NOVEN PHARMACEUTICALS INC
Form 10-Q
May 11, 2009

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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 March 31, 2009
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 o No þ

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, the Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o 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. (Check one):

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

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 April 30, 2009
Common stock $.0001 par value	24,914,418

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 Part I Item 1A Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2008, 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. Unaudited Condensed Consolidated Financial Statements

NOVEN PHARMACEUTICALS, INC. AND SUBSIDIARIES

Condensed Consolidated Balance Sheets

(amounts in thousands, except share data) (unaudited)

	March 31, 2009	December 31, 2008
Assets		
Current Assets:		
Cash and cash equivalents	$ 72,174	$ 62,875
Investments in auction rate securities, current portion		3,650
Accounts receivable (less allowances of $217 at 2009 and $509 at 2008)	6,729	8,577
Accounts receivable Novogyne, net	6,737	6,510
Inventories	14,673	13,924
Net deferred income tax asset, current portion	7,235	7,026
Prepaid income taxes	3,356	8,178
Prepaid and other current assets	2,990	2,898
	113,894	113,638
Non-current Assets:		
Property, plant and equipment, net	34,809	34,886
Investments in auction rate securities, non-current portion	11,810	11,810
Investment in Novogyne	19,175	24,319
Net deferred income tax asset, non-current portion	64,766	65,159
Intangible assets, net	35,546	36,508
Goodwill	14,407	14,407
Deposits and other non-current assets	623	839
	181,136	187,928
	$ 295,030	$ 301,566
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable and accrued expenses	$ 7,153	$ 7,384
Accrued compensation and related liabilities	5,355	7,958
Other accrued liabilities	17,147	17,260
Current portion of long-term obligations	101	3,396
Deferred product revenue Stavzor®	1,639	1,537
Deferred license and contract revenues, current portion	25,390	25,459
	56,785	62,994
Non-current Liabilities:		
Long-term obligations, less current portion	26	27

Deferred license and contract revenues, non-current portion	70,892	77,112
Other non-current liabilities	887	997
	71,805	78,136
Total Liabilities	128,590	141,130
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; 25,235,763 issued at March 31, 2009 and December 31, 2008	3	3
Additional paid-in capital	124,797	123,290
Retained earnings	46,764	42,267
Treasury stock, at cost - 322,345 shares at March 31, 2009 and December 31, 2008	(5,124)	(5,124)
Common stock held in trust	(1,725)	(1,569)
Deferred compensation obligation	1,725	1,569
	166,440	160,436
	$ 295,030	$ 301,566

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
(amounts in thousands, except per share data)
(unaudited)

	Three Months Ended March 31,	
	2009	2008
Revenues:		
Product revenues Novogyne:		
Product sales, net	$ 5,480	$ 2,431
Royalties	2,222	2,180
Total net product revenues Novogyne	7,702	4,611
Product revenues, net third parties	13,649	11,585
Total net product revenues	21,351	16,196
License and contract revenues	6,289	5,286
Total net revenues	27,640	21,482
Costs and Expenses:		
Cost of products sold Novogyne	3,648	3,326
Cost of products sold third parties	7,768	7,983
Total cost of products sold	11,416	11,309
Research and development	4,653	3,319
Selling and marketing	5,013	4,823
General and administrative	7,048	7,022
Total costs and expenses	28,130	26,473
Loss from operations	(490)	(4,991)
Equity in earnings of Novogyne	7,545	8,267
Interest and other income, net	89	622
Income before income taxes	7,144	3,898
Provision for income taxes	2,647	1,306
Net income	$ 4,497	$ 2,592

Basic earnings per share	$ 0.18	$ 0.11
Diluted earnings per share	$ 0.18	$ 0.11
Weighted average number of common shares outstanding:		
Basic	24,692	24,560
Diluted	24,769	24,665

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
(amounts in thousands)
(unaudited)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Retained Earnings	Treasury Stock	Other	Total
Balance at December 31, 2008	24,913	$ 3	$ 123,290	$ 42,267	$ (5,124)	$	$ 160,436
Stock-based compensation expense and issuance of shares to outside directors			1,298				1,298
Issuance of SSAR in settlement of executive bonus			219				219
Tax benefit adjustments			(10)				(10)
Common stock held in trust	(13)					(156)	(156)
Deferred compensation obligation	13					156	156
Net income				4,497			4,497
Balance at March 31, 2009	24,913	$ 3	$ 124,797	$ 46,764	$ (5,124)	$	$ 166,440

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
(amounts in thousands)
(unaudited)

	Three Months Ended March 31,	
	2009	2008
Cash flows from operating activities:		
Net income	$ 4,497	$ 2,592
Adjustments to reconcile net income to net cash flows provided by (used in) operating activities:		
Depreciation and amortization	2,057	2,272
Loss on disposal of property, plant and equipment		11
Inventory write-offs	916	3,050
Stock based compensation expense	1,298	858
Income tax benefits on stock-based awards/SSARs		37
Deferred income tax benefit	184	(2,380)
Recognition of deferred license and contract revenues	(6,289)	(5,286)
Equity in earnings of Novogyne	(7,545)	(8,267)
Distributions from Novogyne	12,689	10,916
Other noncash items	271	39
Changes in operating assets and liabilities:		
Decrease (increase) in accounts receivable trade, net	1,848	(1,782)
(Increase) decrease in accounts receivable Novogyne, net	(227)	2,753
Increase in inventories	(1,665)	(6,202)
Decrease in prepaid income taxes	4,822	2,802
Decrease (increase) in prepaid and other current assets	(92)	(462)
Increase in deposits and other assets	(94)	(176)
(Decrease) increase in accounts payable and accrued expenses	(240)	732
Decrease in accrued compensation and related liabilities	(2,384)	(5,165)
Decrease in other accrued liabilities	(101)	(110)
Increase in deferred license and contract revenues		346
Increase in deferred product revenue Stavzor®	102	
Increase in other liabilities	(93)	(654)
Cash flows provided by (used in) operating activities	9,954	(4,076)
Cash flows from investing activities:		
Purchases of property, plant and equipment	(798)	(341)
Payments for intangible assets	(211)	(96)
Purchases of investments		(550)
Proceeds from sale of investments	3,650	18,800
Cash flows provided by investing activities	2,641	17,813
Cash flows from financing activities:		
Issuance of common stock from exercise of stock options/SSARs		10
Payments of long-term obligations	(3,296)	(55)

Cash flows used in financing activities	(3,296)	(45)
Net increase in cash and cash equivalents	9,299	13,692
Cash and cash equivalents, beginning of period	62,875	13,973
Cash and cash equivalents, end of period	$ 72,174	$ 27,665

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:

Incorporated in Delaware in 1987, Noven Pharmaceuticals, Inc. (Noven) is a specialty pharmaceutical company engaged in the research, development, manufacturing, licensing, marketing and sale of prescription pharmaceutical products. Noven s business is focused in three principal areas: (i) Noven Transdermals, the transdermal drug delivery segment; (ii) Novogyne Pharmaceuticals (Novogyne), the women s health joint venture with Novartis Pharmaceuticals Corporation (Novartis); and (iii) Noven Therapeutics, the specialty pharmaceutical segment.

Noven s primary commercialized products include prescription transdermal patches utilizing its proprietary transdermal drug delivery technology for use in the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and in menopausal hormone therapy (HT), as well as oral prescription products for use in the treatment of certain psychiatric conditions. Noven s developmental pipeline includes products in the women s health and central nervous system (CNS) categories.

Noven operates in three segments distinguished along product categories and nature of the business unit: (i) Noven Transdermals, which currently engages in the development, manufacturing and licensing to partners of prescription transdermal products; (ii) Novogyne, the women s health joint venture with Novartis in which Noven owns a 49% equity interest and for which Noven reports its share of Novogyne s earnings as Equity in earnings of Novogyne on its Condensed Consolidated Statements of Operations; and (iii) Noven Therapeutics, which currently engages in the marketing and sale of pharmaceutical products. Historically, Novogyne was viewed as a component of the Noven Transdermals unit since the joint venture s primary activity involves the marketing and sale of patches manufactured by Noven Transdermals. In the fourth quarter of 2008, as a result of organizational changes throughout 2008, Noven revised its presentation of reportable segments to reflect the joint venture as a reportable unit distinct from Noven Transdermals, which is consistent with the manner in which information is reported for management decision making. See Note 15 Segment Data for Noven s segment financial 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 Risk Factors of Noven s Annual Report on Form 10-K for the year ended December 31, 2008 (Form 10-K). 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 2009 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 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 Summary of Significant Accounting Policies of the Notes to Consolidated Financial Statements included in Noven s Form 10-K.

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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 yet have sufficient sales history to reasonably estimate product returns of Stavzor®. Noven s customers are no longer permitted to return the product after it has been dispensed. 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 has deferred recognition of revenue on product shipments of Stavzor® to Noven s customers until such time as Stavzor® units are dispensed through patient prescriptions. Noven estimates 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. Noven will recognize revenue based on prescription units dispensed until Noven has sufficient sales history to reasonably estimate product returns. Noven recognized $0.7 million of net revenues for Stavzor® in the first quarter of 2009, and $1.6 million of deferred product revenue relating to Stavzor® was reflected on Noven s Condensed Consolidated Balance Sheet as of March 31, 2009.

Certain reclassifications have been made to the prior period s Condensed Consolidated Statements 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 Summary of Significant Accounting Policies of the Notes to Consolidated Financial Statements included in Noven s Form 10-K.

In November 2008, the Emerging Issues Task Force (EITF) of the Financial Accounting Standards Board (FASB) ratified the consensus reached in EITF Issue No. 08-6, Equity Method Investment Accounting Considerations (EITF 08-6). The application of the equity method is affected by the accounting for business combinations under SFAS No. 141(R) and the accounting for consolidated subsidiaries under SFAS No. 160. Therefore, the objective of EITF 08-6 is to clarify how to account for certain transactions and impairment considerations involving equity method investments. EITF 08-6 is effective for fiscal years beginning on or after December 15, 2008, and interim periods within those fiscal years, consistent with the effective dates of SFAS No. 141(R) and SFAS No. 160. EITF 08-6 applies prospectively. The adoption of EITF 08-6 did not impact Noven s consolidated financial condition, results of operations or cash flows.

In October 2008, the FASB issued FASB Staff Position (FSP) SFAS 157-3, Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active (FSP SFAS 157-3). FSP SFAS 157-3 clarifies the application of SFAS No. 157, Fair Value Measurements, (SFAS No. 157) when determining the fair value of a financial asset when the market for that asset is not currently active. FSP SFAS 157-3 emphasizes that approaches other than the market approach to determining fair value may be appropriate when it is determined that, as a result of market inactivity, other valuation approaches are more representative of fair value. Other valuation approaches can involve significant assumptions regarding future cash flows. FSP SFAS 157-3 clarifies that these assumptions must incorporate adjustments for nonperformance and liquidity risks that market participants would consider in valuing the asset in an inactive market. FSP SFAS 157-3 emphasizes the existing disclosure requirements under SFAS No. 157 regarding significant unobservable inputs (Level 3 inputs). FSP SFAS 157-3 became effective upon issuance, including with respect to prior periods for which financial statements have not been issued. The adoption of FSP SFAS 157-3 did not impact Noven s consolidated financial condition, results of operations or cash flows.

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In May 2008, the 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. The adoption of SFAS No. 162 did not impact Noven s consolidated financial condition, results of operations or cash flows.

In April 2008, the FASB issued 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. The adoption of FSP 142-3 did not impact Noven s consolidated financial condition, results of operations or cash flows.

In December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements an Amendment of Accounting Research Bulletin (ARB) No. 51 (SFAS No. 160). SFAS No. 160 establishes accounting and reporting standards for the noncontrolling interest (minority interest) in a subsidiary and for the deconsolidation of a subsidiary. SFAS No. 160 amends certain of ARB 51 s consolidation procedures to conform them to the requirements of SFAS No. 141(R), Business Combinations , which was issued at the same time as SFAS No. 160. This new statement is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008 (that is, January 1, 2009, for entities with calendar year-ends). SFAS No. 160 applies prospectively as of the beginning of the fiscal year in which this statement is initially applied, except for the presentation and disclosure requirements, which must be applied retrospectively for all periods presented. The adoption of SFAS No. 160 did not impact Noven s consolidated financial condition, results of operations or cash flows.

In December 2007, the FASB revised SFAS No. 141, Business Combinations (SFAS No. 141(R)). SFAS No. 141(R) establishes principles and requirements for how an acquirer: (i) recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree; (ii) recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase; and (iii) determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS No. 141(R) applies to all transactions or other events in which an entity (the acquirer) obtains control of one or more businesses (the acquiree), including those sometimes referred to as true mergers or mergers of equals and combinations achieved without the transfer of consideration, for example, by contract alone or through the lapse of minority veto rights. In April 2009, the FASB issued FSP SFAS 141(R)-1, Accounting for Assets and Liabilities Assumed in a Business Combination That Arise from Contingencies (FSP SFAS 141(R)-1) to amend and clarify the application of SFAS No. 141(R) to assets and liabilities arising from contingencies in a business combination. SFAS No. 141(R) and FSP SFAS 141(R)-1 apply prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. Noven will apply the provisions of SFAS No. 141(R), as amended by FSP SFAS 141(R)-1, to any business combination transactions consummated after December 31, 2008.

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In December 2007, the EITF reached a consensus on EITF Issue No. 07-1, Accounting for Collaborative Arrangements (EITF 07-1). EITF 07-1 discusses the appropriate income statement presentation and classification for the activities and payments between the participants in arrangements related to the development and commercialization of intellectual property. It requires certain transactions between collaborators to be recorded in the income statement on either a gross or net basis within expenses when certain characteristics exist in the collaboration relationship. The sufficiency of disclosure related to these arrangements is also specified. EITF 07-1 is effective for fiscal years beginning after December 15, 2008. The adoption of EITF 07-1 did not impact Noven s consolidated financial condition, results of operations or cash flows.

3. CASH FLOW INFORMATION:

Income Tax and Interest Payments

Cash payments for income taxes were $0.2 million and $1.2 million for the three months ended March 31, 2009 and 2008, 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. These payments are deemed distributions to Noven from Novogyne. Noven received tax refunds directly from the State of New Jersey of $2.9 million and $2.7 million during the three months ended March 31, 2009 and 2008, respectively, related to these state income tax payments made on Noven s behalf. Cash payments for interest were not material for the three months ended March 31, 2009 or 2008.

Non-cash Operating Activities

Noven recorded $37,000 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 three months ended March 31, 2008.

Non-cash Investing Activities

Noven recorded $0.5 million in unrealized losses on its investments in auction rate securities for the three months ended March 31, 2008. The unrealized losses were recorded as a reduction of stockholders equity through other comprehensive income.

Non-cash Financing Activities

Noven issued immediately exercisable SSARs with a fair value of $0.2 million as a portion of the President and Chief Executive Officer s 2008 incentive bonus award during the three months ended March 31, 2009.

4. INVESTMENTS AVAILABLE-FOR-SALE:

At March 31, 2009, Noven held investments in auction rate securities (classified as available-for-sale) with a par value and fair value of $12.3 million and $11.8 million, respectively. Noven liquidated $3.7 million of its investments in auction rate securities at par value during the three months ended March 31, 2009. Due to uncertainty regarding the timing of Noven s future investment liquidations, Noven continues to classify its auction rate securities as non-current assets as of March 31, 2009.

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In the fourth quarter of 2008, Noven determined that a $0.5 million unrealized decline in fair value of its auction rate portfolio was other-than-temporary. As a result, Noven recognized the impairments in its 2008 Consolidated Statement of Operations. The determination that the unrealized losses were other-than-temporary was primarily based on the length of time that the securities have been impaired and the fact that the continuing auction failures do not enable Noven to reliably estimate when the value of the securities may recover. To the extent future declines in fair value are determined to be other-than-temporary, additional impairment charges will result. Such impairment charges could materially and adversely affect Noven s consolidated financial condition and results of operations.

5. FAIR VALUE MEASUREMENTS:

Noven adopted SFAS No. 157, Fair Value Measurements (SFAS No. 157) in 2008. As of March 31, 2009, the total par value and fair value of Noven s investments in auction rate securities were $12.3 million and $11.8 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 three months ended March 31, 2009 were as follows (in thousands):

Balance at December 31, 2008	$ 15,460
Redemptions of investments at par value	(3,650)
Balance at March 31, 2009	$ 11,810

6. INVENTORIES:

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

	March 31, 2009	December 31, 2008
Finished goods	$ 3,431	$ 3,200
Work in process	3,239	2,510
Raw materials	8,003	8,214
	$ 14,673	$ 13,924

During the three months ended March 31, 2009, Noven recorded a $0.9 million charge to cost of products sold related to the write-off of inventories, of which approximately $0.8 million related to Daytrana® product and $0.1 million related to other products 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 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 exceeded the yield requirements for the three months ended March 31, 2009, resulting in an immaterial payment from Shire to Noven during the three months ended March 31, 2009. During the three months ended March 31, 2009, Noven used $1.0 million of Shire s AMI in the finished product, and had $2.3 million and $2.6 million of consignment AMI inventory on hand at March 31, 2009 and December 31, 2008, respectively, which is not reflected in the table above.

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7. GOODWILL AND INTANGIBLE ASSETS:

All of Noven s goodwill arose from the Noven Therapeutics acquisition in August 2007 and, thus, relates to the Noven Therapeutics segment. The carrying amount of goodwill is $14.4 million at March 31, 2009 and December 31, 2008. 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.

Noven s intangible assets, all of which are subject to amortization, are summarized in the tables below as of March 31, 2009 and December 31, 2008 (amounts in thousands):

	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Weighted-Average Remaining Life (years)
As of March 31, 2009				
Patent development costs	$ 5,140	$ (3,183)	$ 1,957	8.1
Acquired product intangibles	39,290	(6,234)	33,056	8.8
Non-competition agreements	530	(359)	171	1.1
Favorable lease	790	(428)	362	1.5
	$ 45,750	$ (10,204)	$ 35,546	8.6
As of December 31, 2008				
Patent development costs	$ 4,929	$ (3,070)	$ 1,859	7.2
Acquired product intangibles	39,290	(5,289)	34,001	9.0
Non-competition agreements	530	(304)	226	1.6
Favorable lease	790	(368)	422	2.0
	$ 45,539	$ (9,031)	$ 36,508	8.8

The intangible assets for acquired products, non-competition agreements and favorable lease included in the tables above resulted primarily from the Noven Therapeutics acquisition. Amortization expense was $1.2 million and $1.1 million for the three months ended March 31, 2009 and 2008, respectively.

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Noven estimates that the annual amortization expense for intangible assets held at March 31, 2009 for each of the five years through 2014 is as follows (amounts in thousands):

	Remainder of 2009	Years Ending December 31, 2010	2011	2012	2013	2014
Cost of goods sold:						
Intellectual property	$ 3,174	$ 4,174	$ 4,109	$ 4,096	$ 4,042	$ 3,961
General and administrative:						
Non-compete and favorable lease agreements	297	236				
Total	$ 3,471	$ 4,410	$ 4,109	$ 4,096	$ 4,042	$ 3,961

8. OTHER ACCRUED LIABILITIES:

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

	March 31, 2009	December 31, 2008
Income taxes payable	$ 2,463	$ 2,197
Accrued medicaid and other rebates	3,417	2,726
Accrued market withdrawal costs	3,758	3,598
Allowance for product returns	3,034	3,070
Other accrued liabilities	4,475	5,669
Total other accrued liabilities	$ 17,147	$ 17,260

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, Share-Based Payment (SFAS No. 123 (R)). At March 31, 2009, there were 1.5 million stock options and 2.6 million SSARs outstanding under the 1999 Plan.

The weighted average grant date fair values of SSARs granted during the three months ended March 31, 2009 and 2008 were $3.96 and $5.11, respectively, using the Black-Scholes option-pricing model with the assumptions below:

	2009	2008
Volatility	52.2%	45.5%
Risk free interest rate	1.75%	2.63%
Expected life (years)	3.9	4.8
Dividend yield	0.0%	0.0%

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Total stock-based compensation recognized in Noven s Condensed Consolidated Statements of Operations for the three months ended March 31, 2009 and 2008 was as follows (in thousands):

	2009	2008
Selling and marketing	$ 166	$ 154
General and administrative	859	469
Research and development	145	90
Total cost of products sold	128	145
	$ 1,298	$ 858
Tax benefit recognized related to compensation expense	$ 491	$ 293

In accordance with SFAS No. 123(R), tax benefits at the time of exercise in excess of those recognized in conjunction with compensation expense are reported as cash flow from financing activities. No stock options or SSARs were exercised during the three months ended March 31, 2009. Due to the small number of exercises during the three months ended March 31, 2008, cash received from stock option exercises, the tax benefit realized from exercises, and the total intrinsic value of stock options exercised for the three months ended March 31, 2008 were not material.

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 their service on the Board of Directors. The grants fall under the definition of nonvested shares under SFAS No. 123(R). 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. As of March 31, 2009 and December 31, 2008, there were a total of 105,469 and 92,818 shares of common stock in the rabbi trust, respectively.

Stock option and SSAR transactions under the 1999 Plan for the three months ended March 31, 2009 are summarized as follows (stock options/SSARs and aggregate intrinsic value amounts in thousands):

	Stock Options/ SSARs	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Outstanding at beginning of period	4,093	$ 14.31		
Granted	102	9.62		
Exercised				
Canceled or expired	(33)	16.04		
Outstanding at end of period	4,162	$ 14.18	4.6	$ 128
Exercisable at end of period	1,806	$ 16.56	2.6	$ 1
Shares of common stock reserved	4,332			

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As of March 31, 2009, the unamortized compensation expense that Noven expects to record in future periods related to currently outstanding unvested stock options, SSARs and nonvested shares of restricted stock, as determined in accordance with SFAS No. 123(R), is approximately $10.4 million before the effect of income taxes. The weighted average period over which this compensation cost is expected to be recognized is 4.0 years. The total fair value of equity grants that vested in the three months ended March 31, 2009 was $0.5 million. As of March 31, 2009, approximately 3.6 million outstanding stock options/SSARs are vested or are expected to vest. Such stock options have a weighted average exercise price of $14.44, a $0.1 million aggregate intrinsic value and a weighted average remaining life of 4.4 years at March 31, 2009.

Noven has granted a total of 388,780 shares of restricted stock under the 1999 Plan. The following table summarizes information regarding Noven s restricted stock at March 31, 2009 (share amounts in thousands):

	Shares	Weighted Average Grant-Date Fair Value
Nonvested at December 31, 2008	221	$ 9.43
Granted		
Vested	(19)	12.41
Nonvested at March 31, 2009	202	$ 9.16

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 No. 109 (FIN 48).

As of March 31, 2009, the gross amount of unrecognized tax benefits was approximately $1.5 million. If the $1.5 million is ultimately recognized, approximately $1.1 million would affect the effective tax rate due to approximately $0.4 million in related federal tax benefit. As of December 31, 2008, the gross amount of unrecognized tax benefits was approximately $1.3 million. If the $1.3 million is ultimately recognized, approximately $0.9 million would impact the effective income tax rate due to a federal tax benefit of approximately $0.4 million. Interest and penalties related to income taxes are classified as a component of income tax expense. Approximately $0.5 million were accrued for interest and penalties as of March 31, 2009 and December 31, 2008. Noven does not expect the gross amount of unrecognized tax benefits to significantly increase or decrease within 12 months after March 31, 2009. All of Noven s unrecognized tax benefits relate 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 2005 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 returns for the years ended December 31, 2006 and 2007. 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 2004 through 2007. In January 2009, the State of New Jersey Division of Taxation initiated an examination of Noven s tax returns for 2004 through 2007. Noven does not expect the outcome of the examinations to materially impact its tax liabilities. Other than the IRS and New Jersey examinations described above, as well as routine state tax inquiries, Noven has not been notified of any, and is not aware of, 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.

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At March 31, 2009 and December 31, 2008, net deferred tax assets were $72.0 million and $72.2 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 Therapeutics has historically reported taxable losses in these states and expects to continue to incur state taxable losses in the next few years. These circumstances create negative evidence indicating the need for a valuation allowance at March 31, 2009 and December 31, 2008. Noven s valuation allowance for state deferred tax assets was $3.5 million as of March 31, 2009 and December 31, 2008, due to uncertainty regarding Noven s ability to realize these state deferred tax assets based on Noven s projection of future state taxable income relating to Noven Therapeutics. If Noven determines, based on Noven Therapeutics potential future 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 has paid Noven as follows: (i) $25.0 million upon the closing of the transaction in April 2003; (ii) $50.0 million upon receipt of final marketing approval by the FDA in April 2006; and (iii) three installments of $25.0 million each upon Shire s achievement of $25.0 million, $50.0 million and $75.0 million in annual Daytrana® net sales. Noven received the first $25.0 million sales milestone payment in the first quarter of 2007, the second $25.0 million sales milestone payment in the third quarter of 2007 and the third $25.0 million sales milestone payment in the third quarter of 2008. Noven is currently deferring and recognizing approval and sales milestone payments as license revenues on a straight-line basis, beginning on the date the milestone was 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 Pharmaceuticals, LLC (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. Based on net sales of Pexeva® in 2007 and 2008, Noven Therapeutics was required to make milestone payments to Synthon of $3.3 million for each of those years. The 2007 sales milestone was paid in April 2008 and the 2008 sales milestone was paid in March 2009. In addition to the amounts already paid, Noven is obligated to make another $5.0 milestone payment if annual net sales of Pexeva® (or a future product utilizing the same compound as is used in Pexeva®) achieves $30.0 million or more through 2017. Noven recorded a liability for these contingent milestone payments at the time of closing of the Noven Therapeutics acquisition based on projected future sales of Pexeva® which indicated that the achievement of each of the specified sales levels was probable. In the third quarter of 2008, Noven determined that the achievement of $30.0 million in annual net sales for Pexeva®, the next specified sales level, was no longer probable, resulting in a change in accounting estimate. The change resulted from lower forecasted long-term prescription growth than originally expected, as well as a redistribution of selling efforts 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. Although Noven reversed the $5.0 million accrued liability, Noven remains contingently liable for the $5.0 million payment if annual

net sales of Pexeva® (or a future product utilizing the same compound as is used in Pexeva®) achieves $30.0 million or more through 2017.

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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 2009 and 2008 to meet Novartis annual preferred return for those periods and for Noven to recognize earnings from Novogyne under the formula.

During the three months ended March 31, 2009 and 2008, Noven had the following transactions with Novogyne (amounts in thousands):

	2009	2008
Revenues:		
Product sales	$ 5,480	$ 2,431
Royalties	2,222	2,180
	$ 7,702	$ 4,611
Reimbursed expenses	$ 8,146	$ 7,272

Reimbursed expenses are primarily comprised of selling and marketing expenses paid by Noven on behalf of Novogyne. As of March 31, 2009 and December 31, 2008, Noven had amounts due from Novogyne of $6.7 million and $6.5 million, respectively.

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The Unaudited Condensed Statements of Operations of Novogyne for the three months ended March 31, 2009 and 2008 are as follows (amounts in thousands):

	2009	2008
Gross revenues	$ 48,230	$ 45,294
Sales allowances	6,666	5,853
Sales return allowances	1,373	(85)
Sales allowances and returns	8,039	5,768
Net revenues	40,191	39,526
Cost of sales	8,077	7,808
Selling, general and administrative expenses	10,711	9,012
Income from operations	21,403	22,706
Interest income	94	267
Net income	$ 21,497	$ 22,973
Noven s equity in earnings of Novogyne	$ 7,545	$ 8,267

The activity in the Investment in Novogyne account for the three months ended March 31, 2009 is as follows (amounts in thousands):

Investment in Novogyne, beginning of period	$ 24,319
Equity in earnings of Novogyne	7,545
Cash distributions from Novogyne	(12,689)
Investment in Novogyne, end of period	$ 19,175

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 months ended March 31, 2009 and 2008, Noven received cash distributions from Novogyne representing return on investment of $12.7 million and $10.9 million, respectively. This amount was recorded as a reduction in the investment in Novogyne when received.

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. During the fourth quarter of 2007, Noven repurchased 322,345 shares of its common stock at an aggregate price of approximately $5.1 million. These shares remained in treasury as of March 31, 2009 and December 31, 2008, and no additional shares have been repurchased under the program since December 31, 2007.

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 is funding 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.

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SUPPLY AGREEMENTS:

Noven s supply agreement with Novogyne for Vivelle® and Vivelle-Dot® patches expired in January 2003. While the parties have continued to operate in accordance with certain of the supply agreement s pricing terms, there is no assurance that the parties will continue to do so. Novogyne s designation of a new supplier and approval of a new supply agreement would require the affirmative vote of four of the five members of Novogyne s Management Committee. Since Noven appoints two members of Novogyne s Management Committee, both Novartis and Noven must agree on Novogyne s supplier. In connection with a transition to Vivelle-Dot®, effective December 2006, Noven ceased supplying Vivelle® product to Novogyne.

Noven and Shire are also 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 March 31, 2009 and 2008, Noven s net product sales of Daytrana® to Shire were $2.9 million and $3.0 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.

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.

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.

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In July 2008, a 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.

In March 2009, a complaint was filed in the United States District Court, Southern District of Illinois 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 CombiPatch®. The plaintiff claims compensatory and other damages in an unspecified amount. Noven has not yet been served with the complaint.

In April 2009, a complaint was filed in the United States District Court, District of Oregon against Noven and Novartis. The complaint alleges liability in connection with personal injury claims allegedly arising from the use of the HT product, CombiPatch®. The plaintiff claims compensatory and other damages in an unspecified amount. Noven has not yet been served with the complaint.

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 28 additional lawsuits that include approximately 29 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 five of the lawsuits specifically 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 March 31, 2009 was $10.0 million. Novogyne has established reserves in the amount of $9.6 million with an offsetting insurance recovery of $7.1 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 March 31, 2009.

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 commenced formal discovery and the case has been scheduled for trial in late 2009.

As of March 31, 2009 and December 31, 2008, Noven had reserved $1.2 million and $2.0 million, respectively, for the matters described above. 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 certain 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 a list of observations from the FDA 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 recalls 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 those recalls. This payment was 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 ® s release liner; and (ii) data supporting the peel force characteristics of Daytrana ® s enhanced release liner throughout the product s shelf life. Noven submitted its response to the warning letter on January 30, 2008, which remains under review by the FDA.

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. 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 paid Shire $3.7 million related to its June and August 2008 recalls, of which approximately $3.1 million has been charged to general and administrative expenses, $0.4 million was recorded as a reduction in revenues and $0.2 million was charged to cost of products sold in 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 product sold represents the value of AMI included in such product for which Noven is required to reimburse Shire, and the amount charged to general and administrative expenses represents amounts Noven is obligated to reimburse Shire for direct costs of the recalls.

In the fourth quarter of 2008, Noven implemented: (i) new product release testing intended to predict which Daytrana® lots are at risk of developing peel force issues during the product s shelf life; and (ii) new manufacturing processes and procedures that helped improve efficiencies associated with existing Daytrana® production. Product that fails to meet the predictive release test will be destroyed, which will result in increased Daytrana® manufacturing costs, including reimbursements to Shire for the AMI included in the destroyed product. For the three months ended March 31, 2009, Daytrana® cost of products sold exceeded Noven s Daytrana® net revenues by $0.7 million. Although Noven has implemented the new manufacturing processes and procedures described above, Noven expects 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 included in destroyed product, unless and until the peel force issue is resolved.

In March 2009, Shire initiated a voluntary recall of certain lots of Daytrana® due to the failure of some of the patches to meet the product s release liner removal specification. Noven believes the reserve established in 2008 ($3.7 million at March 31, 2009) will be sufficient to cover Noven s cost related to this recall. 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 predictive release testing will detect all production issues or that there will not be future Daytrana® market withdrawals or recalls.

In January 2009, Noven received from the FDA a list of observations on Form 483 following an on-site inspection of its manufacturing facilities. Like the warning letter and the prior Form 483, the majority of the observations in the Form 483 relate to the manufacture of Daytrana® product that exhibits high peel force characteristics, an issue which Noven and Shire continue to work to resolve. In February 2009, Noven submitted its response to the Form 483. 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.

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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.

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 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 March 31, 2009, no borrowings were outstanding under this facility.

15. SEGMENT DATA:

The accounting policies of Noven s segments are the same as those described in Note 2 Summary of Significant Accounting Policies of the Notes to Consolidated Financial Statements included in Noven s Form 10-K. In the fourth quarter of 2008, as a result of management and organizational changes throughout 2008, Noven revised its presentation of reportable segments to reflect Novogyne as a reportable unit distinct from the manufacturing and licensing activities of Noven Transdermals. Noven evaluates segment performance for Noven Transdermals and Noven Therapeutics based on segment profit (loss) which consists of segment net revenues less cost of products sold and selling and marketing expenses. Noven evaluates segment performance for Novogyne based on Noven s equity in earnings of Novogyne. Noven Transdermals net revenues include product revenues from sales to Novogyne of $7.7 million and $4.6 million for the three months ended March 31, 2009 and 2008, respectively. 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. There are no other inter-segment revenues.

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The table below presents segment information for the periods identified and reconciles segment profit (loss) to the applicable consolidated amounts. Segment disclosures for 2008 have been revised to conform to the current presentation (amounts in thousands):

	Three Months Ended March 31,	
	2009	2008
Net Revenues:		
Noven Transdermals		
Product revenues	$ 14,777	$ 10,491
License and contract revenues	6,289	5,286
	21,066	15,777
Noven Therapeutics		
Product revenues	$ 6,574	$ 5,705
Net revenues	$ 27,640	$ 21,482
Segment profit (loss):		
Noven Transdermals	$ 11,681	$ 6,310
Noven Therapeutics	(470)	(960)
Equity in earnings of Novogyne	7,545	8,267
Total segment profit	$ 18,756	$ 13,617
Reconciliation of segment profit to income before income taxes:		
Segment profit	$ 18,756	$ 13,617
Research and development	(4,653)	(3,319)
General and administrative	(7,048)	(7,022)
Interest and other income, net	89	622
Income before income taxes	$ 7,144	$ 3,898

Segment assets consisted of the following as of March 31, 2009 and December 31, 2008 (amounts in thousands):

	March 31, 2009	December 31, 2008
Noven Transdermals	$ 56,018	$ 56,362
Noven Therapeutics	54,489	55,902
Novogyne	19,175	24,319
Assets not allocated to segments[1]	165,348	164,983
Total Assets	$ 295,030	$ 301,566

[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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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 March 31, 2009, and our consolidated results of operations for the three months ended March 31, 2009 (the 2009 Quarter) and March 31, 2008 (the 2008 Quarter). The contents of this section include:

An executive summary of our consolidated results of operations for the 2009 Quarter;

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 for 2009.

This discussion should be read in conjunction with Noven s Unaudited Condensed Consolidated Financial Statements for the three months ended March 31, 2009 and 2008 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.

For the 2009 Quarter, we reported net income of $4.5 million ($0.18 diluted earnings per share), compared to net income of $2.6 million ($0.11 diluted earnings per share) for the 2008 Quarter. Our net revenues in the 2009 Quarter were $27.6 million, a 29% increase over the 2008 Quarter. Contributing to this comparative increase, net revenues in the 2008 Quarter were negatively affected by an equipment failure in transdermal manufacturing. The increase in net revenues in the 2009 Quarter also reflected higher license and contract revenues, primarily due to amortization of deferred revenue from the additional Daytrana® sales milestone payment (received in the third quarter of 2008), as well as product sales of Stavzor® (commercially launched in August 2008).

Gross margin, as a percentage of net product revenues, was 47% in the 2009 Quarter compared to 30% in the 2008 Quarter. Gross margin for the 2009 Quarter benefited from new manufacturing processes and procedures implemented in the fourth quarter of 2008 designed to improve efficiencies associated with transdermal production. Gross margin for the 2008 Quarter was negatively affected by the impact of the equipment failure in transdermal manufacturing, as well as increased quality assurance activities and expenses, primarily related to Daytrana® production. Notwithstanding improvements following implementation of new manufacturing processes, we expect the peel force issue to continue to negatively affect margins unless and until this issue is resolved.

Research and development expenses in the 2009 Quarter increased $1.3 million, or 40%, compared to the 2008 Quarter, primarily reflecting expenses associated with the Mesafem Phase 2 clinical study and additional research and development expenses to support our long-term growth objectives. Compared to the 2008 Quarter, selling and marketing expenses increased $0.2 million, or 4%, and general and administrative expenses remained substantially unchanged.

We recognized $7.5 million in equity in earnings of Novogyne in the 2009 Quarter, a decrease of 9% compared to the 2008 Quarter. Net revenues at Novogyne increased 2% to $40.2 million in the 2009 Quarter compared to the 2008 Quarter, reflecting higher gross sales of Vivelle-Dot®, driven primarily by pricing and increased prescription demand, substantially offset by a decrease in sales volume resulting from inventory reductions in the distribution channel. The increase in gross revenues was also partially offset by higher sales deductions for product returns. Demand for Vivelle-Dot® increased for the period, with new and total prescriptions for the product increasing 6% and 3%, respectively, compared to the 2008 Quarter. Novogyne s gross margin percentage for the 2009 Quarter remained substantially unchanged at 80%. Novogyne s selling, general and administrative expenses for the 2009 Quarter were $10.7 million, a 19% increase over the 2008 Quarter, primarily due to the timing of sample shipments and other expenses in support of Vivelle-Dot®. Novogyne s net income for the 2009 Quarter decreased 6% to $21.5 million

compared to the 2008 Quarter.

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At March 31, 2009, we had $72.2 million in cash and cash equivalents and $11.8 million in investments in auction rate securities. This compares to $62.9 million in cash and cash equivalents and $15.5 million in investments in auction rate securities at December 31, 2008. Our investments in auction rate securities at March 31, 2009 had a fair value of $11.8 million, and all were classified as non-current on our balance sheet. We liquidated $3.7 million of these investments at par value in the 2009 Quarter. As of March 31, 2009, no amounts were outstanding under our $15.0 million revolving credit facility.

Total prescriptions for Vivelle-Dot® increased 3% in the 2009 Quarter compared to the 2008 Quarter, and total prescriptions for Novogyne s HT products, taken as a whole, increased 1% over the same period. By comparison, the United States HT market declined 5% for the same period. Total prescriptions for Daytrana® decreased 13% in the 2009 Quarter compared to the 2008 Quarter, while prescriptions for ADHD stimulant therapies as a class increased 9% over the same period. Total prescriptions for Pexeva® decreased 21% in the 2009 Quarter compared to the 2008 Quarter, while for the same period prescriptions for the selective serotonin re-uptake inhibitor (SSRI) class increased 1%. Reflecting ongoing generic substitution, total prescriptions for Lithobid® decreased 32% in the 2009 Quarter compared to the 2008 Quarter.

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.

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.

In the third quarter of 2007, Shire initiated two voluntary recalls 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 recalls. 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, which remains under review by the FDA.

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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. 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. During 2008, we paid Shire $3.7 million related to its June and August 2008 recalls, of which approximately $3.1 million has been charged to general and administrative expenses, $0.4 million was recorded as a reduction in revenues and $0.2 million was charged to cost of products sold in 2008. For each of the recalls described above, the amount charged to general and administrative expenses represents amounts we are obligated to reimburse Shire for direct costs of the recalls, the amounts reflected as reductions of revenue represent the amounts recognized for product which is expected to be returned and the charge to cost of product sold represents the value of AMI included in such product for which we are required to reimburse Shire.

In the fourth quarter of 2008, we implemented: (i) new product release testing intended to predict which Daytrana® lots are at risk of developing peel force issues during the product s shelf life; and (ii) new manufacturing processes and procedures that helped improve efficiencies associated with existing Daytrana® production. Product that fails to meet the predictive release test will be destroyed, which will result in increased Daytrana® manufacturing costs, including reimbursements to Shire for the AMI included in the destroyed product. In the 2009 Quarter, Daytrana® cost of products sold exceeded our Daytrana® net revenues by $0.7 million. Although we have implemented new manufacturing processes and procedures that helped improve efficiencies associated with existing Daytrana® production in the fourth quarter of 2008, 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 included in destroyed product, unless and until the peel force issue is resolved.

In March 2009, Shire initiated a voluntary recall of certain lots of Daytrana® due to the failure of some of the patches to meet the product s release liner removal specification. We believe the reserve established in 2008 ($3.7 million at March 31, 2009) will be sufficient to cover our cost related to this recall. 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 predictive release testing will detect all production issues or that there will not be future Daytrana® market withdrawals or recalls.

In January 2009, we received from the FDA a list of observations on Form 483 following an on-site inspection of our manufacturing facilities. Like the warning letter and the prior Form 483, the majority of the observations in the Form 483 relate to the manufacture of Daytrana® product that exhibits high peel force characteristics, an issue which Noven and Shire continue to work to resolve. In February 2009, we submitted our response to the Form 483.

We believe we have identified the root cause of the peel force issue, and are testing manufacturing solutions intended to address the issue. Implementation of a solution will require the prior agreement of the FDA. We estimate that the steps necessary to begin manufacturing commercial product incorporating a solution, including obtaining the FDA s agreement, may carry over into 2010. We cannot assure, however, that we will receive the FDA s agreement on a timely basis or at all. Noven s January 2008 response to the warning letter remains under review by the FDA.

In March 2009, Shire announced its withdrawal of the European Marketing Authorization Application (MAA) for Daytrana®. Shire indicated that its decision to withdraw the MAA was based on the fact that European regulatory authorities had requested an additional clinical study for Daytrana® in a European patient population, and that Shire planned to enter the European ADHD market through its previously-announced pending acquisition of an oral methylphenidate product that is already approved in Europe.

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Results of Operations

As discussed in Note 15 Segment Data to our Unaudited Condensed Consolidated Financial Statements, we operate in three segments distinguished along product categories and nature of the business unit: (i) Noven Transdermals, which currently engages in the manufacturing, licensing and sale to partners of prescription transdermal products; (ii) Novogyne, our women s health joint venture with Novartis in which we own a 49% equity interest; and (iii) Noven Therapeutics, which currently engages in the marketing and sale of pharmaceutical products.

2009 Quarter compared to the 2008 Quarter

Revenues

Our revenues by segment and type for the 2009 Quarter and the 2008 Quarter are summarized as follows (dollar amounts in thousands):

	Three Months Ended March 31,		
	2009	2008	% Change
Noven Transdermals			
Novogyne:			
Product sales	$ 5,480	$ 2,431	125%
Royalties	2,222	2,180	2%
Product revenues Novogyne	7,702	4,611	67%
Third Parties:			
Product sales	7,004	5,801	21%
Royalties	71	79	-10%
Product revenues third parties	7,075	5,880	20%
Total product revenues	14,777	10,491	41%
License and contract revenues	6,289	5,286	19%
Total Transdermals	21,066	15,777	34%
Noven Therapeutics			
Third Parties:			
Product sales	6,574	5,705	15%
Net Revenues	$ 27,640	$ 21,482	29%

Net Revenues

As described in more detail below, our net revenues in the 2009 Quarter were $27.6 million, an increase of 29% compared to $21.5 million reported in the 2008 Quarter. The increase was primarily due to a $4.3 million increase in product revenues from our Noven Transdermals segment comprised primarily of a $2.9 million increase in sales of Vivelle-Dot® and a $1.2 million increase in transdermal product revenues from third parties in the 2009 Quarter. This increase was also due to a $1.0 million, or 19%, increase in license and contract revenues and a $0.9 million increase in product revenues from our Noven Therapeutics segment compared to the 2008 Quarter.

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®.

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The $3.1 million increase in Novogyne product revenues for the 2009 Quarter compared to the 2008 Quarter was primarily due to the impact of an equipment failure in transdermal manufacturing which negatively affected product revenues in the 2008 Quarter, as well as the timing of orders from Novogyne. By product, Vivelle-Dot® increased $2.9 million primarily due to the equipment failure in the 2008 Quarter and CombiPatch® increased $0.3 million primarily due to the timing of orders.

Product Revenues Third Parties

Product revenues third parties primarily consist of: (i) sales of Estradot® and Estalis® HT patches to Novartis Pharma at a price based on a percentage of Novartis Pharma s net selling price (subject to certain minimum amounts) 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) 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 $1.2 million increase in product revenues third parties in our Noven Transdermals segment for the 2009 Quarter compared to the 2008 Quarter primarily consisted of a $0.8 million increase in unit sales and a $0.4 million increase related to pricing. The increase in unit sales was primarily due to the impact of an equipment failure in transdermal manufacturing which occurred in the 2008 Quarter, as well as 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 $1.6 million and $1.2 million of such payments in the 2009 Quarter and 2008 Quarter, respectively.

Noven Therapeutics generated $6.6 million of net revenues in the 2009 Quarter from sales of Stavzor®, Pexeva® and Lithobid® compared to $5.7 million of net revenues in the 2008 Quarter from sales of Pexeva® and Lithobid®. By product, the addition of Stavzor® contributed to $0.7 million of the increase, Lithobid® increased $0.5 million due to the timing of orders from trade customers as prescriptions have declined. The increase in net revenues was partially offset by a $0.3 million decrease in net revenues for Pexeva® primarily due to lower prescriptions.

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 third quarter of 2008, we do not yet have sufficient sales history to reasonably estimate product returns of Stavzor®. Our customers are no longer permitted to return the product once it has been dispensed. 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 have deferred recognition of revenue on product shipments of Stavzor® to our customers until such time as Stavzor® units are dispensed through patient prescriptions. 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 sales history to reasonably estimate product returns. We recognized $0.7 million of net revenues for Stavzor® in the 2009 Quarter, and $1.6 million of deferred product revenue relating to Stavzor® was reflected on our Condensed Consolidated Balance Sheet as of March 31, 2009.

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.

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License and contract revenues increased $1.0 million for the 2009 Quarter compared to the 2008 Quarter, primarily attributable to a $1.3 million increase in amortization of milestone payments received from Shire related to the license of Daytrana®, partially offset by a $0.4 million decrease in contract revenues during the 2009 Quarter due to the timing of work performed on research and development projects.

Gross to Net Revenues

We record revenues net of sales allowances for rebates, chargebacks, cash and other discounts, as well as sales returns allowances. We establish return allowances on product sold through our Noven Transdermals segment when it is probable that such product will be recalled or withdrawn. Sales returns allowances in our Noven Therapeutics segment represent allowances for estimated product returns based on expiration dating and are estimated based on historical return rates, current sales levels and other factors on a product-by-product basis. The following table sets forth the reconciliation of our gross revenues to net revenues for the 2009 Quarter and 2008 Quarter, respectively (dollar amounts in thousands):

	Three Months Ended March 31,			
	2009	% of gross revenues	2008	% of gross revenues
Noven Transdermals:				
Gross revenues	$ 21,135	100%	$ 16,013	100%
Sales returns allowances	(69)	0%	(236)	1%
Net revenues	$ 21,066	100%	$ 15,777	99%
Noven Therapeutics:				
Gross revenues	$ 9,531	100%	$ 9,508	100%
Cash discounts	(172)	2%	(192)	2%
Medicaid, Medicare & State program rebates and credits including redemption offers	(2,038)	21%	(2,289)	24%
Chargebacks	(163)	2%	(267)	3%
Wholesaler fees	(389)	4%	(594)	6%
Sales returns allowances	(195)	2%	(461)	5%
Sales and returns allowances	(2,957)	31%	(3,803)	40%
Net revenues	$ 6,574	69%	$ 5,705	60%

The decrease in Medicaid, Medicare & state program rebates and credits for Noven Therapeutics (as a percentage of gross revenues) is attributable to our decision not to renew unprofitable managed care contracts. The decrease in sales returns allowances for Noven Therapeutics (as a percentage of gross revenues) was primarily attributable to a decrease in return reserves for Lithobid® due to lower actual returns of product.

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.

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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 $7.0 million and $7.9 million in the 2009 Quarter and the 2008 Quarter, 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. 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.

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

	Three Months Ended March 31,			
	2009		2008	
Noven Transdermals				
Novogyne:				
Product revenues	$ 7,702		$ 4,611	
Cost of products sold	3,648		3,326	
Gross profit	4,054	53%	1,285	28%
Third parties:				
Product revenues	7,075		5,880	
Cost of products sold	5,737		5,947	
Gross profit (loss)	1,338	19%	(67)	-1%
Total Noven Transdermals:				
Product revenues	14,777		10,491	
Cost of products sold	9,385		9,273	
Gross profit	5,392	36%	1,218	12%
Noven Therapeutics				
Product revenues	6,574		5,705	
Cost of products sold	2,031		2,036	
Gross profit	4,543	69%	3,669	64%
Total Company				
Product revenues	21,351		16,196	
Cost of products sold	11,416		11,309	
Gross profit	$ 9,935	47%	$ 4,887	30%

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.

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As noted in the tables above, Overall Gross Margin increased in the 2009 Quarter compared to the 2008 Quarter. Improvement in overall Gross Margin in the 2009 Quarter resulted primarily from: (i) the impact of inventory write-offs of $2.8 million which occurred in the 2008 Quarter due to an equipment failure in transdermal manufacturing (comprised of $1.8 million of write-offs of products manufactured for Novogyne and $1.0 million of third party HT product write-offs), as well as additional manufacturing costs incurred in the 2008 Quarter to address this issue; (ii) the reduction of approximately $0.9 million in manufacturing expenses compared to the 2008 Quarter; and (iii) improved gross margins for our Noven Therapeutics products. Overall Gross Margin in the 2009 Quarter was negatively affected by inventory write-offs of approximately $0.8 million related to Daytrana® product, of which $0.3 million related to the peel force issue.

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 2009 Quarter, Daytrana® net product revenues were $2.9 million and cost of products sold related to Daytrana® was $3.6 million, resulting in negative gross margin for the product. This compares with Daytrana® product revenues of $3.0 million and cost of products sold related to Daytrana® of $3.3 million for the 2008 Quarter. Although we have implemented new manufacturing practices and procedures in the fourth quarter of 2008 designed to improve efficiencies associated with existing Daytrana® production, 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 included in destroyed product, unless and until the peel force issue is resolved.

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 and a significant portion of these continuing costs will be allocated to Daytrana®, which we expect to negatively affect the gross margin on sales of this product for the remainder of 2009 and beyond.

Our expectations for gross margins for all of 2009 are addressed under Outlook below.

Operating Expenses

Operating expenses for the 2009 Quarter and the 2008 Quarter are summarized as follows (dollar amounts in thousands):

	Three Months Ended March 31,		
	2009	2008	% Change
Research and development	$4,653	$3,319	40%
Selling and marketing	5,013	4,823	4%
General and administrative	7,048	7,022	0%

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 $1.3 million increase in research and development expenses for the 2009 Quarter compared to the 2008 Quarter was primarily attributable to $0.8 million associated with Mesafem Phase 2 clinical trials and $0.5 million in additional research and development expenses to support our long-term growth objectives.

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Selling and Marketing

The $0.2 million increase in selling and marketing costs for the 2009 Quarter compared to the 2008 Quarter was primarily related to the timing of sample shipments to the sales force.

General and Administrative

General and administrative expenses remained substantially unchanged for the 2009 Quarter compared to the 2008 Quarter, primarily due to a $0.9 million increase in salary and related benefits, which was offset by a $0.7 million decrease in audit and accounting fees and a $0.2 million decrease in executive recruiting fees.

Other Income and Expenses

Interest and Other Income

Interest and other income decreased $0.5 million for the 2009 Quarter compared to the 2008 Quarter. This decrease was primarily attributable to sales of $39.0 million of our investments in auction rate securities at par value during 2008 and reinvestment of the proceeds into lower-yielding, cash equivalent investments.

Income Taxes

Our effective tax rate was approximately 37% and 34% for the 2009 Quarter and 2008 Quarter, 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. As of March 31, 2009 we had a net deferred tax asset of $72.0 million compared to $72.2 million at December 31, 2008. 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. Noven Therapeutics has historically reported taxable losses in these states and we expect that Noven Therapeutics will continue to incur state taxable losses in the next few years. These circumstances create negative evidence indicating the need for a valuation allowance at March 31, 2009. Our valuation allowance for state deferred tax assets was $3.5 million as of March 31, 2009 and December 31, 2008, due to uncertainty about our ability to realize these state deferred tax assets based on our projection of future state taxable income. If we determine, based on estimated future profitability of Noven Therapeutics, that these state deferred tax assets will more likely than not be realized, then the 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 earnings increase, subject to a cap of 49%. Novogyne earned sufficient income in each of the 2009 Quarter and the 2008 Quarter 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 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 2009 Quarter and the 2008 Quarter are summarized as follows (dollar amounts in thousands):

	Three Months Ended March 31,		
	2009	2008	% Change
Gross revenues	$ 48,230	$ 45,294	6%
Sales allowances	6,666	5,853	14%
Sales returns allowances	1,373	(85)	N/M
Sales allowances and returns	8,039	5,768	39%
Net revenues	40,191	39,526	2%
Cost of sales	8,077	7,808	3%
Selling, general and administrative expenses	10,711	9,012	19%
Income from operations	21,403	22,706	-6%
Interest income	94	267	-65%
Net income	$ 21,497	$ 22,973	-6%
Noven s equity in earnings of Novogyne	$ 7,545	$ 8,267	-9%

N/M Not Meaningful

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 $2.9 million for the 2009 Quarter compared to the 2008 Quarter. By product, Vivelle-Dot® and CombiPatch® increased $2.6 million and $0.3 million, respectively. The $2.6 million Vivelle-Dot® increase consisted of a $4.0 million increase related to pricing, partially offset by a $1.4 million decrease in unit sales. The decrease in unit sales of Vivelle-Dot® relates to a reduction of inventory levels in the distribution channel, as total prescriptions have increased 3% for the 2009 Quarter compared to the 2008 Quarter. The $0.3 million CombiPatch® increase was primarily attributable to pricing.

Sales allowances consist of chargebacks, Medicaid rebates, managed healthcare rebates, cash discounts and other allowances, which tend to fluctuate based on changes in gross revenues. For the 2009 Quarter and the 2008 Quarter, these sales allowances were 14% and 13% of gross revenues, respectively.

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Sales returns allowances consist of allowances for returns of expiring product. The activity in the sales returns allowances for the 2009 Quarter and the 2008 Quarter was as follows (amounts in thousands):

	Three Months Ended March 31,	
	2009	2008
Sales returns allowances included in net revenues	$ 1,373	$ (85)
Actual returns primarily for expiring product	(1,106)	(610)
Change in allowances for returns primarily for expiring product	$ 267	$ (695)

The increase in sales returns allowances for the 2009 Quarter compared to the 2008 Quarter is primarily attributable to a revision to the return accrual rate for Vivelle-Dot® in the fourth quarter of 2008 due to an increase in the rate of actual returns for the product. In addition, the 2008 Quarter benefited from a reduction in allowance for returns for prior periods due to lower actual returns at the time.

Novogyne Gross Margin

Gross margin at Novogyne was 80% for both the 2009 Quarter and the 2008 Quarter as price increases for all products in the 2009 Quarter were offset by higher sales returns allowances.

Novogyne Selling, General and Administrative Expenses

Novogyne s selling, general and administrative expenses increased $1.7 million for the 2009 Quarter compared to the 2008 Quarter primarily due to a $0.6 million increase in sales force expenses related to re-alignment to target areas, a $0.5 million increase in market research expenses due to the timing of projects, a $0.5 million increase in sample expenses due to the timing of shipments by Noven to Novogyne and a $0.1 million increase in HT litigation expenses.

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Liquidity and Capital Resources

As of March 31, 2009 and December 31, 2008, we had the following (amounts in thousands):

	March 31, 2009	December 31, 2008
Cash and cash equivalents	$72,174	$62,875
Short-term investments		3,650
Working capital	57,109	50,644

In addition to our cash and working capital, as of March 31, 2009, we owned investments in auction rate securities with a fair value of $11.8 million. Due to the current illiquid market conditions and failed auctions for auction rate securities, we continue to classify our investments in auction rate securities as non-current assets. During the 2009 Quarter, we received proceeds of $3.7 million from the redemption of an auction rate security investment at par value. On a combined basis, our cash and cash equivalents and investments in auction rate securities were as follows (amounts in thousands):

	March 31, 2009	December 31, 2008
Cash and cash equivalents	$ 72,174	$ 62,875
Investments in auction rate securities:		
Current		3,650
Non-current	11,810	11,810
Total cash and cash equivalents and investments	$ 83,984	$ 78,335

Cash provided by (used in) operating, investing and financing activities for the 2009 Quarter and the 2008 Quarter is summarized as follows (amounts in thousands):

	2009	2008
Cash flows:		
Operating activities	$ 9,954	$ (4,076)
Investing activities	2,641	17,813
Financing activities	(3,296)	(45)
Net Cash Flows	$ 9,299	$ 13,692

Operating Activities

Net cash provided by operating activities for the 2009 Quarter reflects the receipt of $12.7 million in distributions from Novogyne. Changes in working capital, including a $2.4 million decrease in accrued compensation and related liabilities and a $1.7 million increase in inventories partially offset the net cash provided by operating activities.

Net cash used in operating activities for the 2008 Quarter primarily resulted from the timing of certain payments, including inventory purchases of $6.2 million, $5.8 million in compensation and related liabilities and the payment to Shire of $3.3 million related to its 2007 withdrawal of certain Daytrana® product. The net cash used was partially offset by the receipt of $10.9 million in distributions from Novogyne.

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Investing Activities

Noven has invested a portion of its cash in investments, consisting 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 2009 Quarter was primarily attributable to $3.7 million from the redemption of an auction rate security investment at par value, partially offset by $0.8 million in equipment purchases to support operations.

Net cash provided by investing activities for the 2008 Quarter was primarily attributable to $18.8 million in sales of short-term investments at par value, partially offset by $0.3 million in equipment purchases to support operations.

Financing Activities

Net cash used in financing activities for the 2009 Quarter was primarily attributable to a $3.3 million sales milestone payment to Synthon, an obligation we assumed as part of the Noven Therapeutics acquisition.

Net cash used in financing activities for the 2008 Quarter was primarily attributable to payments on capital leases of $0.1 million.

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, license 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 2009 Quarter, our cash and cash equivalents and investments in auction rate securities increased from $78.3 million to $84.0 million. The increase primarily resulted from the receipt of $12.7 million of distributions from Novogyne. The increase in cash was partially offset by certain cash outlays during the 2009 Quarter, including (i) a $3.3 million sales milestone payment to Synthon; (ii) $1.0 million for insurance premiums; (iii) $0.8 million for equipment purchases; and (iv) cash used to fund increases in inventory and other working capital items. In April 2009, we paid $3.2 million for income taxes as our first quarterly installment for 2009. 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 its sales of Daytrana® in the first quarter of 2007, the second $25.0 million Daytrana® sales milestone payment in the third quarter of 2007 and the third and final $25.0 million Daytrana® sales milestone payment in the third quarter of 2008. We expect to pay income taxes related to the final Daytrana® milestone payment of approximately $8.5 million during 2009.

As discussed elsewhere herein, we paid Shire $3.7 million related to Shire s voluntary recalls of Daytrana® product in 2008. In addition, we established a reserve in 2008 ($3.7 million at March 31, 2009) 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 would require additional reimbursements to Shire.

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In April 2008, we made a $3.3 million milestone payment to Synthon based on our achieving specified net sales of Pexeva® during 2007. In March 2009, we made a $3.3 million milestone payment to Synthon based on our achieving specified net sales of Pexeva® during 2008.

As of March 31, 2009, we owned investments in auction rate securities with a total par value and fair value of $12.3 million and $11.8 million, respectively, 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 2008, we recorded $0.5 million of other-than-temporary impairments on our investments in auction rate securities which are classified as available-for-sale under SFAS No. 115. We redeemed $3.7 million of our investments in auction rate securities at par value during the 2009 Quarter. 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.

Changes to investments measured at fair value on a recurring basis using unobservable inputs (Level 3) during the 2009 Quarter were as follows (amounts in thousands):

Balance at December 31, 2008	$ 15,460
Redemptions of investments at par value	(3,650)
Balance at March 31, 2009	$ 11,810

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 regarding the timing of our future investment liquidations, we continue to classify our investments in auction rate securities as non-current assets as of March 31, 2009. As illiquid conditions persist in the auction market for these securities, it may become increasingly more likely that we will need to recognize additional other-than-temporary impairment charges in future periods. Such impairment charges could materially and adversely affect our consolidated financial condition and results of operations.

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 agreed not to pledge, grant any security interest in, or allow any lien or encumbrance in or on, certain of our financial assets. The facility expires in July 2009. As of the date of this report, no borrowings were outstanding under this facility and we have no long-term debt.

To the extent the sources of liquidity described above are insufficient to fund our operations, we would expect to seek to obtain funds through 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, including plant and equipment purchases, research and development activities 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. Current conditions in the credit markets and equity markets could make it particularly difficult to raise funds on attractive terms, if at all. We cannot provide any assurance that such financing will be available, if at all, in a timely manner, or on favorable terms.

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Capital expenditures totaled $0.8 million for the 2009 Quarter. We expect to fund our foreseeable capital expenditures from our operating cash flows, existing cash, short-term investments and debt.

If our transdermal products under development are successful, we may need 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.

For the 2009 Quarter and the 2008 Quarter, 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

Since December 31, 2008, 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.

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 in the Notes to Unaudited Condensed Consolidated Financial Statements.

Outlook

A summary of our current financial guidance is provided below. 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 2009, there will not be any material:

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

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

regulatory or technological developments;

changes in the supply of, demand for, or distribution of our products (including any changes resulting from competitive products, product recalls/withdrawals for which we have not already established a reserve, 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 observations on Form 483, the January 2008 warning letter or otherwise;

changes in our business relationships/collaborations; or

changes in the economy, health care reimbursement policies 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 the 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 2009 to be in the range of $110 million to $115 million, including license and contract revenues of approximately $26 million.

Gross Margin. We expect our overall gross margin, as a percentage of total net product revenues, to be in the low 40% range for full year 2009.

Research and Development Expense. We expect our consolidated research and development expense for full year 2009 to be in the low-to-mid $20 million range, reflecting (among other clinical projects) the cost of our ongoing Phase 2 study for Mesafem . Estimates of research and development expenses for future periods are subject to substantial adjustment as each product advances through various stages of development.

Selling, General and Administrative Expense. We expect our consolidated selling, general and administrative expense for full year 2009 to be in the low-to-mid $50 million range.

Noven Therapeutics. We expect to improve the pre-tax contribution from our Noven Therapeutics segment by approximately $5 million in full year 2009 compared to 2008 levels.

Equity in Earnings of Novogyne. We expect our equity in earnings of Novogyne to be in the low-to-mid $50 million range for full year 2009.

Interest Income. We expect our interest income to be less than $0.5 million for full year 2009.

Effective Tax Rate. We estimate that our effective tax rate will be in the range of 34% to 36% for full year 2009.

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Earnings Per Share. For full year 2009, we expect to report diluted earnings per share in the range of $0.95 to $1.05.

Cash. We expect to use less than $5 million of cash in 2009, including capital expenditures, reflecting our continued funding of products in development intended to drive long-term growth, including Mesafem . In 2009, we expect to generate positive cash flow from operations.

Item 3. Quantitative and Qualitative Disclosures 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 Noven s investments in 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 March 31, 2009, 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.

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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.

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, 2008. 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 March 2009, a complaint was filed in the United States District Court, Southern District of Illinois 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 CombiPatch®. The plaintiff claims compensatory and other damages in an unspecified amount. Noven has not yet been served with the complaint.

See Note 14 Commitments and Contingencies Litigation, Claims and Assessments, in the Notes to Unaudited Condensed Consolidated Financial Statements for additional information regarding legal proceedings.

Item 1A. Risk Factors

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 could 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, financial condition and results of operations. 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.

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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 first quarter of 2009:

	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]
January 1, 2009 to January 31, 2009				$19,876,238
February 1, 2009 to February 28, 2009				19,876,238
March 1, 2009 to March 31, 2009				19,876,238
Totals				$19,876,238

1 In September 2007, we established a stock repurchase program authorizing the repurchase of up to $25.0 million of our common stock. During the third quarter of 2007, Noven repurchased 322,345 shares of its 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 have a Rule 10b5-1 trading plan in place.

Item 6. Exhibits

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: May 11, 2009

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