NOVEN PHARMACEUTICALS INC
Form 10-Q
August 06, 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 June 30, 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 x

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.

Large accelerated filer o	Accelerated filer x	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 x

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 July 31, 2009
Common stock $.0001 par value	25,082,398

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

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

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PART I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Consolidated Financial Statements

NOVEN PHARMACEUTICALS, INC. AND SUBSIDIARIES

Condensed Consolidated Balance Sheets

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

	June 30, 2009	December 31, 2008
Assets		
Current Assets:		
Cash and cash equivalents	$ 69,773	$ 62,875
Investments in auction rate securities, current portion		3,650
Accounts receivable (less allowances of $548 at 2009 and $509 at 2008)	6,063	8,577
Accounts receivable Novogyne, net	7,853	6,510
Inventories	14,082	13,924
Net deferred income tax asset, current portion	6,764	7,026
Prepaid income taxes	5,602	8,178
Prepaid and other current assets	2,789	2,898
	112,926	113,638
Non-current Assets:		
Property, plant and equipment, net	35,363	34,886
Investments in auction rate securities, non-current portion	11,600	11,810
Investment in Novogyne	25,049	24,319
Net deferred income tax asset, non-current portion	64,054	65,159
Intangible assets, net	34,568	36,508
Goodwill	14,407	14,407
Deposits and other non-current assets	715	839
	185,756	187,928
	$ 298,682	$ 301,566
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable and accrued expenses	$ 9,821	$ 7,384
Accrued compensation and related liabilities	7,047	7,958
Other accrued liabilities	13,443	17,260
Current portion of long-term obligations	71	3,396
Deferred product revenue Stavzor®	1,865	1,537
Deferred license and contract revenues, current portion	25,437	25,459
	57,684	62,994
Non-current Liabilities:		

Long-term obligations, less current portion	25	27
Deferred license and contract revenues, non-current portion	64,782	77,112
Other non-current liabilities	947	997
	65,754	78,136
Total Liabilities	123,438	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; 25,351,332 and 25,235,763 issued at June 30, 2009 and December 31, 2008	3	3
Additional paid-in capital	126,330	123,290
Retained earnings	54,035	42,267
Treasury stock, at cost - 322,345 shares at June 30, 2009 and December 31, 2008	(5,124)	(5,124)
Common stock held in trust	(1,858)	(1,569)
Deferred compensation obligation	1,858	1,569
	175,244	160,436
	$ 298,682	$ 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 June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Revenues:				
Product revenues Novogyne:				
Product sales, net	$ 7,406	$ 5,553	$ 12,886	$ 7,984
Royalties	2,591	2,349	4,813	4,529
Total net product revenues Novogyne	9,997	7,902	17,699	12,513
Product revenues, net third parties	10,131	11,641	23,780	23,226
Total net product revenues	20,128	19,543	41,479	35,739
License and contract revenues	6,643	5,060	12,932	10,346
Total net revenues	26,771	24,603	54,411	46,085
Costs and Expenses:				
Cost of products sold Novogyne	3,771	3,463	7,419	6,789
Cost of products sold third parties	9,346	9,320	17,114	17,303
Total cost of products sold	13,117	12,783	24,533	24,092
Research and development	3,751	3,293	8,404	6,612
Selling and marketing	3,983	5,336	8,996	10,159
General and administrative	8,651	8,906	15,699	15,928
Total costs and expenses	29,502	30,318	57,632	56,791
Loss from operations	(2,731)	(5,715)	(3,221)	(10,706)
Equity in earnings of Novogyne	13,902	12,429	21,447	20,696
Interest and other income, net	58	500	147	1,122
Loss on auction rate securities	(210)		(210)	
Income before income taxes	11,019	7,214	18,163	11,112
Provision for income taxes	3,748	2,704	6,395	4,010

Net income	$ 7,271	$ 4,510	$ 11,768	$ 7,102
Basic earnings per share	$ 0.29	$ 0.18	$ 0.48	$ 0.29
Diluted earnings per share	$ 0.29	$ 0.18	$ 0.47	$ 0.29
Weighted average number of common shares outstanding:				
Basic	24,733	24,603	24,713	24,582
Diluted	24,859	24,754	24,814	24,710

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
Exercises of stock options/SSARs	25		262				262
Stock-based compensation expense and issuance of shares to outside directors	90		2,670				2,670
Issuance of SSARs in settlement of executive bonus			219				219
Tax benefit adjustments			(111)				(111)
Common stock held in trust	(26)					(289)	(289)
Deferred compensation obligation	26					289	289
Net income				11,768			11,768
Balance at June 30, 2009	25,028	$ 3	$ 126,330	$ 54,035	$ (5,124)	$	$ 175,244

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

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

	Six Months Ended June 30,	
	2009	2008
Cash flows from operating activities:		
Net income	$ 11,768	$ 7,102
Adjustments to reconcile net income to net cash flows provided by (used in) operating activities:		
Depreciation and amortization	3,899	4,571
Loss on disposal of property, plant and equipment	82	37
Inventory write-offs	4,169	3,871
Loss on auction rate securities	210	
Stock based compensation expense	2,670	2,345
Deferred income taxes	1,256	(6,946)
Recognition of deferred license and contract revenues	(12,932)	(10,346)
Equity in earnings of Novogyne	(21,447)	(20,696)
Distributions from Novogyne	18,497	17,247
Other noncash items	(9)	(40)
Changes in operating assets and liabilities:		
Decrease (increase) in accounts receivable trade, net	2,514	(1,346)
Increase in milestone payment receivable Shire		(25,000)
(Increase) decrease in accounts receivable Novogyne, net	(1,343)	2,091
Increase in inventories	(3,319)	(8,013)
Decrease in prepaid income taxes	4,796	3,129
Decrease in prepaid and other current assets	109	113
Decrease (increase) in deposits and other assets	166	(176)
Increase (decrease) in accounts payable and accrued expenses	2,517	(1,897)
Decrease in accrued compensation and related liabilities	(692)	(4,324)
(Decrease) increase in other accrued liabilities	(4,781)	1,923
Increase in deferred license and contract revenues	580	26,345
Increase in deferred product revenue Stavzor®	328	
(Decrease) increase in other liabilities	(74)	97
Cash flows provided by (used in) operating activities	8,964	(9,913)
Cash flows from investing activities:		
Purchases of property, plant and equipment	(2,185)	(1,205)
Payments for intangible assets	(413)	(152)
Purchase of company-owned life insurance	(53)	(335)
Purchases of investments		(62,800)
Proceeds from sale of investments	3,650	99,175
Cash flows provided by investing activities	999	34,683

Cash flows from financing activities:		
Proceeds from exercise of stock options	262	10
Payments of long-term obligations	(3,327)	(3,348)
Cash flows used in financing activities	(3,065)	(3,338)
Net increase in cash and cash equivalents	6,898	21,432
Cash and cash equivalents, beginning of period	62,875	13,973
Cash and cash equivalents, end of period	$ 69,773	$ 35,405

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.

On July 14, 2009, Noven and Hisamitsu Pharmaceutical Co., Inc. (Hisamitsu) entered into a definitive merger agreement pursuant to which Hisamitsu proposed to acquire Noven for total cash consideration of approximately $428 million, or $16.50 per share, in an all-cash tender offer for 100% of the outstanding shares of Noven. The tender offer commenced on July 23, 2009. If successful, the tender offer would be followed by the merger of a Hisamitsu subsidiary with and into Noven, with Noven surviving as a wholly-owned subsidiary of Hisamitsu. Refer to Note 16 Subsequent Event Merger Agreement for further information.

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 in 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 HT 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 disclosures.

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), and as supplemented by Part II Item 1A Risk Factors of this Quarterly Report on Form 10-Q. Accordingly, the results of operations and cash flows for the periods presented are not, and should not be construed as, necessarily indicative of the results of operations or cash flows which may be reported for the remainder of 2009 or for periods thereafter.

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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.

Noven Therapeutics commercially launched Stavzor® in August 2008. Noven sells Stavzor® primarily to pharmaceutical wholesalers. 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®. Returns are no longer permitted once the product has been dispensed through patient prescriptions. 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 utilize a sample of Stavzor® prescription data from pharmacies, hospitals, mail order and other retail outlets and project this sample on a national level. Noven will continue to recognize revenue on product shipments of Stavzor® to Noven s customers based on prescription units dispensed until Noven has sufficient sales history to reasonably estimate product returns. Noven recognized $0.9 million and $1.6 million of net revenues for Stavzor® in the three and six months ended June 30, 2009, respectively, and $1.9 million and $1.5 million of deferred product revenue relating to Stavzor® was reflected on Noven s Condensed Consolidated Balance Sheet as of June 30, 2009 and December 31, 2008, respectively.

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 June 2009, the Financial Accounting Standards Board (FASB) issued SFAS No. 168, The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles, a replacement of FASB Statement No. 162 (SFAS No. 168). SFAS No. 168 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. SFAS No. 168 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. Noven does not expect the adoption of SFAS No. 168 to impact Noven s consolidated financial condition, results of operations or cash flows.

In May 2009, the FASB issued SFAS No. 165, Subsequent Events (SFAS No. 165). SFAS No. 165 provides guidance on management s assessment of subsequent events. SFAS No. 165 clarifies that management must evaluate, as of each reporting period, events or transactions that occur after the balance sheet date through the date that the financial statements are issued. Management must perform its assessment for both interim and annual financial reporting periods. SFAS No. 165 is effective prospectively for interim and annual periods ending after June 15, 2009. Noven adopted SFAS No. 165 during the second quarter of 2009, and its adoption did not impact Noven s consolidated financial condition, results of operations or cash flows. Noven evaluated subsequent events through the time these Unaudited Condensed Consolidated Financial Statements were filed with the SEC on August 6, 2009.

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In April 2009, the FASB issued FASB Staff Position (FSP) No. 115-2 and 124-2, Recognition and Presentation of Other-Than-Temporary Impairments (FSP 115-2 and 124-2). FSP 115-2 and 124-2 modifies the existing other-than-temporary impairment (OTTI) model for investments in debt securities. Under FSP 115-2 and 124-2, the primary change to the OTTI model for debt securities is the change in focus from an entity s intent and ability to hold a security until recovery. Instead, an OTTI is triggered if (1) an entity has the intent to sell the security, (2) it is more likely than not that it will be required to sell the security before recovery, or (3) it does not expect to recover the entire amortized cost basis of the security. In addition, FSP 115-2 and 124-2 changes the presentation of an OTTI in the income statement if the only reason for recognition is a credit loss. That is, if the entity has the intent to sell the security or it is more likely than not that it will be required to sell the security, the entire impairment will be recognized in earnings. However, if the entity does not intend to sell the security and it is not more likely than not that the entity will be required to sell the security, but the security has suffered a credit loss, the impairment charge will be separated into the credit loss component, which is recorded in earnings, and the remainder of the impairment charge, which is recorded in other comprehensive income. FSP 115-2 and 124-2 is effective for interim and annual periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. Noven does not meet the conditions necessary to recognize the noncredit loss component of its auction rate securities in other comprehensive income. Accordingly, Noven did not reclassify any previously recognized other-than-temporary impairment losses from retained earnings to accumulated other comprehensive income, and the adoption of FSP 115-2 and 124-2 did not have a material impact Noven s consolidated financial condition, results of operations or cash flows.

In April 2009, the FASB issued FSP No. FAS 157-4, Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly (FSP 157-4). FSP 157-4 provides guidance on (1) estimating the fair value of an asset or liability when the volume and level of activity for the asset or liability have significantly decreased and (2) identifying transactions that are not orderly. FSP 157-4 does not change the objective of fair value measurements when market activity declines. FSP 157-4 emphasizes that fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date under current market conditions. FSP 157-4 reinforces that fair value is a current market-based measurement and not an entity-specific or hypothetical future market-based measurement. The guidance in FSP 157-4 supersedes FSP No. 157-3, Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active. FSP 157-4 is effective for interim and annual periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. The adoption of FSP 157-4 did not have a material impact Noven s consolidated financial condition, results of operations or cash flows.

In November 2008, the Emerging Issues Task Force (EITF) of the 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 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.

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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 No. 141(R)-1, Accounting for Assets and Liabilities Assumed in a Business Combination That Arise from Contingencies (FSP 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 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 141(R)-1, to any business combinations consummated after December 31, 2008.

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.

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3. CASH FLOW INFORMATION:

Income Tax and Interest Payments

Cash payments for income taxes were $3.8 million and $7.5 million for the six months ended June 30, 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. For the six months ended June 30, 2009 and 2008, Novogyne paid $2.2 million and $1.8 million, respectively, primarily to the New Jersey Department of Revenue, representing Noven s portion of Novogyne s estimated state income tax payment. 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 six months ended June 30, 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 six months ended June 30, 2009 or 2008.

Non-cash Investing Activities

Noven recorded $0.2 million in unrealized losses on its investments in auction rate securities for the six months ended June 30, 2009. Noven determined that the $0.2 million unrealized decline in fair value of its investments in auction rate securities was other-than-temporary. As a result, Noven recognized this impairment in its Condensed Consolidated Statements of Operations.

Noven recorded $0.5 million in unrealized losses on its investments in auction rate securities for the six months ended June 30, 2008. The unrealized losses were recorded as a reduction of stockholders equity through other comprehensive income. In the fourth quarter of 2008, Noven determined that the $0.5 million unrealized decline in fair value of its investments in auction rate securities was other-than-temporary. As a result, Noven recognized this impairment in its 2008 Consolidated Statements of Operations contained in its Form 10-K.

Non-cash Financing Activity

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 six months ended June 30, 2009.

4. INVESTMENTS AVAILABLE-FOR-SALE:

At June 30, 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 $11.6 million, respectively. Noven liquidated $3.7 million of its investments in auction rate securities at par value during the six months ended June 30, 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 June 30, 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 investments in auction rate securities was other-than-temporary. As a result, Noven recognized this impairment in its 2008 Consolidated Statement of Operations contained in Noven s Form 10-K. In the second quarter of 2009, Noven recognized a $0.2 million other-than-temporary impairment in fair value of its investments in auction rate securities in its Condensed Consolidated Statements of Operations. The determination that the unrealized losses were other-than-temporary was primarily based on the length of time that the securities had 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 in 2008. As of June 30, 2009, the total par value and fair value of Noven s investments in auction rate securities were $12.3 million and $11.6 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 six months ended June 30, 2009 were as follows (in thousands):

Balance at December 31, 2008	$ 15,460
Redemptions of investments at par value	(3,650)
Unrealized losses, other-than-temporary	(210)
Balance at June 30, 2009	$ 11,600

6. INVENTORIES:

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

	June 30, 2009	December 31, 2008
Finished goods	$ 2,796	$ 3,200
Work in process	3,300	2,510
Raw materials	7,986	8,214
	$ 14,082	$ 13,924

During the six months ended June 30, 2009, Noven recorded a $4.2 million charge to cost of products sold related to the write-off of inventories, of which approximately $3.8 million related to Daytrana® product, (including $1.0 million in charges for the active methylphenidate ingredient (AMI) used in this Daytrana® product) and $0.4 million related to other products in the ordinary course of business. During the six months ended June 30, 2008, Noven recorded a $3.9 million charge to cost of products sold related to the write-off of inventories. These write-offs primarily related to an equipment failure in transdermal manufacturing during the three months ended March 31, 2008 which resulted in $1.8 million of Novogyne product write-offs and $1.0 million of third party HT product write-offs, as well as inventory write-offs of approximately $0.8 million during the three months ended June 30, 2008 primarily due to Daytrana® product that exhibited high peel force characteristics (including $0.2 million in charges for the AMI

used in this Daytrana® product).

Shire plc (Shire) retains title to the 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 six months ended June 30, 2009, resulting in a $0.1 million payment from Shire to Noven during the six months ended June 30, 2009. During the six months ended June 30, 2009, Noven used $1.9 million of Shire s AMI in the finished product, and had $3.7 million and $2.6 million of consignment AMI inventory on hand at June 30, 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 June 30, 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 June 30, 2009 and December 31, 2008 (amounts in thousands):

	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Weighted-Average Remaining Life (years)
As of June 30, 2009				
Patent development costs	$ 5,342	$ (3,303)	$ 2,039	7.5
Acquired product intangibles	39,290	(7,179)	32,111	8.5
Non-competition agreements	530	(414)	116	1.0
Favorable lease	790	(488)	302	1.3
	$ 45,952	$ (11,384)	$ 34,568	8.4
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	1.3
Favorable lease	790	(368)	422	1.8
	$ 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 $2.4 million and $2.3 million for the six months ended June 30, 2009 and 2008, respectively.

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Noven estimates that the annual amortization expense for intangible assets held at June 30, 2009 for each of the five years through 2014 is as follows (amounts in thousands):

	Remainder of 2009	2010	Years Ending December 31, 2011	2012	2013	2014
Cost of goods sold:						
Intellectual property	$ 2,123	$ 4,201	$ 4,136	$ 4,123	$ 4,069	$ 3,988
General and administrative:						
Non-compete and favorable lease agreements	182	236				
Total	$ 2,305	$ 4,437	$ 4,136	$ 4,123	$ 4,069	$ 3,988

8. OTHER ACCRUED LIABILITIES:

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

	June 30, 2009	December 31, 2008
Income taxes payable	$ 1,555	$ 2,197
Accrued medicaid and other rebates	2,633	2,726
Accrued market withdrawal costs		3,598
Allowance for product returns	2,931	3,070
Daytrana® peel force reserves	1,008	
Other accrued liabilities	5,316	5,669
Total other accrued liabilities	$ 13,443	$ 17,260

9. EQUITY PLANS:

Noven established the 2009 Equity Incentive Plan (the 2009 Plan) on May 22, 2009, which succeeds Noven s 1999 Long-Term Incentive Plan (the 1999 Plan , and collectively with the 2009 Plan, the Plans). The 2009 Plan provides for the granting of stock options, stock-settled stock appreciation rights (SSARs), stock awards (including restricted common stock), and other permitted awards to selected individuals for up to 1.9 million shares plus the number of shares of common stock available under the 1999 Plan which were not subject to an outstanding award on May 22, 2009. As of June 30, 2009, 2.1 million shares were available for issuance under the 2009 Plan. The number of shares available for issuance under the 2009 Plan may increase due to the lapse, expiration or termination of shares under the Plans.

The terms and conditions of equity awards (including price, vesting schedule, term and number of shares) under the 2009 Plan are determined by the Compensation Committee of the Board of Directors, which administers the 2009 Plan. The per share exercise price of: (i) SSARs and stock options cannot be less than the fair market value of the common stock on the date of grant; and (ii) incentive stock options granted to employees owning in excess of 10% of Noven s issued and outstanding common stock cannot be less than 110% of the fair market value of the common stock on the date of grant.

Each equity award granted under the 2009 Plan is exercisable after the period(s) specified in the relevant grant agreement, and no equity award can be exercised after ten years from the date of grant (or five years from the date of grant in the case of a grantee of an incentive stock option holding more than 10% of the issued and outstanding shares

of Noven s common stock). At June 30, 2009, there were 2.6 million stock options and 1.4 million SSARs outstanding under the Plans.

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Prior to January 1, 2006, all awards granted to employees and directors under the 1999 Plan were stock options. In 2006, Noven began granting 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)).

The weighted average grant date fair values of SSARs granted during the six months ended June 30, 2009 and 2008 were $4.03 and $4.55, respectively, using the Black-Scholes option-pricing model with the assumptions below:

	2009	2008
Volatility	51.9%	50.2%
Risk free interest rate	1.81%	3.18%
Expected life (years)	4.0	4.8
Dividend yield	0.0%	0.0%

Total stock-based compensation recognized in Noven s Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2009 and 2008 was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Selling and marketing	$ 156	$ 169	$ 322	$ 323
General and administrative	878	1,159	1,737	1,627
Research and development	167	85	312	176
Total cost of products sold	171	74	299	219
	$ 1,372	$ 1,487	$ 2,670	$ 2,345
Tax benefit recognized related to compensation expense	$ 521	$ 511	$ 1,012	$ 804

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. Cash received from stock option exercises under stock-based compensation arrangements for the six months ended June 30, 2009 was $0.3 million. The tax benefit realized on the tax deductions from stock option exercises and the total intrinsic value of stock options exercised for the six months ended June 30, 2009 were not material. Due to the small number of exercises during the six months ended June 30, 2008, cash received from stock option exercises, the tax benefit realized from exercises, and the total intrinsic value of stock options exercised for the six months ended June 30, 2008 were not material.

Noven granted 90,469 and 70,847 shares of restricted stock to Noven s non-employee directors in May 2009 and June 2008, 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 June 30, 2009 and December 31, 2008, there were a total of 118,393 and 92,818 shares of common stock in the rabbi trust, respectively.

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Stock option and SSAR transactions under the Plans for the six months ended June 30, 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	109	9.71		
Exercised	(25)	10.43		
Canceled or expired	(215)	15.38		
Outstanding at end of period	3,962	$ 14.15	4.4	$ 7,530
Exercisable at end of period	1,781	$ 16.25	2.6	$ 2,152
Shares of common stock reserved	6,166			

As of June 30, 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 $10.5 million before the effect of income taxes. The weighted average period over which this compensation cost is expected to be recognized is 5.3 years. The total fair value of equity grants that vested in the six months ended June 30, 2009 was $1.4 million. As of June 30, 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 $14.30, a $6.7 million aggregate intrinsic value and a weighted average remaining life of 4.2 years at June 30, 2009.

Noven has granted a total of 492,778 shares of restricted stock under the Plans. The following table summarizes information regarding Noven s restricted stock at June 30, 2009 (share amounts in thousands):

	Shares	Weighted Average Grant-Date Fair Value
Nonvested at December 31, 2008	221	$ 9.43
Granted	91	10.28
Vested	(59)	10.67
Nonvested at June 30, 2009	253	$ 9.45

The consumption of the tender offer in accordance with the merger agreement with Hisamitsu described in Note 16 Subsequent Event Merger Agreement will constitute a change in control under the Plans. Upon the occurrence of the change in control, all outstanding unvested equity awards (including stock options, SSARs and restricted stock) will immediately vest and each holder thereof will become entitled to receive an amount in cash equal to (i) in the case of unvested stock options and SSARs, the difference between the exercise price and the tender offer purchase price of $16.50 per share underlying such options and SSARs, and (ii) in the case of unvested restricted stock and restricted

stock units, the tender offer purchase price of $16.50 per share.

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10. INCOME TAXES:

As of June 30, 2009 and 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 tax rate due to approximately $0.4 million in related federal tax benefit. Interest and penalties related to income taxes are classified as a component of income tax expense. Approximately $0.5 million was accrued for interest and penalties as of June 30, 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 June 30, 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 does not expect the outcome of the IRS examination to materially impact its tax liabilities. Noven files and remits state income taxes in various states where Noven has determined it is required to file state income taxes. Noven s filings with those states remain open for audit for the years 2004 through 2007. In June 2009, the State of New Jersey Division of Taxation concluded an examination of Noven s tax returns for 2004 through 2007. The outcome of this examination did not impact Noven s tax liabilities. Other than the IRS examination 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.

At June 30, 2009 and December 31, 2008, net deferred tax assets were $70.8 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 June 30, 2009 and December 31, 2008. Noven s valuation allowance for state deferred tax assets was $3.7 million and $3.5 million as of June 30, 2009 and December 31, 2008, respectively, 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.

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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. 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.

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.

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During the three and six months ended June 30, 2009 and 2008, Noven had the following transactions with Novogyne (amounts in thousands):

	Three Months		Six Months	
	2009	2008	2009	2008
Revenues:				
Product sales	$ 7,406	$ 5,553	$ 12,886	$ 7,984
Royalties	2,591	2,349	4,813	4,529
	$ 9,997	$ 7,902	$ 17,699	$ 12,513
Reimbursed expenses	$ 8,753	$ 7,381	$ 16,899	$ 14,653

Reimbursed expenses are primarily comprised of selling and marketing expenses paid by Noven on behalf of Novogyne. As of June 30, 2009 and December 31, 2008, Noven had amounts due from Novogyne of $7.9 million and $6.5 million, respectively.

The Unaudited Condensed Statements of Operations of Novogyne for the three and six months ended June 30, 2009 and 2008 are as follows (amounts in thousands):

	Three Months		Six Months	
	2009	2008	2009	2008
Gross revenues	$ 56,435	$ 50,054	$ 104,665	$ 95,348
Sales allowances	7,357	5,702	14,023	11,555
Sales return allowances	1,118	585	2,491	500
Sales allowances and returns	8,475	6,287	16,514	12,055
Net revenues	47,960	43,767	88,151	83,293
Cost of sales	9,441	8,788	17,518	16,596
Selling, general and administrative expenses	10,196	9,798	20,907	18,810
Income from operations	28,323	25,181	49,726	47,887
Interest income	67	174	161	441
Net income	$ 28,390	$ 25,355	$ 49,887	$ 48,328
Noven s equity in earnings of Novogyne	$ 13,902	$ 12,429	$ 21,447	$ 20,696

The activity in the Investment in Novogyne account for the six months ended June 30, 2009 is as follows (amounts in thousands):

Investment in Novogyne, beginning of period	$ 24,319
Equity in earnings of Novogyne	21,447
Cash distributions from Novogyne	(18,497)
Deemed distribution by Novogyne for state income tax payment	(2,220)

Investment in Novogyne, end of period	$ 25,049

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Subject to the approval of Novogyne s management committee, Novogyne may, from time to time, distribute cash to Novartis and Noven based upon a contractual formula. For the three and six months ended June 30, 2009, Noven received cash distributions from Novogyne representing return on investment of $5.8 million and $18.5 million, respectively. For the three and six months ended June 30, 2008, Noven received cash distributions from Novogyne representing return on investment of $6.3 million and $17.2 million, respectively. In addition, as discussed in Note 3 Cash Flow Information, tax payments of $2.2 million and $1.8 million were made by Novogyne on Noven s behalf primarily to the New Jersey Department of Revenue during the six months ended June 30, 2009 and 2008, respectively. These amounts were recorded as reductions in the investment in Novogyne when received (or in the case of tax payments, when paid).

13. SHARE REPURCHASE PROGRAM:

In September 2007, Noven s Board of Directors authorized a share repurchase program under which Noven may acquire up to $25.0 million of its common stock. 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 June 30, 2009 and December 31, 2008, and no additional shares have been repurchased under the program since the fourth quarter of 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.

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.

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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 June 30, 2009 and 2008, Noven s net product sales of Daytrana® to Shire were $1.6 million and $2.7 million, respectively. During the six months ended June 30, 2009 and 2008, Noven s net product sales of Daytrana® to Shire were $4.5 million and $5.7 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.

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.

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.

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Novartis has advised Noven that Novartis is currently named as a defendant in at least 30 additional lawsuits that include approximately 31 plaintiffs that allege liability in connection with personal injury claims allegedly arising from the use of HT patches distributed and sold by Novartis and Novogyne, including Noven s Vivelle-Dot®, Vivelle®, and CombiPatch® products. Novogyne has been named as a defendant in one lawsuit in addition to 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 June 30, 2009 was $10.0 million. Novogyne has established reserves in the amount of $10.5 million with an offsetting insurance recovery of $7.8 million for expected defense and settlement expenses as well as for estimated future cases alleging use of Noven s HT products. This accrual represents Novartis management s best estimate as of June 30, 2009.

In June 2007, Johnson Matthey Inc. filed a complaint in the United States District Court for the Eastern District of Texas alleging that Noven was infringing one of its patents through Noven s manufacture and sale of the Daytrana® product. The plaintiff is seeking injunctions from further infringement and claiming compensatory and other damages. In July 2007, Johnson Matthey Inc. added Shire US Inc. and Shire Pharmaceuticals Ireland Limited as co-defendants in this lawsuit. Fact discovery concluded in June 2009, though Johnson Matthey Inc. has sought additional fact discovery. The claim construction hearing was held in July 2009, and in a written opinion that same month, the Court adopted a claim construction consistent with Noven s proposed construction. Summary judgment motions are due in August 2009 and jury selection is scheduled to commence in October 2009.

As of June 30, 2009 and December 31, 2008, Noven had reserved $0.1 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.

On July 15, 2009, a plaintiff filed a purported stockholder class action complaint in the Court of Chancery of the State of Delaware (the First Complaint) in connection with the proposed transaction with Hisamitsu. The First Complaint names as defendants the members of the Board of Directors, as well as Noven and Hisamitsu. The plaintiff claims that Noven s directors breached their fiduciary duties to Noven s stockholders, and further claims that Hisamitsu participated in or aided and abetted the purported breach of fiduciary duty. In support of the plaintiff s claims, the First Complaint alleges that the proposed transaction between Noven and Hisamitsu involves an unfair price, an inadequate sales process and unreasonable deal protection devices, among other things. The First Complaint seeks to enjoin the transaction and seeks attorneys and other fees and costs, in addition to seeking other relief.

A second plaintiff filed a purported stockholder class action complaint on July 15, 2009 in the Eleventh Judicial Circuit of Florida and later filed a nearly identical complaint in the Court of Chancery of the State of Delaware on July 23, 2009. The complaints name as defendants Noven and each of its Board members and assert similar claims and requests for relief as those asserted in the First Complaint.

On July 16, 2009, a third plaintiff filed in the Court of Chancery of the State of Delaware a purported stockholder class action complaint relating to the proposed transaction with Hisamitsu. The complaint names as defendants the members of the Board of Directors as well as Noven and Hisamitsu, and asserts claims and requests relief nearly identical to the First Complaint.

On July 17, 2009, a fourth plaintiff filed a purported class action complaint in the Eleventh Judicial Circuit of Florida, which names as defendants the members of the Board of Directors as well as Noven and Hisamitsu. Noven has been provided with a copy of an amendment to this complaint, which plaintiffs counsel indicated would be filed in July 2009. The amended complaint alleges that Noven s directors breached their fiduciary duties to Noven s stockholders and that Noven and Hisamitsu aided and abetted the directors breaches of fiduciary duties. The complaint makes allegations similar to those contained in the First Complaint as well as an allegation that Noven s disclosure contained in its Solicitation/Recommendation Statement on Schedule 14D-9 was inadequate and omitted material information.

On July 24, 2009, a fifth plaintiff filed a purported class action complaint in the Eleventh Judicial Circuit of Florida, which names as defendants the members of the Board of Directors as well as Noven and Hisamitsu, and asserts claims and requests relief nearly identical to the First Complaint.

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Noven believes that the allegations set forth in all of these complaints lack merit and will contest them vigorously.

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.

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 in November 2008 related to its June and August 2008 recalls, of which approximately $3.1 million was 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 Noven believes helped improve efficiencies associated with existing Daytrana® production. Product that is determined to be probable of developing peel force issues during its shelf life based on the results of 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 and six months ended June 30, 2009, Daytrana® cost of products sold exceeded Noven s Daytrana® net revenues by $3.7 million and $4.4 million, respectively. The negative margin was primarily due to inventory write-offs and associated AMI reserves of approximately $3.0 million and $3.8 million related to Daytrana® product for the three and six months ended June 30, 2009, respectively, of which $3.0 million and $3.3 million, respectively, related to the peel force issue.

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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, 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 has agreed to reimburse Shire $3.4 million related to this recall. The $3.4 million was charged to operations in 2008 for Daytrana® product determined to be probable of being voluntarily withdrawn or recalled from the market prior to the expiration of its shelf life. In addition, as of June 30, 2009, Noven has reserved $3.3 million for Daytrana® inventory and associated AMI that is at risk of developing peel force issues during the product s shelf life, of which $2.3 million was included in inventory reserves and $1.0 million was included in other accrued liabilities. 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 February 2009, Noven received from the FDA a list of observations on Form 483 following an on-site inspection of its manufacturing facilities. Similar to 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 and the observations on Form 483, as well as the production and other issues involving Daytrana®, could result in additional regulatory action, including fines, recalls of products, injunctions, seizures, suspension of production or withdrawal of the approval of products. Any such regulatory action would be expected to have a material adverse effect on Noven, including the potential for litigation related to this matter, harm to Noven s reputation and various costs associated with the foregoing.

CONTRACT AND LICENSE AGREEMENTS:

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

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 June 30, 2009, no borrowings were outstanding under this facility. The agreement has been amended to expire in August 2009. Noven is in the process of negotiating a new credit facility agreement.

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INVESTMENT ADVISOR:

In connection with the negotiation and execution of the merger agreement between Noven and Hisamitsu, Noven has incurred transaction-related costs for legal and other professional services. During the three months ended June 30, 2009, Noven charged approximately $1.5 million of transaction-related costs to operations. In addition, under the terms of its agreement with its investment advisor, Noven has agreed to pay the advisor a fee, based upon a percentage of the aggregate value of the transaction, in the amount of approximately $6.8 million, of which $2.0 million was paid in July 2009 upon the advisor s delivery of a fairness opinion. The balance of the advisor s fee is payable only if the transaction closes. In addition to the advisory fee, the advisor is entitled to reimbursement of certain expenses, including the fees and disbursements of its legal counsel.

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 $10.0 million and $7.9 million for the three months ended June 30, 2009 and 2008, respectively. Noven Transdermals net revenues include product revenues from sales to Novogyne of $17.7 million and $12.5 million for the six months ended June 30, 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 June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Net Revenues:				
Noven Transdermals				
Product revenues	$ 14,542	$ 12,968	$ 29,319	$ 23,459
License and contract revenues	6,643	5,060	12,932	10,346
	21,185	18,028	42,251	33,805
Noven Therapeutics				
Product revenues	5,586	6,575	12,160	12,280
Net revenues	$ 26,771	$ 24,603	$ 54,411	$ 46,085
Segment profit (loss):				
Noven Transdermals	$ 9,988	$ 7,054	$ 21,669	$ 13,364
Noven Therapeutics[1]	(317)	(570)	(787)	(1,530)
Equity in earnings of Novogyne	13,902	12,429	21,447	20,696
Total segment profit	$ 23,573	$ 18,913	$ 42,329	$ 32,530
Reconciliation of segment profit to income before income taxes:				
Segment profit	$ 23,573	$ 18,913	$ 42,329	$ 32,530
Research and development	(3,751)	(3,293)	(8,404)	(6,612)
General and administrative	(8,651)	(8,906)	(15,699)	(15,928)
Interest and other income, net	58	500	147	1,122
Loss on auction rate securities	(210)		(210)	
Income before income taxes	$ 11,019	$ 7,214	$ 18,163	$ 11,112

[1] Segment loss for Noven Therapeutics includes patent amortization of $0.9 million for each of the three months ended June 30, 2009 and 2008, and

$1.9 million and $1.8 million for the six months ended June 30, 2009 and 2008, respectively.

Segment assets consisted of the following as of June 30, 2009 and December 31, 2008 (amounts in thousands):

	June 30, 2009	December 31, 2008
Noven Transdermals	$ 56,488	$ 56,362
Noven Therapeutics	53,524	55,902
Novogyne	25,049	24,319
Assets not allocated to segments[2]	163,621	164,983
Total Assets	$ 298,682	$ 301,566

[2] Assets not allocated to segments consist primarily of cash and cash equivalents, investments in auction rate securities and deferred income taxes.

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16. SUBSEQUENT EVENT MERGER AGREEMENT:

On July 14, 2009, Noven and Hisamitsu entered into a definitive merger agreement pursuant to which Hisamitsu has proposed to acquire Noven for total cash consideration of approximately $428 million, or $16.50 per share, in an all-cash tender offer for 100% of the outstanding shares of Noven.

The merger agreement was unanimously approved by the boards of directors of both Noven and Hisamitsu. The tender offer commenced on July 23, 2009, and will expire at midnight on August 19, 2009, unless extended pursuant to the terms and conditions contained in the merger agreement. Consummation of the tender offer is subject to the satisfaction of certain customary conditions, including the tender of a majority of the outstanding shares of Noven on a fully-diluted basis and the receipt of regulatory approvals. The tender offer, if successful, would be followed, after satisfaction or waiver of conditions in the merger agreement, by the merger of a subsidiary of Hisamitsu with and into Noven, with Noven surviving as a wholly-owned subsidiary of Hisamitsu. Noven has been advised by Hisamitsu that after the merger is completed it expects that Noven will continue as a standalone business unit, operating at its current locations in Miami and New York with its existing work force.

Hisamitsu s shareholders are not required to vote on or approve the tender offer or merger. Prior to commencing the tender offer, Hisamitsu was the beneficial owner of 1,240,000 shares of Noven common stock, representing approximately 4.9% of shares outstanding.

Following the consummation of the transactions contemplated by the merger agreement, Jeffrey F. Eisenberg, currently Noven s Executive Vice President and President of the Novogyne joint venture, will be named Noven s President and Chief Executive Officer. He will assume the responsibilities of Peter Brandt, who will leave Noven after the proposed merger is completed.

As described in more detail in Note 14, Commitments and Contingencies Investment Advisor, in July 2009, Noven paid $2.0 million to its investment advisor upon the advisor s delivery of a fairness opinion. The balance of the advisor s $6.8 million fee is payable only if the transaction closes.

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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 June 30, 2009, and our consolidated results of operations for the three months ended June 30, 2009 (the 2009 Quarter) and June 30, 2008 (the 2008 Quarter), and the six months ended June 30, 2009 (the 2009 Period) and June 30, 2008 (the 2008 Period). 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; and

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

This discussion should be read in conjunction with Noven s Unaudited Condensed Consolidated Financial Statements for the three and six months ended June 30, 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 $7.3 million ($0.29 diluted earnings per share), compared to net income of $4.5 million ($0.18 diluted earnings per share) for the 2008 Quarter. Our net revenues in the 2009 Quarter were $26.8 million, a 9% increase over the 2008 Quarter. The increase in net revenues in the 2009 Quarter reflects increased product sales to Novogyne in the U.S. and to Novartis Pharma A.G. outside the U.S. primarily due to the timing of orders and shipments, 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). The increase in net revenues in the 2009 Quarter was partially offset by lower sales of Pexeva® and Daytrana® compared to the 2008 Quarter.

Gross margin, as a percentage of net product revenues, was 35% in both the 2009 and 2008 Quarters. 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; however, these improvements were offset by reserves for Daytrana® inventory and associated AMI that is at risk of developing peel force issues during the product s shelf life. Gross margin for the 2008 Quarter was negatively affected by the impact of increased quality assurance activities and expenses, primarily related to Daytrana® production. We expect the peel force issue to continue to negatively affect margins until this issue is resolved.

Research and development expenses in the 2009 Quarter increased $0.5 million, or 14%, 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 decreased $1.4 million, or 25%, primarily due to additional costs incurred in 2008 associated with the commercial launch of Stavzor®. Compared to the 2008 Quarter, general and administrative expenses decreased $0.3 million, or 3%, primarily due to charges for reimbursements to Shire for voluntary recalls of certain Daytrana® product in the 2008 Quarter, partially offset by transaction costs in the 2009 Quarter related to the proposed merger with Hisamitsu.

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We recognized $13.9 million in equity in earnings of Novogyne in the 2009 Quarter, an increase of 12% compared to the 2008 Quarter. Net revenues at Novogyne increased 10% to $48.0 million in the 2009 Quarter compared to the 2008 Quarter, reflecting higher gross sales of Vivelle-Dot®, driven by improved pricing and increased prescription demand. Novogyne s gross margin for the 2009 Quarter remained unchanged at 80%. Novogyne s selling, general and administrative expenses for the 2009 Quarter were $10.2 million, a 4% increase over the 2008 Quarter, primarily due to the timing of expenses in support of Vivelle-Dot®. Novogyne s net income for the 2009 Quarter increased 12% compared to the 2008 Quarter to $28.4 million.

At June 30, 2009, we had $69.8 million in cash and cash equivalents and $11.6 million in investments in auction rate securities at fair value. This compares to $62.9 million in cash and cash equivalents and $15.5 million in investments in auction rate securities at fair value at December 31, 2008. Our investments in auction rate securities at June 30, 2009 were classified as non-current on our balance sheet. As of June 30, 2009, no amounts were outstanding under our $15.0 million revolving credit facility.

Total prescriptions for Vivelle-Dot® increased 5% in the 2009 Quarter compared to the 2008 Quarter, and total prescriptions for Novogyne s HT products, taken as a whole, increased 5% over the same period. By comparison, the United States HT market declined 3% for the same period. Total prescriptions for Daytrana® decreased 14% in the 2009 Quarter compared to the 2008 Quarter, while prescriptions for ADHD stimulant therapies as a class increased 10% over the same period. Total prescriptions for Pexeva® decreased 20% 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 3%. Reflecting ongoing generic substitution, total prescriptions for Lithobid® decreased 29% in the 2009 Quarter compared to the 2008 Quarter.

As discussed in Note 16 Subsequent Event Merger Agreement to our Unaudited Condensed Consolidated Financial Statements, on July 14, 2009, we entered into a definitive merger agreement with Hisamitsu pursuant to which Hisamitsu has proposed to acquire Noven for $16.50 per share in an all-cash tender offer for 100% of the outstanding shares of Noven. Following the tender offer, Hisamitsu has agreed to merge a wholly-owned subsidiary of Hisamitsu with and into Noven, subject to satisfaction or waiver of conditions in the merger agreement. The tender offer commenced on July 23, 2009 and will expire at midnight on August 19, 2009, unless extended.

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 and liquidity and capital resources 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.

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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.

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 was 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 we believe helped improve efficiencies associated with existing Daytrana® production. Product that is determined to be probable of developing peel force issues during its shelf life based on the results of our 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 and 2009 Period, Daytrana® cost of products sold exceeded our Daytrana® net revenues by $3.7 million and $4.4 million, respectively. The negative margin was primarily due to inventory write-offs and associated AMI reserves of approximately $3.0 million and $3.8 million related to Daytrana® product in the 2009 Quarter and 2009 Period, respectively, of which $3.0 million and $3.3 million, respectively, related to the peel force issue. We expect the peel force issue to continue to negatively affect margins as a result of increased Daytrana® manufacturing costs, including reimbursements to Shire for the AMI included in destroyed product, 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 have agreed to reimburse Shire $3.4 million related to this recall. The $3.4 million was charged to operations in 2008 for Daytrana® product determined to be probable of being voluntarily withdrawn or recalled from the market prior to the expiration of its shelf life. In addition, as of June 30, 2009, we have reserved $3.3 million for Daytrana® inventory and associated AMI that is at risk of developing peel force issues during the product s shelf life, of which $2.3 million was included in inventory reserves and $1.0 million was included in other accrued liabilities. 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, that there will not be future Daytrana® market withdrawals or recalls, or that our costs related to this issue will not exceed the amount of any established reserves.

In February 2009, we received from the FDA a list of observations on Form 483 following an on-site inspection of our manufacturing facilities. Similar to 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.

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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.

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.

Three and six months ended June 30, 2009 compared to the three and six months ended June 30, 2008

Revenues

Our revenues by segment and type for the three and six months ended June 30, 2009 and 2008 are summarized as follows (dollar amounts in thousands):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2009	2008	% Change	2009	2008	% Change
Noven Transdermals						
Novogyne:						
Product sales	$ 7,406	$ 5,553	33%	$ 12,886	$ 7,984	61%
Royalties	2,591	2,349	10%	4,813	4,529	6%
Product revenues Novogyne	9,997	7,902	27%	17,699	12,513	41%
Third Parties:						
Product sales	4,469	4,978	-10%	11,473	10,779	6%
Royalties	76	88	-14%	147	167	-12%
Product revenues third parties	4,545	5,066	-10%	11,620	10,946	6%
Total product revenues	14,542	12,968	12%	29,319	23,459	25%
License and contract revenues	6,643	5,060	31%	12,932	10,346	25%
Total Transdermals	21,185	18,028	18%	42,251	33,805	25%
Noven Therapeutics						
Third Parties:						

Product sales	5,586	6,575	-15%	12,160	12,280	-1%
Net Revenues	$ 26,771	$ 24,603	9%	$ 54,411	$ 46,085	18%

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Net Revenues

As described in more detail below, our net revenues in the 2009 Quarter were $26.8 million, an increase of 9% compared to $24.6 million reported in the 2008 Quarter. The increase was primarily due to a $3.2 million increase in net revenues from our Noven Transdermals segment, comprised primarily of a $2.5 million increase in sales of Vivelle-Dot® and a $1.6 million, or 31%, increase in license and contract revenues, partially offset by a $0.8 million decrease in sales of CombiPatch® and a $0.5 million decrease in transdermal product revenues from third parties compared to the 2008 Quarter. The increase in net revenues for the 2009 Quarter was also partially offset by a $1.0 million decrease in product revenues from our Noven Therapeutics segment, comprised of a $1.3 million decrease in sales of Pexeva® and a $0.6 million decrease in sales of Lithobid®, partially offset by a $0.9 million increase attributable to sales of Stavzor®.

As described in more detail below, our net revenues in the 2009 Period were $54.4 million, an increase of 18% compared to $46.1 million reported in the 2008 Period. The increase was primarily due to an $8.4 million increase in net revenues from our Noven Transdermals segment, comprised primarily of a $5.3 million increase in sales of Vivelle-Dot® and a $2.6 million, or 25%, increase in license and contract revenues, and a $0.7 million increase in transdermal product revenues from third parties compared to the 2008 Period.

Product Revenues Novogyne

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

The $2.1 million increase in Novogyne product revenues for the 2009 Quarter compared to the 2008 Quarter was primarily due to the timing of orders from Novogyne. By product, Vivelle-Dot® sales increased $2.5 million, Estradot® sales increased $0.2 million and CombiPatch® sales decreased $0.8 million, primarily due to the timing of orders. Royalties increased $0.2 million due to increased sales of Vivelle-Dot® by Novogyne for the 2009 Quarter.

The $5.2 million increase in Novogyne product revenues for the 2009 Period compared to the 2008 Period was primarily due to the timing of orders from Novogyne. By product, Vivelle-Dot® sales increased $5.3 million, Estradot® sales increased $0.1 million and CombiPatch® sales decreased $0.5 million primarily due to the timing of orders, and royalties increased $0.3 million due to increased sales of Vivelle-Dot® by Novogyne for the 2009 Period. Novogyne product revenues for the 2008 Period were negatively affected by production issues related to an equipment failure in transdermal manufacturing during the first quarter of 2008, which resulted in write-offs of inventory representing approximately $1.6 million of potential first quarter revenue, creating a backlog of unfilled orders which was not substantially filled until the third quarter of 2008. As a result of the backlog, Novogyne adjusted orders to ensure that the supply of product to end users would not be interrupted and Noven estimates that its revenues were approximately $2.6 million lower than expected for the 2008 Period.

Product Revenues Third Parties

The line item, Product revenues third parties includes: (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.

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The $0.5 million decrease in Product revenues third parties in our Noven Transdermals segment for the 2009 Quarter compared to the 2008 Quarter primarily consisted of a $1.1 million decrease in Daytrana® net product revenues primarily due to the timing of release of product subjected to the predictive peel force test. The delayed timing of release of product created a $3.0 million backlog of unfilled orders of Daytrana® product from Shire as of June 30, 2009, which is expected to be filled during the remainder of 2009. This decrease was partially offset by a $0.6 million increase in unit sales of third party HT products primarily due to the timing of orders from Novartis Pharma.

The $0.7 million increase in Product revenues third parties in our Noven Transdermals segment for the 2009 Period compared to the 2008 Period primarily consisted of a $1.9 million increase in net revenues from third party sales of HT products, partially offset by a $1.2 million decrease in Daytrana® net product revenues primarily due to the timing of release of product subjected to the predictive peel force test, as discussed above. The increase in net revenues from third party sales of HT products resulted from a $1.5 million increase due to increased unit sales and a $0.4 million increase due to improved pricing, as reflected by higher price reconciliation payments received during the 2009 Period. 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 Period and 2008 Period, respectively.

Noven Therapeutics generated $5.6 million of net revenues in the 2009 Quarter from sales of Stavzor®, Pexeva® and Lithobid® compared to $6.6 million of net revenues in the 2008 Quarter from sales of Pexeva® and Lithobid®. By product, Pexeva® sales decreased $1.3 million and Lithobid® sales decreased $0.6 million, primarily due to a reduction of inventory levels in the distribution channel and lower prescriptions. The decrease in net revenues in the 2009 Quarter was partially offset by a $0.9 million increase in net revenues due to the addition of Stavzor®, which was commercially launched in August 2008.

Noven Therapeutics generated $12.2 million of net revenues in the 2009 Period from sales of Stavzor®, Pexeva® and Lithobid® compared to $12.3 million of net revenues in the 2008 Period from sales of Pexeva® and Lithobid®. By product, Pexeva® sales decreased $1.6 million and Lithobid® sales decreased $0.2 million, primarily due to lower prescriptions, and to a lesser extent, reduction of inventory levels in the distribution channel. The decrease in net revenues in the 2009 Period was partially offset by a $1.6 million increase in net revenues due to sales of Stavzor®.

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®. Returns are no longer permitted once the product has been dispensed through patient prescriptions. 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 utilize a sample of Stavzor® prescription data from pharmacies, hospitals, mail order and other retail outlets and project this sample on a national level. We will recognize revenue on product shipments of Stavzor® to our customers based on prescription units dispensed until we have sufficient sales history to reasonably estimate product returns. We recognized $0.9 million and $1.6 million of net revenues for Stavzor® in the 2009 Quarter and 2009 Period, respectively, and $1.9 million and $1.5 million of deferred product revenue relating to Stavzor® was reflected on our Condensed Consolidated Balance Sheet as of June 30, 2009 and December 31, 2008, respectively.

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 $1.6 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®, and a $0.3 million increase in contract revenues during the 2009 Quarter due to the timing of work performed on research and development projects.

License and contract revenues increased $2.6 million for the 2009 Period compared to the 2008 Period, primarily attributable to a $2.6 million increase in amortization of sales milestone payments received from Shire related to the license of Daytrana®, reflecting the amortization of the payment of the third and final $25.0 million sales milestone payment in the third quarter of 2008.

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 three and six months ended June 30, 2009 and 2008, respectively (dollar amounts in thousands):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2009	% of gross revenues	2008	% of gross revenues	2009	% of gross revenues	2008	% of gross revenues
Noven Transdermals:								
Gross revenues	$ 21,293	100%	$ 18,386	100%	$ 42,428	100%	$ 34,399	100%
Sales returns allowances	(108)	1%	(358)	2%	(177)	0%	(594)	2%
Net revenues	$ 21,185	99%	$ 18,028	98%	$ 42,251	100%	$ 33,805	98%
Noven Therapeutics:								
Gross revenues	$ 8,580	100%	$ 10,133	100%	$ 18,111	100%	$ 19,641	100%
Cash discounts	(180)	2%	(193)	2%	(352)	2%	(385)	2%
Medicaid, Medicare & State program rebates and credits including redemption offers	(1,550)	18%	(1,289)	13%	(3,588)	20%	(3,578)	18%
Chargebacks	(384)	4%	(365)	4%	(547)	3%	(632)	3%
Wholesaler fees	(459)	5%	(608)	6%	(848)	5%	(1,202)	6%
Sales returns allowances	(421)	5%	(1,103)	11%	(616)	3%	(1,564)	8%
Sales and returns allowances	(2,994)	35%	(3,558)	35%	(5,951)	33%	(7,361)	37%
Net revenues	$ 5,586	65%	$ 6,575	65%	$ 12,160	67%	$ 12,280	63%

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® and Pexeva® due to lower actual returns of product.

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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.

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 $14.0 million in the 2009 Quarter and the 2009 Period, respectively, include compensation and benefits, supplies and tools, equipment costs, depreciation and amortization, and insurance costs, and represent a substantial portion of our inventory production costs. Manufacturing expenses for the 2008 Quarter and the 2008 Period were $8.6 million and $16.5 million, respectively. The allocation of manufacturing expenses among manufactured products requires us to make significant estimates that involve subjective and often complex judgments. Using different estimates would likely result in materially different results for Gross Margin Novogyne and Gross Margin Third Parties than are presented in the gross margin table below.

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

	Three Months Ended June 30,				Six Months Ended June 30,			
	2009		2008		2009		2008	
Noven Transdermals								
Novogyne:								
Product revenues	$ 9,997		$ 7,902		$ 17,699		$ 12,513	
Cost of products sold	3,771		3,463		7,419		6,789	
Gross profit	6,226	62%	4,439	56%	10,280	58%	5,724	46%
Third parties:								
Product revenues	4,545		5,066		11,620		10,946	
Cost of products sold	7,426		7,298		13,163		13,245	
Gross profit (loss)	(2,881)	-63%	(2,232)	-44%	(1,543)	-13%	(2,299)	-21%
Total Noven Transdermals:								
Product revenues	14,542		12,968		29,319		23,459	
Cost of products sold	11,197		10,761		20,582		20,034	
Gross profit	3,345	23%	2,207	17%	8,737	30%	3,425	15%
Noven Therapeutics								
Product revenues	5,586		6,575		12,160		12,280	
Cost of products sold	1,920		2,022		3,951		4,058	
Gross profit	3,666	66%	4,553	69%	8,209	68%	8,222	67%
Total Company								
Product revenues	20,128		19,543		41,479		35,739	

Cost of products sold	13,117		12,783		24,533		24,092	
Gross profit	$ 7,011	35%	$ 6,760	35%	$ 16,946	41%	$ 11,647	33%

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

As noted in the tables above, Overall Gross Margin remained unchanged in the 2009 Quarter compared to the 2008 Quarter. Overall Gross Margin in the 2009 Quarter benefited from the reduction of approximately $1.6 million in manufacturing expenses compared to the 2008 Quarter, primarily due to higher quality assurance activities and expenses related to Daytrana® production in the 2008 Quarter. Overall Gross Margin in the 2009 Quarter and 2008 Quarter was negatively affected by inventory write-offs and associated AMI reserves related to Daytrana® product of approximately $3.0 million and $0.8 million, respectively, all of which related to the peel force issue.

As noted in the tables above, Overall Gross Margin increased in the 2009 Period compared to the 2008 Period. Improvement in Overall Gross Margin in the 2009 Period resulted primarily from: (i) the impact of inventory write-offs of $2.8 million which occurred in the 2008 Period 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; and (ii) the reduction of approximately $2.5 million in manufacturing expenses compared to the 2008 Period, primarily due to higher quality assurance activities and expenses related to Daytrana® production in the 2008 Period. Overall Gross Margin in the 2009 Period and 2008 Period was negatively affected by inventory write-offs and associated AMI reserves related to Daytrana® product of approximately $3.8 million and $0.9 million, respectively, of which $3.3 million and $0.8 million, respectively, related to the peel force issue.

We sell Daytrana® finished product to Shire at a fixed price and, consequently, our profit on product sales depends on our ability to manufacture the product efficiently and to fully utilize our facilities. For the 2009 Quarter, Daytrana® net product revenues were $1.6 million and cost of products sold was $5.3 million (including $3.0 million of inventory write-offs and associated AMI reserves), resulting in negative gross margin for the product. This compares with Daytrana® product revenues of $2.7 million and cost of products sold of $5.2 million (including $0.8 million of inventory write-offs and associated AMI reserves) for the 2008 Quarter. For the 2009 Period, Daytrana® net product revenues were $4.5 million and cost of products sold was $8.9 million (including $3.8 million of inventory write-offs and associated AMI reserves), resulting in negative gross margin for the product. This compares with Daytrana® product revenues of $5.7 million and cost of products sold of $8.5 million (including $0.9 million of inventory write-offs and associated AMI reserves) for the 2008 Period. 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, 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 in its Form 483 and warning letter 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 until we are able to adequately resolve the peel force issue.

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Operating Expenses

Operating expenses for the three and six months ended June 30, 2009 and 2008 are summarized as follows (dollar amounts in thousands):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2009	2008	% Change	2009	2008	% Change
Research and development	$ 3,751	$ 3,293	14%	$ 8,404	$ 6,612	27%
Selling and marketing	3,983	5,336	-25%	8,996	10,159	-11%
General and administrative	8,651	8,906	-3%	15,699	15,928	-1%

Research and Development

Research and development expenses include costs associated with, among other things, product formulation, pre-clinical testing, clinical studies, regulatory and medical affairs, production for clinical and regulatory purposes, production related development engineering for developmental products, and the personnel associated with each of these functions. The $0.5 million increase in research and development expenses for the 2009 Quarter compared to the 2008 Quarter was primarily attributable to $0.3 million associated with Mesafem Phase 2 clinical trials and $0.2 million in additional research and development expenses to support our long-term growth objectives. The $1.8 million increase in research and development expenses for the 2009 Period compared to the 2008 Period was primarily attributable to $1.1 million associated with Mesafem Phase 2 clinical trials and $0.7 million in additional research and development expenses to support our long-term growth objectives.

Selling and Marketing

The $1.4 million and $1.2 million decreases in selling and marketing costs for the 2009 Quarter and the 2009 Period compared to the 2008 Quarter and the 2008 Period, respectively, were primarily related to non-recurring costs incurred in 2008 associated with the commercial launch of Stavzor®, as well as the timing of sample shipments to the sales force.

General and Administrative

The $0.3 million decrease in general and administrative expenses for the 2009 Quarter compared to the 2008 Quarter was primarily due to $1.7 million in charges for reimbursements to Shire for voluntary recalls of certain Daytrana® product in the 2008 Quarter, a $0.3 million reduction in the 2009 Quarter for the expected costs of the March 2009 voluntary recall of certain lots of Daytrana® product and a $0.5 million decrease in executive recruiting fees. These decreases were partially offset by $1.5 million of transaction costs in the 2009 Quarter related to the proposed merger with Hisamitsu, a $0.5 million increase in executive relocation expenses and a $0.2 million increase in salaries and related benefits.

The $0.2 million decrease in general and administrative expenses for the 2009 Period compared to the 2008 Period was primarily due to $1.7 million in charges for reimbursements to Shire for voluntary recalls of certain Daytrana® product in the 2008 Period, a $0.3 million reduction in the 2009 Period for the expected costs of the March 2009 voluntary recall of certain lots of Daytrana® product, a $0.8 million decrease in accounting and audit fees and a $0.6 million decrease in executive recruiting fees. These decreases were partially offset by $1.5 million of transaction costs in the 2009 Period related to the proposed merger with Hisamitsu, a $1.1 million increase in salaries and related benefits and a $0.6 million increase in executive relocation expenses.

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Other Income and Expenses

Interest and Other Income

Interest and other income decreased $0.4 million and $1.0 million for the 2009 Quarter and 2009 Period compared to the 2008 Quarter and 2008 Period, respectively. 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 35% and 36% for the 2009 Period and 2008 Period, respectively. The provision for income taxes is based on the Federal statutory and state income tax rates. Net deferred income tax assets are measured using the average graduated tax rate for the estimated amount of annual taxable income in the years that the liability is expected to be settled or the asset recovered. The effect of adjusting the expected tax rate related to the net deferred income tax assets is included in the provision for income taxes. As of June 30, 2009 we had a net deferred tax asset of $70.8 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 June 30, 2009. Our valuation allowance for state deferred tax assets was $3.7 million and $3.5 million as of June 30, 2009 and December 31, 2008, respectively, 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 first quarters of 2009 and 2008 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 three and six months ended June 30, 2009 and 2008 are summarized as follows (dollar amounts in thousands):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2009	2008	% Change	2009	2008	% Change
Gross revenues	$ 56,435	$ 50,054	13%	$ 104,665	$ 95,348	10%
Sales allowances	7,357	5,702	29%	14,023	11,555	21%
Sales returns allowances	1,118	585	91%	2,491	500	N/M
Sales allowances and returns	8,475	6,287	35%	16,514	12,055	37%
Net revenues	47,960	43,767	10%	88,151	83,293	6%
Cost of sales	9,441	8,788	7%	17,518	16,596	6%
Selling, general and administrative expenses	10,196	9,798	4%	20,907	18,810	11%
Income from operations	28,323	25,181	12%	49,726	47,887	4%
Interest income	67	174	-61%	161	441	-63%
Net income	$ 28,390	$ 25,355	12%	$ 49,887	$ 48,328	3%
Noven s equity in earnings of Novogyne	$ 13,902	$ 12,429	12%	$ 21,447	$ 20,696	4%

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 $6.4 million for the 2009 Quarter compared to the 2008 Quarter. By product, Vivelle-Dot® sales increased $6.2 million and Estradot® sales increased $0.2 million. The $6.2 million Vivelle-Dot® increase consisted of a $4.6 million increase related to pricing and a $1.6 million increase in unit sales, which consisted of a $2.5 million increase in prescription demand, partially offset by $0.9 million of channel inventory reductions. The $0.2 million Estradot® increase was attributable to unit sales. Gross revenues for CombiPatch® remained substantially unchanged due to a $0.3 million increase related to pricing which was offset by a $0.3 million decrease in unit sales, which consisted of $0.6 million of channel inventory reductions, partially offset by a $0.3 million increase in prescription demand.

Novogyne s gross revenues increased $9.3 million for the 2009 Period compared to the 2008 Period. By product, Vivelle-Dot® sales increased $8.8 million, CombiPatch® sales increased $0.3 million and Estradot® sales increased $0.2 million. The $8.8 million Vivelle-Dot® increase consisted of an $8.6 million increase related to pricing and a $0.2 million increase in unit sales, which consisted of a $4.0 million increase in prescription demand, partially offset by $3.8 million of channel inventory reductions. The $0.3 million CombiPatch® increase consisted of a $0.6 million increase related to pricing, partially offset by a $0.3 million decrease in unit sales, which consisted of $0.6 million of channel inventory reductions, partially offset by a $0.3 million increase in prescription demand. The $0.2 million Estradot® increase was attributable to unit sales primarily due to the timing of orders.

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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 13% and 11% of gross revenues, respectively. For the 2009 Period and the 2008 Period, these sales allowances were 13% and 12% of gross revenues, respectively.

Sales returns allowances consist of allowances for returns of expiring product. The activity in the sales returns allowances for the three and six months ended June 30, 2009 and 2008 was as follows (amounts in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Sales returns allowances included in net revenues	$ 1,118	$ 585	$ 2,491	$ 500
Actual returns primarily for expiring product	(865)	(889)	(1,971)	(1,499)
Change in allowances for returns primarily for expiring product	$ 253	$ (304)	$ 520	$ (999)

The increase in sales returns allowances for the 2009 Quarter and the 2009 Period compared to the 2008 Quarter and the 2008 Period, respectively, 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 all periods presented, as price increases for all products in both the 2009 Quarter and 2009 Period were offset by higher sales returns allowances.

Novogyne Selling, General and Administrative Expenses

Novogyne s selling, general and administrative expenses increased $0.4 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 of target areas, a $0.4 million increase in advertising expenses due to the timing of expenditures, and a $0.1 million increase in HT litigation expenses, partially offset by a $0.7 million decrease in sample expenses due to the timing of shipments by Noven to Novogyne.

Novogyne s selling, general and administrative expenses increased $2.1 million for the 2009 Period compared to the 2008 Period primarily due to a $1.2 million increase in advertising and market research expenses resulting from the timing of expenditures, a $0.9 million increase in sales force expenses related to re-alignment of target areas, and a $0.2 million increase in HT litigation expenses, partially offset by a $0.2 million decrease in sample expenses due to the timing of shipments by Noven to Novogyne.

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Liquidity and Capital Resources

As of June 30, 2009 and December 31, 2008, we had the following (amounts in thousands):

	June 30, 2009	December 31, 2008
Cash and cash equivalents	$ 69,773	$ 62,875
Short-term investments		3,650
Working capital	55,242	50,644

In addition to our cash and working capital, as of June 30, 2009, we owned investments in auction rate securities with a fair value of $11.6 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 Period, 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):

	June 30, 2009	December 31, 2008
Cash and cash equivalents	$ 69,773	$ 62,875
Investments in auction rate securities:		
Current		3,650
Non-current	11,600	11,810
Total cash and cash equivalents and investments	$ 81,373	$ 78,335

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

	2009	2008
Cash flows:		
Operating activities	$ 8,964	$ (9,913)
Investing activities	999	34,683
Financing activities	(3,065)	(3,338)
Net Cash Flows	$ 6,898	$ 21,432

Operating Activities

Net cash provided by operating activities for the 2009 Period reflects the receipt of $18.5 million in distributions from Novogyne as well as changes in working capital, including a $2.3 million net decrease in payables and other accrued liabilities, a $3.3 million increase in inventories, a $1.3 million increase in amounts due from Novogyne, a $2.5 million decrease in trade receivables, a $4.8 million decrease in prepaid taxes, and a $0.7 million decrease in accrued compensation and related liabilities. Significant payments during the period which impacted the changes in operating assets and liabilities included income tax payments of $3.8 million and $2.5 million in payments related to insurance premiums.

Net cash used in operating activities for the 2008 Period primarily resulted from the timing of certain payments, including income tax payments of $7.5 million, a payment to Shire of $3.3 million related to its 2007 voluntary

withdrawal of certain Daytrana® product and $3.1 million in payments related to insurance premiums. Changes in working capital, including an $8.0 million increase in inventories and a $4.3 million decrease in accrued compensation and related liabilities, also contributed to the net cash used in operating activities in 2008. The net operating cash used was partially offset by the receipt of $17.2 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 Period was primarily attributable to $3.7 million from the redemption of an auction rate security investment at par value, partially offset by $2.2 million in equipment purchases to support operations.

Net cash provided by investing activities for the 2008 Period was primarily attributable to $36.4 million from sales of auction rate security investments at par value, partially offset by $1.2 million in equipment purchases to support operations.

Financing Activities

Net cash used in financing activities for both the 2009 Period and 2008 Period was primarily attributable to the payment in each year of a $3.3 million sales milestone to Synthon, an obligation we assumed as part of the Noven Therapeutics acquisition.

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 Period, our cash and cash equivalents and investments in auction rate securities increased from $78.3 million to $81.4 million. The increase primarily resulted from the receipt of $18.5 million of distributions from Novogyne. The increase in cash was partially offset by certain cash outlays during the 2009 Period, including (i) a $3.3 million sales milestone payment to Synthon; (ii) $2.2 million for equipment purchases; (iii) cash used to fund increases in inventory and other working capital items; and (iv) $3.8 million for income tax payments. 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.

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As discussed elsewhere herein, we paid Shire $3.7 million related to Shire s voluntary recalls of Daytrana® product in 2008. 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 have agreed to reimburse Shire $3.4 million related to this recall. The $3.4 million was charged to operations in 2008 for Daytrana® product determined to be probable of being voluntarily withdrawn or recalled from the market prior to the expiration of its shelf life. In addition, as of June 30, 2009, we have reserved $3.3 million for Daytrana® inventory and associated AMI that is at risk of developing peel force issues during the product s shelf life, of which $2.3 million was included in inventory reserves and $1.0 million was included in other accrued liabilities. 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, that there will not be future Daytrana® market withdrawals or recalls or that our costs related to this issue will not exceed the amount of any established reserves.

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 another $3.3 million milestone payment to Synthon based on our achieving specified net sales of Pexeva® during 2008.

As of June 30, 2009, we owned investments in auction rate securities with a total par value and fair value of $12.3 million and $11.6 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. During the 2009 Quarter, we recorded an additional $0.2 million of other-than-temporary impairments on our investments in auction rate securities. During the 2009 Period, $3.7 million of our investments in auction rate securities were redeemed by the issuer at par value. 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, which consist entirely of auction rate securities, measured at fair value on a recurring basis using unobservable inputs (Level 3) during the 2009 Period were as follows (amounts in thousands):

Balance at December 31, 2008	$ 15,460
Redemptions of investments at par value	(3,650)
Unrealized losses, other-than-temporary	(210)
Balance at June 30, 2009	$ 11,600

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 June 30, 2009. As illiquid conditions persist in the auction market for these securities, we may be required 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. As of the date of this report, no borrowings were outstanding under this facility and we have no long-term debt. The agreement has been amended to expire in August 2009. We are in the process of negotiating a new credit facility agreement.

To the extent the sources of liquidity described above are insufficient to fund our operations, we would expect to seek to obtain funds through additional 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, if we seek additional debt financing, such 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.

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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 additional financing to complete any such acquisitions. Current conditions in the credit 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.

Capital expenditures totaled $2.2 million for the 2009 Period. 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 require additional financing to fund such expansion. We cannot assure that we will successfully complete the development of such products, that we will obtain regulatory approval for any such products, that any approved product will be produced in commercial quantities, at reasonable costs, and be successfully marketed, or that we will successfully negotiate future licensing or product acquisition arrangements. Because much of the cost associated with product development and expansion of manufacturing facilities is incurred prior to product launch, if we are unsuccessful in out-licensing, or if we are unable to launch additional commercially-viable products that we develop or that we license or acquire from others, we will have incurred the up-front costs associated with product development or acquisition without the benefit of the cash generated by sales of those products, which could adversely affect our long-term liquidity needs. Factors that could impact our ability to develop or acquire and launch additional commercially-viable products are discussed in Part I Item 1A Risk Factors of our Form 10-K, as supplemented by Part II Item 1A Risk Factors of this Quarterly Report on Form 10-Q.

For the 2009 Period and the 2008 Period, our equity in earnings of Novogyne and the recognition of deferred license and contract revenues (both of which are non-cash items) contributed significantly to our income before income taxes. Accordingly, our net income may not be reflective of our cash flow in any given period.

In connection with the negotiation and execution of the merger agreement between Noven and Hisamitsu, we have incurred transaction-related costs for legal and other professional services. During the 2009 Quarter, we charged approximately $1.5 million of transaction-related costs to operations. In addition, under the terms of the agreement with our investment advisor, we have agreed to pay the advisor a fee, based upon a percentage of the aggregate value of the transaction, in the amount of approximately $6.8 million, of which $2.0 million was paid in July 2009 upon the advisor s delivery of a fairness opinion. The balance of the advisor s fee is payable only if the transaction closes. In addition to the advisory fee, the advisor is entitled to reimbursement of certain expenses, including the fees and disbursements of its legal counsel.

Aggregate Contractual Obligations

Except as described below, 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.

Under the terms of Noven s agreement with its investment advisor in connection with the merger agreement between Noven and Hisamitsu, Noven has agreed to pay the advisor a fee, based upon a percentage of the aggregate value of the transaction, in the amount of approximately $6.8 million, of which $2.0 million was paid in July 2009 upon the advisor s delivery of a fairness opinion. The balance of the advisor s fee is payable only if the transaction closes. In addition to the advisory fee, the advisor is entitled to reimbursement of certain expenses, including the fees and disbursements of its legal counsel.

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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

Due to the pending transaction with Hisamitsu (as described in Note 16 Subsequent Event Merger Agreement), we are withdrawing our prior financial guidance, which we most recently provided in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2009. Any financial guidance previously provided in any of our prior filings with the Securities and Exchange Commission, press releases, public conference calls, investor presentations or otherwise, is no longer current and is hereby withdrawn.

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 June 30, 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.

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Changes in Internal Control over Financial Reporting

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

Certifications

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

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 June 2007, Johnson Matthey Inc. filed a complaint in the United States District Court for the Eastern District of Texas alleging that Noven was infringing one of its patents through Noven s manufacture and sale of the Daytrana® product. The plaintiff is seeking injunctions from further infringement and claiming compensatory and other damages. In July 2007, Johnson Matthey Inc. added Shire US Inc. and Shire Pharmaceuticals Ireland Limited as co-defendants in this lawsuit. Fact discovery concluded in June 2009, though Johnson Matthey Inc. has sought additional fact discovery. The claim construction hearing was held in July 2009, and in a written opinion that same month, the Court adopted a claim construction consistent with Noven s proposed construction. Summary judgment motions are due in August 2009 and jury selection is scheduled to commence in October 2009.

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.

On July 15, 2009, a plaintiff filed a purported stockholder class action complaint in the Court of Chancery of the State of Delaware (the First Complaint) in connection with the proposed transaction with Hisamitsu. The First Complaint names as defendants the members of the Board of Directors, as well as Noven and Hisamitsu. The plaintiff claims that Noven s directors breached their fiduciary duties to Noven s stockholders, and further claims that Hisamitsu participated in or aided and abetted the purported breach of fiduciary duty. In support of the plaintiff s claims, the First Complaint alleges that the proposed transaction between Noven and Hisamitsu involves an unfair price, an inadequate sales process and unreasonable deal protection devices, among other things. The First Complaint seeks to enjoin the transaction and seeks attorneys and other fees and costs, in addition to seeking other relief.

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A second plaintiff filed a purported stockholder class action complaint on July 15, 2009 in the Eleventh Judicial Circuit of Florida and later filed a nearly identical complaint in the Court of Chancery of the State of Delaware on July 23, 2009. The complaints name as defendants Noven and each of its directors and assert similar claims and requests for relief as those asserted in the First Complaint.

On July 16, 2009, a third plaintiff filed in the Court of Chancery of the State of Delaware a purported stockholder class action complaint relating to the proposed transaction with Hisamitsu. The complaint names as defendants the members of the Board of Directors as well as Noven and Hisamitsu, and asserts claims and requests relief nearly identical to the First Complaint.

On July 17, 2009, a fourth plaintiff filed a purported class action complaint in the Eleventh Judicial Circuit of Florida, which names as defendants the members of the Board of Directors as well as Noven and Hisamitsu. Noven has been provided with a copy of an amendment to this complaint, which plaintiffs counsel indicated would be filed in July 2009. The amended complaint alleges that Noven s directors breached their fiduciary duties to Noven s stockholders and that Noven and Hisamitsu aided and abetted the directors breaches of fiduciary duties. The complaint makes allegations similar to those contained in the First Complaint as well as an allegation that Noven s disclosure contained in its Solicitation/Recommendation Statement on Schedule 14D-9 was inadequate and omitted material information.

On July 24, 2009, a fifth plaintiff filed a purported class action complaint in the Eleventh Judicial Circuit of Florida, which names as defendants the members of the Board of Directors as well as Noven and Hisamitsu, and asserts claims and requests relief nearly identical to the First Complaint.

Noven believes that the allegations set forth in all of these complaints lack merit and will contest them vigorously.

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

Except as described below, there have been no material changes or additions to the risk factors previously disclosed in our Form 10-K. Readers are urged to carefully review our risk factors because they may cause our results to differ from the forward-looking statements made in this report or otherwise made by us or on our behalf. The risk factors are not necessarily listed in order of priority or probability and are not the only ones we face. If any of these risks actually occurs, our business, financial condition and results of operations 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.

We have entered into a merger agreement with Hisamitsu which, if consummated, will result in Noven no longer being a publicly traded company. We cannot assure that the tender offer and subsequent planned merger will be successfully consummated.

On July 14, 2009, we entered into a definitive merger agreement with Hisamitsu pursuant to which Hisamitsu has proposed to acquire Noven for $16.50 per share in an all-cash tender offer for 100% of the outstanding shares of Noven. Following the tender offer, Hisamitsu plans to merge a wholly-owned subsidiary of Hisamitsu with and into Noven. If the merger takes place, Noven will no longer be a publicly traded company. Even if for some reason the merger does not take place, following the tender offer, there may be so few remaining stockholders and publicly held shares that our common stock will no longer be eligible to be listed on or traded through the Nasdaq Global Select Market or other securities exchanges, there may not be an active public trading market for our common stock, and Noven may no longer be required to make filings with the SEC or otherwise comply with the SEC rules relating to publicly held companies.

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The tender offer, which Hisamitsu commenced on July 23, 2009, is subject to the satisfaction of certain conditions, including the requirement that at least a majority of our shares of common stock are validly tendered in the offer. In addition, several plaintiffs law firms have filed purported class action lawsuits against Noven, its directors and Hisamitsu seeking to enjoin the transaction, and alleging, among other things, that Noven s directors breached their fiduciary duties to stockholders and that the proposed transaction involves an unfair price. We cannot assure that the tender offer and planned merger will be successfully consummated.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

The following table provides information with respect to our stock repurchases during the second 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]
April 1, 2009 to April 30, 2009				$ 19,876,238
May 1, 2009 to May 31, 2009				19,876,238
June 1, 2009 to June 30, 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 4. Submission of Matters to a Vote of Security Holders

The following proposals were approved at our Annual Meeting of Stockholders held on May 22, 2009:

1. Election of the Board of Directors:

	For	Withheld
Peter Brandt	21,103,644	704,216
John G. Clarkson, M.D.	18,490,371	3,317,489
Donald A. Denkhaus	21,102,327	705,533
Pedro P. Granadillo	19,820,597	1,987,263
Phillip M. Satow	20,973,766	834,094
Robert G. Savage	19,665,356	2,142,504
Wayne P. Yetter	21,078,356	729,504

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2. Proposal to approve Noven s 2009 Equity Incentive Plan:

For	Against	Abstained	Broker Non-Vote
13,619,989	5,496,721	46,575	2,644,576

3. Proposal to ratify and approve the appointment of Deloitte & Touche LLP as Noven s independent registered public accounting firm for 2009:

For	Against	Abstained	Broker Non-Vote
21,613,527	156,289	38,044	0

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

2.1 Agreement and Plan of Merger among Noven and Hisamitsu Pharmaceutical Co., Inc., Hisamitsu U.S., Inc. and Northstar Merger Sub, Inc. dated July 14, 2009 (incorporated by reference to Exhibit 2.1 of Noven s Form 8-K dated July 15, 2009).

4.1 Amendment No. 2 to Rights Agreement between Noven and American Stock Transfer & Trust Company, LLC dated July 14, 2009 (incorporated by reference to Exhibit 4.1 of Noven s Form 8-K dated July 15, 2009).

10.1 Noven Pharmaceuticals, Inc. 2009 Equity Incentive Plan (incorporated by reference to Noven s definitive Proxy Statement dated April 9, 2009, for the Annual Meeting of Stockholders held on May 22, 2009).

10.2 Amended and Restated Employment Agreement between Noven and Jeffrey F. Eisenberg dated July 14, 2009 (incorporated by reference to Exhibit 10.1 of Noven s Form 8-K dated July 15, 2009).

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: August 6, 2009

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