4.2 million and $13.9 million increases in selling and marketing costs for the 2008 Quarter and 2008 Period, compared to the 2007 Quarter and 2007 Period, respectively, were attributable to the addition of Noven Therapeutics in August 2007 and costs associated with the commercial launch of Stavzor® in August 2008.

General and Administrative

General and administrative expenses increased $2.4 million, or 27%, for the 2008 Quarter, compared to the 2007 Quarter. The increase was primarily due to the $1.7 million charge related to certain previously manufactured lots that would not have met the new release testing standard and therefore may not meet the peel force specification through the product s shelf life, and $0.7 million loss from the disposal of assets.

General and administrative expenses increased $7.6 million, or 39%, for the 2008 Period, compared to the 2007 Period. The increase was primarily attributable to a $1.7 million charge related to costs that we expect to owe Shire for certain previously-manufactured Daytrana® lots that would not have met the new release testing standard and are probable of being recalled or withdrawn during the product s shelf life, a $1.4 million increase in professional fees, mostly attributable to accounting, auditing and executive recruiting fees, a $1.0 million increase in charges related to reimbursements owed to Shire in connection with their voluntary recall of two lots of Daytrana®, and a $1.4 million increase in other areas of general and administrative expense, primarily as a result of the addition of Noven Therapeutics. The increase was also attributable to a $0.8 million increase in salary and related benefits, $0.7 million loss on the disposal of assets and a $0.3 million increase in expenses relating to information management services and supplies.

Reversal of Contingent Milestone Liability

In the 2008 Quarter, we recognized $5.0 million in operating income as a result of the reversal of an accrued liability for the final contingent milestone payment to Synthon upon a determination that the achievement of the final sales milestone of $30.0 million in annual net sales for Pexeva® was no longer probable.

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Other Income and Expenses

Interest Income

Interest income decreased $1.0 million and $3.3 million for the 2008 Quarter and the 2008 Period, compared to the 2007 Quarter and the 2007 Period, respectively. This decrease was primarily attributable to a decrease in cash available for investment as a result of the payment of $130.4 million in connection with the JDS acquisition in August 2007, as well as additional sales of auction rate securities at par during the 2008 Quarter and 2008 Period and lower interest rates on our remaining investments.

Income Taxes

Our effective tax rate was approximately 34% and 35% for the 2008 Period and 2007 Period, respectively. 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 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 resulted in a significant increase in our deferred income tax assets, primarily due to the $100.2 million expense recognized in 2007 relating to in-process research and development that is not immediately deductible for tax purposes. As of September 30, 2008 we had a net deferred tax asset of $73.9 million compared to $65.7 million at December 31, 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. Noven Therapeutics files separate state income tax returns in states where it has determined that it is required to file state income taxes. As a result, state deferred tax assets relating to Noven Therapeutics are evaluated separately in determining whether the state deferred tax assets are realizable. We expect that Noven Therapeutics will incur taxable losses in the next few years due to 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, 2008. Our valuation allowance for state deferred tax assets was $4.1 million and $3.2 million as of September 30, 2008 and December 31, 2007, respectively, 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 profitability of Noven Therapeutics that these state deferred tax assets will more likely than not 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 each of the first quarters of 2008 and 2007 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 condensed consolidated statements of operations.

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Novogyne records revenues net of sales allowances for rebates, chargebacks, cash and other discounts and sales returns allowances. The financial results of Novogyne for the three and nine months ended September 30, 2008 and 2007 are summarized as follows (dollar amounts in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	2007	% Change	2008	2007	% Change
Gross revenues	$ 53,281	$ 45,224	18%	$ 148,629	$ 125,432	18%
Sales allowances	7,024	5,770	22%	18,579	16,769	11%
Sales returns allowances	432	781	-45%	931	772	21%
Sales and returns allowances	7,456	6,551	14%	19,510	17,541	11%
Net revenues	45,825	38,673	18%	129,119	107,891	20%
Cost of sales	8,893	8,152	9%	25,489	22,994	11%
Gross profit	36,932	30,521	21%	103,630	84,897	22%
Gross margin percentage	81%	79%		80%	79%	
Selling, general and administrative expenses	9,013	8,278	9%	27,823	27,990	-1%
Income from operations	27,919	22,243	26%	75,807	56,907	33%
Interest income	341	286	19%	782	783	0%
Net income	$ 28,260	$ 22,529	25%	$ 76,589	$ 57,690	33%
Noven s equity in earnings of Novogyne	$ 13,849	$ 10,948	26%	$ 34,545	$ 25,025	38%

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 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 $8.1 million for the 2008 Quarter compared to the 2007 Quarter. By product, Vivelle-Dot® and CombiPatch® increased $8.9 million and $0.7 million, respectively, while Vivelle® (a discontinued product) decreased $1.5 million. The $8.9 million Vivelle-Dot® increase consisted of a $4.4 million increase related to pricing and a $4.5 million increase in unit sales, which is consistent with increases in prescription trends. The $0.7 million CombiPatch® increase was primarily attributable to a $0.4 million increase related to pricing.

Novogyne s gross revenues increased $23.2 million for the 2008 Period compared to the 2007 Period. By product, Vivelle-Dot® and CombiPatch® increased $26.3 million and $1.3 million, respectively, while Vivelle® (a discontinued product) decreased $4.4 million. The $26.3 million Vivelle-Dot® increase consisted of a $15.2 million increase related

to pricing and a $11.1 million increase in unit sales, which is consistent with increases in prescription trends. The $1.3 million CombiPatch® increase was attributable to a $1.4 million increase related to pricing, partially offset by a $0.1 million decline in unit sales which resulted from a continued decline in the market for combination therapies, and the impact of a competitive product.

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. For the 2008 Quarter and the 2007 Quarter, these sales allowances were 13% of gross revenues. For the 2008 Period and the 2007 Period, these sales allowances were also 13% of gross revenues.

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Sales returns allowances consist of allowances for returns of expiring product. The activity in the sales returns allowances for the three and nine months ended September 30, 2008 and 2007 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Sales returns allowances included in net revenues	$ 432	$ 781	$ 931	$ 772
Actual returns primarily for expiring product	(944)	(880)	(2,443)	(2,354)
Change in allowances for returns primarily for expiring product	$ (512)	$ (99)	$ (1,512)	$ (1,582)

The decrease in sales returns allowances for the 2008 Quarter compared to the 2007 Quarter is attributable to lower actual returns as a percentage of related sales. The increase in sales returns allowances for the 2008 Period compared to the 2007 Period is attributable to an increase in sales volume as sales returns as a percentage of gross revenues remained relatively consistent in both periods.

Novogyne Gross Margin

The increases in gross margin percentage for the 2008 Quarter and 2008 Period compared to the 2007 Quarter and the 2007 Period, respectively, were primarily related to higher sales of Vivelle-Dot®, which has a higher gross margin than the other products sold by Novogyne, as well as price increases for all products.

Novogyne Selling, General and Administrative Expenses

Novogyne s selling, general and administrative expenses increased $0.7 million for the 2008 Quarter compared to the 2007 Quarter, primarily due to a $0.6 million increase in marketing administration expenses and a $0.6 million increase in sample expenses due to the timing of shipments by Noven to Novogyne. Novogyne s policy is to immediately expense samples when shipped from Noven. These increases were partially offset by a $0.3 million decrease in advertising expenses and a $0.2 million decrease in sales force expenses.

Novogyne s selling, general and administrative expenses decreased $0.2 million for the 2008 Period compared to the 2007 Period, primarily due to a $0.8 million decrease in sample expenses due to the timing of shipments by Noven to Novogyne, as discussed above. These decreases were partially offset by a $0.3 million increase in litigation expenses, a $0.2 million increase in marketing administration expenses and a $0.1 million increase in sales force expenses.

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Liquidity and Capital Resources

As of September 30, 2008 and December 31, 2007, we had the following (amounts in thousands):

	September 30, 2008	December 31, 2007
Cash and cash equivalents	$65,288	$13,973
Short-term investments		21,565
Working capital	39,523	24,024

In addition to our cash and working capital, as of September 30, 2008, we owned investments in auction rate securities with a fair value of $15.5 million. Due to the current illiquid market conditions and failed auctions, we have classified these investments as non-current; however, these investments have been a source of liquidity during 2008, including proceeds of $39.0 million from sales of these auction rate securities at par during the 2008 Period. On a combined basis, our cash and cash equivalents and investments in auction rate securities were as follows (amounts in thousands):

	September 30, 2008	December 31, 2007
Cash and cash equivalents	$ 65,288	$ 13,973
Investment in auction rate securities:		
Current		21,565
Non-current	15,460	32,835
Total cash and cash equivalents and investments	$ 80,748	$ 68,373

Cash provided by (used in) operating, investing and financing activities for the 2008 Period and the 2007 Period is summarized as follows (amounts in thousands):

	2008	2007
Cash flows:		
Operating activities	$21,318	$ 57,801
Investing activities	33,359	(49,771)
Financing activities	(3,362)	(5,921)
Net cash flow	$51,315	$ 2,109

Operating Activities

Net cash provided by operating activities for the 2008 Period primarily resulted from the receipt of $29.0 million in distributions from Novogyne and $25.0 million in milestone payments from Shire. Significant operating cash outflows during the 2008 Period included income tax payments of $13.2 million, payment to Shire of $3.3 million related to its 2007 withdrawal of certain Daytrana® product and $3.1 million in payments related to insurance premiums. In addition, changes in working capital accounts, including an $8.0 million increase in inventories and a $4.0 million decrease in accrued compensation and related liabilities also partially offset the net cash provided by operating activities.

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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 distributions from Novogyne, and our receipt of $5.9 million in connection with the development agreements with Shire for an amphetamine transdermal patch. 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 premiums and $2.6 million in compensation and related liabilities.

Investing Activities

Noven has invested a portion of its cash in investments, which primarily consist of investment grade, 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 provided by investing activities for the 2008 Period was primarily attributable to $39.0 million in sales of short-term investments at par, partially offset by $3.0 million in equipment purchases to support operations and a $1.5 million milestone payment to Banner upon approval of Stavzor® in the 2008 Quarter.

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

Financing Activities

Net cash used in financing activities for the 2008 Period was primarily attributable to a $3.3 million sales milestone payment to Synthon, an obligation recorded as part of the acquisition of JDS.

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 acquisition of 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.

Short-Term and Long-Term Liquidity

Our principal sources of short-term liquidity are existing cash and distributions from Novogyne. Additional sources of short-term liquidity include cash generated from product sales, milestones, fees and royalties under development and license agreements.

Our short-term cash flow is significantly dependent on distributions from Novogyne and sales, royalties and license fees associated with our products. Any material decrease in sales of those products by us or our licensees, a material decline in the HT market, the introduction of a generic version of Vivelle-Dot, material increases in operating expenses, 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, investments, equity or debt offerings or on borrowings to support our operations and business.

During the 2008 Period, our cash and cash equivalents and investments in auction rate securities increased from $68.4 million to $80.7 million. The increase primarily resulted from the receipt of the third $25.0 million sales milestone payment from Shire. Excluding the milestone payment, our cash and cash equivalents and investments decreased by $12.6 million. This decrease primarily occurred during the first half of 2008 due to the payment of certain obligations previously charged to operations in 2007 and/or accrued as of December 31, 2007,

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including (i) $5.4 million of employee severance, bonus and retention payments, (ii) $3.3 million of Daytrana® voluntary market withdrawal costs, and (iii) a $3.3 million milestone payment related to Noven Therapeutics products. During the 2008 Quarter, our cash and cash equivalents and investments increased by $27.8 million, including the $25.0 million sales milestone payment received from Shire. We believe that our existing cash balances and expected collections of receivables, together with the available capacity under our credit facility (described below), will be sufficient to meet our operating needs and short-term capital requirements.

We received the first $25.0 million sales milestone payment from Shire relating to their sales of Daytrana® in the first quarter of 2007, the second $25.0 million Daytrana® sales milestone payment in the 2007 Quarter and the third $25.0 million Daytrana® sales milestone payment in the 2008 Quarter. We expect to pay income taxes related to the Daytrana® milestone payments of approximately $2.3 million and $8.5 million during the remainder of 2008 and 2009, respectively.

Our liquidity may be significantly and adversely impacted if we are unable to adequately resolve the issues raised by the FDA in the July 2007 Form 483 and in the warning letter we received in January 2008. No assurance can be given that Noven s response to the warning letter will be acceptable to the FDA or satisfactorily address the FDA s concerns. Failure to take effective corrective actions can result in FDA enforcement action such as monetary fines, product recalls, injunctions, seizures, suspension of production or withdrawal of product approval. Any enforcement action by the FDA would have a material adverse effect on us, including the potential loss of Daytrana® sales, the potential loss of sales of other products, the potential for litigation related to this matter, harm to our reputation and various costs associated with the foregoing.

As discussed elsewhere herein, we have agreed to reimburse Shire $1.95 million related to the June 2008 Daytrana® recall and $1.7 million related to the August 2008 Daytrana® recall. In addition, we reserved $4.3 million in the 2008 Quarter for certain previously-manufactured Daytrana® lots that would not meet the new release testing standard and are probable of being voluntarily withdrawn or recalled from the market prior to expiration of their shelf life, and which therefore may require additional reimbursements to Shire.

In April 2008, we made a $3.3 million milestone payment to Synthon based on achieving specified net sales of Pexeva® during 2007. We expect to pay an additional $3.3 million milestone to Synthon in 2009 based on 2008 net sales of Pexeva®.

We expect that the increased sales and marketing expenses relating to the operations of Noven Therapeutics, including for the commercial launch of Stavzor®, will continue during the remainder of 2008. We expect to fund the additional sales and marketing expenses from our operating cash flows, existing cash and investments.

We have invested a significant portion of our cash in auction rate securities, which subjects us to the liquidity risk described in Part II Item 7A Quantitative and Qualitative Disclosures About Market Risk in our Form 10-K. During the 2008 Period, we recorded a $0.5 million unrealized loss on our investments in auction rate securities, which are classified as available for sale under SFAS No. 115. As of September 30, 2008, the total par value and fair value of our investments in auction rate securities was $16.0 million and $15.5 million, respectively. Due to continuing auction failures beginning in February 2008, we utilized valuation models to determine the fair values of our investments in auction rate securities. The fair values of our investments were calculated based on the following: (i) the underlying structure of each security; (ii) the present value of future principal and interest payments discounted at rates considered to reflect current market conditions; (iii) consideration of the probabilities of default, auction failure, or repurchase at par for each period; and (iv) consideration of third party credit enhancement. These estimated fair values could change significantly based on future market conditions.

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Changes to investments measured at fair value on a recurring basis using unobservable inputs (Level 3) during the nine months ended September 30, 2008 were as follows (in thousands):

Balance at December 31, 2007	$ 54,400
Purchases of investments	550
Sales of investments at par	(38,975)
Unrealized losses recorded as other comprehensive loss	(515)
Balance at September 30, 2008	$ 15,460

As a result of failed auctions, our auction rate securities pay interest at rates as defined by the governing documents or indenture. Due to uncertainty about when we will be able to liquidate these investments, we have classified our auction rate securities as non-current assets as of September 30, 2008.

In July 2008, we entered into an agreement for a $15.0 million credit facility. In connection with the credit facility and in lieu of granting a security interest in our assets, we granted a negative pledge in favor of the lender whereby we agreed not to pledge, grant any security interest in, or allow any lien or encumbrance in or on, certain of our financial assets. As of the date of this report, no borrowings were outstanding under this facility.

We paid approximately $125.0 million in cash to acquire JDS in August 2007 and incurred approximately $5.4 million in transaction-related costs. We funded the purchase price and related transaction expenses from our sale of short-term investments. In addition, we assumed approximately $16.1 million of accrued expenses and other current liabilities and assumed certain contractual arrangements under which we may be required to pay to third parties up to $18.7 million in product development and sales milestones. In April 2008, we paid Synthon $3.3 million in connection with a Pexeva® sales milestone and in the 2008 Quarter we made a $1.5 million milestone payment to Banner upon FDA approval for Stavzor®.

Our liquidity for the 2007 Period benefited from $2.5 million received upon the exercise of stock options by employees. During the 2008 Period, proceeds from stock option exercises were not significant. We expect this amount to fluctuate from period to period depending on the performance of our common 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. Accordingly, we expect that funds received from option exercises will become less of a source of funds over time.

We currently have no long-term debt and have not drawn on the credit facility described above. To the extent the sources of liquidity described above are insufficient to fund our operations, we would expect to seek to obtain funds through a debt and/or equity financing. We cannot provide any assurance that such financing will be available, if at all, in a timely manner, or on favorable terms. If we are unable to obtain satisfactory financing, we may be required to delay or reduce our proposed expenditures, plant and equipment and strategic acquisitions. Furthermore, debt financing would likely require us to devote funds to service and ultimately repay such debt and could subject us to financial or operational covenants that could limit or hinder our ability to conduct our business.

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 that we will be required to seek debt and/or equity financing to complete such an acquisition. We cannot provide any assurance that such financing will be available, if at all, in a timely manner, or on favorable terms.

Capital expenditures totaled $3.0 million for the 2008 Period. We expect to fund our foreseeable capital expenditures from our operating cash flows, existing cash, short-term investments and debt.

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If our transdermal 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 sources described above. To the extent available, we may use funds generated through sales of products under development and payments received pursuant to development and licensing arrangements. If such funds are insufficient, 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 cash 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 Risk Factors of our Form 10-K as supplemented by Part II Item 1A Risk Factors of this quarterly report on Form 10-Q.

For the 2008 Period and 2007 Period, our equity in earnings of Novogyne and the recognition of deferred license and contract revenues (both of which are non-cash items) contributed significantly to our income before income taxes. Accordingly, our net income may not be reflective of our cash flow in any given period.

Aggregate Contractual Obligations

There have been no material changes outside of the ordinary course of our business to our aggregate contractual obligations previously disclosed in our Form 10-K since December 31, 2007.

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.

Recent Accounting Pronouncements

For a discussion of recent accounting pronouncements see Note 2 Recent Accounting Pronouncements.

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 Pharmaceuticals (now known as Noven Therapeutics), which we acquired in August 2007. This financial guidance supersedes all financial guidance that we may have previously provided. Any financial guidance previously provided in areas not addressed below, whether in prior filings with the Securities and Exchange Commission, press releases, public conference calls or otherwise, is no longer current and is hereby withdrawn. The forward-looking information contained in this section is based on our current assumptions and expectations, many of which are based upon matters beyond our control. In particular, for purposes of this guidance we have assumed that, during the remainder of 2008, 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;

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changes in the supply of, demand for, or distribution of our products (including any changes resulting from competitive products, unexpected 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;
adverse actions by the FDA in connection with the January 2008 warning letter or otherwise;
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 Noven Therapeutics, readers should carefully consider the risks, uncertainties and cautionary factors discussed in Part I Item 1A Risk Factors of our Form 10-K, as supplemented by Part II Item 1A Risk Factors of this quarterly report on Form 10-Q, as well as other information contained in this Form 10-Q and in other reports filed from time to time with the Securities and Exchange Commission.

Net revenues, gross margin, expenses, net income and other aspects of our financial results can vary substantially from quarter-to-quarter based upon a number of factors, including the timing of product orders by our licensees, the timing of release of manufactured product following quality control and quality assurance measures undertaken by Noven and/or its customers, the availability of raw materials, the timing of commencement of clinical studies, and other factors.

Net Revenues. We expect total net revenues for full year 2008 to be in the $106 million to $109 million range, reflecting: (i) a full year of sales of Pexeva® and Lithobid®; (ii) recognition of nominal revenues associated with the commercial launch of Stavzor®; (iii) Daytrana® net sales to Shire in 2008 of approximately $10.0 million; (iv) higher license and contract revenues compared to 2007 due to the amortization of Daytrana® sales milestone payments received in 2007 and 2008; (v) aggregate HT product sales by Noven for sale in the U.S. and international markets consistent with 2007 levels; and (vi) the expected recognition in the fourth quarter of 2008 of $7.2 million of previously-deferred license revenues in connection with the reacquisition of rights to our developmental amphetamine patch for ADHD upon termination of a prior collaborative development arrangement.

Pexeva® Recognition. Results for full year 2008 will include the recognition of $5.0 million in operating income (recorded in the third quarter of 2008) due to the reversal of a $5.0 million accrued liability for a future Pexeva® contingent sales milestone.

Gross Margin. We expect our overall gross margin, as a percentage of product sales, to be in the mid-to-upper 20% range for full year 2008. Among other factors influencing our gross margin, Noven is in the process of implementing new product release testing intended to predict which Daytrana® lots are at risk of developing peel force issues during the product s shelf life. Product that fails to meet this test will be destroyed, which will result in increased Daytrana® manufacturing costs, including reimbursements to Shire for the AMI for destroyed product, and will contribute to significant negative gross margins for the product unless and until the peel force issue is resolved.

Research and Development Expense. We expect our consolidated research and development expense for full year 2008 to be approximately $16.0 million.

Selling, General and Administrative Expense. We expect our consolidated selling, general and administrative expense for full year 2008 to be approximately $60.0 million, including $4.8 million in expenses associated with Daytrana® voluntary product recalls by Shire, as well as selling and promotional expenses in support of Noven Therapeutics products, including the commercial launch of Stavzor® in the 2008 Quarter.

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Equity in Earnings of Novogyne. We expect our equity in earnings of Novogyne to increase by approximately 30% in 2008 compared to 2007.

Interest Income. We expect our interest income to decrease in 2008 compared to 2007, primarily reflecting lower cash and investment balances, as well as sales of auction rate securities at par during 2008 and lower interest rates on our remaining investments.

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Item 3. Quantitative and Qualitative Disclosure About Market Risk

For a discussion of quantitative and qualitative impact of market risk see Part II Item 7A Quantitative and Qualitative Disclosure About Market Risk of our Form 10-K, as supplemented by the discussion of the liquidity and other risks associated with auction rate securities above.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

As of the end of the period covered by this report, our management evaluated, with the participation of our Chief Executive Officer (CEO) and Chief Financial Officer (CFO), the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 promulgated under the Securities Exchange Act of 1934 (the Exchange Act). Based upon that evaluation, our CEO and CFO concluded that, as of September 30, 2008, our disclosure controls and procedures were effective in ensuring that information relating to Noven, including its consolidated subsidiaries, required to be disclosed in reports that it files or submits under the Exchange Act was: (1) recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms; and (2) accumulated and communicated to our management, including our CEO and CFO, as appropriate to allow timely decisions regarding required disclosure. 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 CEO and CFO, does not expect that our disclosure controls and procedures will prevent all errors 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 Noven.

Changes in Internal Control over Financial Reporting

No changes were made in our internal control over financial reporting during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Certifications

Provided with this quarterly report on Form 10-Q are certifications of our CEO and CFO. 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 Part I 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.

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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 for the year ended December 31, 2007. Except as described below, there have been no material developments related to the legal proceedings described in our Form 10-K during the period covered by this Form 10-Q, and through the filing of this Form 10-Q. All proceedings described in our Form 10-K remain outstanding. In addition to the cases in which Noven is a named defendant, Novartis has advised Noven that it has been named as a defendant in a total of 30 cases that include approximately 31 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-Dot®, Vivelle® and CombiPatch® products.

In addition to the proceedings described in our Form 10-K, in July 2008, one additional complaint was filed in the United States District Court, District of Minnesota against Wyeth Inc. and other named pharmaceutical companies, including Noven, Novogyne and Novartis. The complaint alleges liability in connection with personal injury claims allegedly arising from the use of HT products, including Vivelle-Dot®. The plaintiffs claim compensatory and other damages in an unspecified amount.

Each of the HT related federal court cases in which Noven is a named defendant, including the cases described above, has been, or is expected to be, transferred to the federal multi-district litigation proceedings that are pending in the United States District Court, Eastern District of Arkansas.

With respect to the patent infringement case brought by Johnson-Matthey Inc. against Noven in the United States District Court, Eastern District of Texas, the parties have completed initial discovery and the case has been scheduled for trial in late 2009.

Item 1A. Risk Factors

Except as described below, there have been no material changes or additions to the risk factors previously disclosed in our Form 10-K. 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 us or on our behalf. The risk factors are not necessarily listed in order of priority or probability 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 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.

The recent volatility in the financial markets could adversely affect us or our partners, customers or suppliers

As widely reported, financial markets in the United States, Europe and Asia have been experiencing extreme disruption in recent months, including, among other things, extreme volatility in securities prices, severely diminished liquidity and credit availability, rating downgrades of certain investments and declining valuations of others. Among other risks we face, the current tightening of credit in financial markets may adversely affect our ability to access our credit facility or obtain financing in the future, including, if necessary, to fund a product or technology acquisition. In addition, current economic conditions could harm the liquidity or financial position of our partners, customers or suppliers, which could in turn cause such parties to fail to meet their contractual or other obligations to us. Novogyne has currently recorded a product liability insurance receivable in the amount of $6.9 million due from a subsidiary of American International Group (AIG). Although AIG has advised that its commercial insurance subsidiaries remain well-capitalized despite the parent company s recent liquidity issues and diminished financial position, we cannot assure that the insurance carrier will pay the amounts that Novogyne believes are owed under the policy, either due to a change in the carrier s financial condition, a coverage dispute or otherwise.

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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 2008:

	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[1]
July 1, 2008 to July 31, 2008				$ 19,876,238
August 1, 2008 to August 31, 2008				19,876,238
September 1, 2008 to September 30, 2008				19,876,238
Totals				$ 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. During the third quarter of 2007, we repurchased 322,345 shares of our common stock at an aggregate price of approximately $5.1 million. There is no expiration date specified for this program.

Item 5. Other Information

From time to time, Noven s directors, executive officers and employees may adopt trading plans intended to comply with the guidelines specified in Rule 10b5-1 under the Securities Exchange Act of 1934. As of the date hereof, no Noven directors or executive officers, other than Jeffrey F. Eisenberg, have a Rule 10b5-1 trading plan in place.

On November 5, 2008, we entered into a letter agreement (the Termination Agreement) with Shire terminating our agreements with Shire for the development of an amphetamine patch. The Termination Agreement terminates the amphetamine letter agreements dated as of (i) June 15, 2004, (ii) May 4, 2007, and (iii) June 4, 2007. Under the

Termination Agreement, rights to the developmental amphetamine patch were returned to us. We intend to pursue the further development and commercialization of the product. Shire will be entitled to a modest royalty if we elect to commercialize a product that incorporates intellectual property arising from the development project with Shire. As of September 30, 2008, our consolidated balance sheet reflected deferred license and contract revenues of $7.2 million related to this project. As a result of the termination of this project with Shire, we expect to recognize the $7.2 million as license and contract revenues in the fourth quarter of 2008.

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Item 6. Exhibits

10.1	Development and License Agreement between Noven Pharmaceuticals, Inc. and Procter & Gamble Pharmaceuticals, Inc., dated June 30, 2008 (with certain provisions omitted pursuant to Rule 24b-2).
10.2	Supply Agreement among Noven Pharmaceuticals, Inc., Procter & Gamble Pharmaceuticals, Inc. and P&G Pharmaceuticals, S.A.R.L., dated August 14, 2008 (with certain provisions omitted pursuant to Rule 24b-2).
10.3	Credit Agreement between Noven Pharmaceuticals, Inc. and SunTrust Bank, dated July 31, 2008 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K of Noven Pharmaceuticals, Inc. filed on August 6, 2008).
31.1	Certification of Peter Brandt, President and Chief Executive Officer, 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 Michael D. Price, 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 Peter Brandt, President and Chief Executive Officer, 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 Michael D. Price, 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.*

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

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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 10, 2008

By: /s/ Michael D. Price
Michael D. Price
Vice President and
Chief Financial Officer