

NOVEN PHARMACEUTICALS INC

Form 10-Q

August 08, 2008

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

Quarterly Report Pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934  
For the quarterly period ended June 30, 2008  
Commission file number 0-17254

**NOVEN PHARMACEUTICALS, INC.**  
(Exact name of registrant as specified in its charter)

STATE OF DELAWARE 59-2767632  
  
(State or other jurisdiction of (I.R.S. Employer  
incorporation or organization) Identification Number)  
11960 S.W. 144th Street, Miami, FL 33186  
  
(Address of principal executive offices) (Zip Code)  
(305) 253-5099

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a smaller reporting company)

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

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, 2008 |
|--------------------------------|------------------------------|
| Common stock \$.0001 par value | 24,895,185                   |

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| <b><u>Cautionary Factors:</u></b> Statements in this report that are not descriptions of historical facts are forward-looking statements provided under the safe harbor protection of the Private Securities Litigation Reform Act of 1995. Our actual results, performance and achievements may be materially different from those expressed or implied by such statements and readers should consider the risks and uncertainties associated with our business that are discussed in |          |

Item 1A of Part I of our Annual Report on Form 10-K for the year ended December 31, 2007 as supplemented by Part II Item 1A Risk Factors of this quarterly report on Form 10-Q, as well as other reports filed from time to time with the Securities and Exchange Commission.

Trademark Information: Lithobid® and Pexeva® are registered trademarks, and Mesafem and Stavzor are trademarks 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.

**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****NOVEN PHARMACEUTICALS, INC. AND SUBSIDIARIES**

Condensed Consolidated Balance Sheets

(in thousands, except share data) (unaudited)

|  | <b>June 30,<br/>2008</b> | <b>December<br/>31,<br/>2007</b> |
|--|--------------------------|----------------------------------|
| <b><u>Assets</u></b>   |                          |                                  |
| Current Assets:  |                          |                                  |
| Cash and cash equivalents  | \$ 35,405                | \$ 13,973                        |
| Short-term investments available-for-sale, at fair value                 |                          | 21,565                           |
| Accounts receivable (less allowances of \$264 at 2008 and \$252 at 2007) | 8,302                    | 6,956                            |
| Milestone payment receivable Shire                                       | 25,000                   |                                  |
| Accounts receivable Novogyne, net  | 6,592                    | 8,683                            |
| Inventories  | 16,278                   | 12,136                           |
| Net deferred income tax asset, current portion                           | 8,786                    | 7,614                            |
| Prepaid income taxes   | 3,596                    | 4,925                            |
| Prepaid and other current assets   | 4,358                    | 5,251                            |
|  | 108,317                  | 81,103                           |
| Non-current Assets:  |                          |                                  |
| Property, plant and equipment, net                                       | 35,415                   | 36,213                           |
| Investments in auction rate securities                                   | 17,510                   | 32,835                           |
| Investment in Novogyne   | 25,959                   | 24,310                           |
| Net deferred income tax asset, non-current portion                       | 63,827                   | 58,053                           |
| Intangible assets, net   | 37,190                   | 38,773                           |
| Goodwill   | 14,407                   | 14,734                           |
| Deposits and other non-current assets                                    | 972                      | 677                              |
|  | 195,280                  | 205,595                          |
|  | \$ 303,597               | \$ 286,698                       |
| <b><u>Liabilities and Stockholders' Equity</u></b>                       |                          |                                  |
| Current Liabilities:   |                          |                                  |
| Accounts payable and accrued expenses                                    | \$ 6,809                 | \$ 8,399                         |
| Accrued compensation and related liabilities                             | 5,440                    | 9,801                            |
| Other accrued liabilities  | 17,193                   | 15,270                           |
| Current portion of long-term obligations                                 | 3,416                    | 3,421                            |
| Deferred license and contract revenues, current portion                  | 26,252                   | 20,188                           |
|  | 59,110                   | 57,079                           |
| Non-current Liabilities:   |                          |                                  |

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|   |            |            |
|---|------------|------------|
| Long-term obligations, less current portion   | 5,095      | 8,438      |
| Deferred license and contract revenues, non-current portion   | 94,991     | 85,056     |
| Other non-current liabilities   | 1,165      | 1,831      |
|   | 101,251    | 95,325     |
| Total Liabilities   | 160,361    | 152,404    |
| Commitments and Contingencies (Note 14)   |            |            |
| Stockholders' Equity:   |            |            |
| Preferred stock - authorized 100,000 shares par value \$.01 per share; no shares issued or outstanding  |            |            |
| Common stock - authorized 80,000,000 shares, par value \$.0001 per share; 25,217,530 and 24,881,867 issued at June 30, 2008 and December 31, 2007 | 2          | 2          |
| Additional paid-in capital  | 120,916    | 118,561    |
| Retained earnings   | 27,957     | 20,855     |
| Accumulated other comprehensive loss  | (515)      |            |
| Treasury stock, at cost - 322,345 shares at June 30, 2008 and December 31, 2007   | (5,124)    | (5,124)    |
| Common stock held in trust  | (1,256)    | (950)      |
| Deferred compensation obligation  | 1,256      | 950        |
|   | 143,236    | 134,294    |
|   | \$ 303,597 | \$ 286,698 |

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

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

## Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

(unaudited)

|                                     | Three Months Ended June |          | Six Months Ended June |           |
|-------------------------------------|-------------------------|----------|-----------------------|-----------|
|                                     | 30,                     |          | 30,                   |           |
|                                     | 2008                    | 2007     | 2008                  | 2007      |
| Revenues:                           |                         |          |                       |           |
| Product revenues Novogyne:          |                         |          |                       |           |
| Product sales, net                  | \$ 5,553                | \$ 4,804 | \$ 7,984              | \$ 10,173 |
| Royalties                           | 2,349                   | 1,899    | 4,529                 | 3,664     |
| Total net product revenues Novogyne | 7,902                   | 6,703    | 12,513                | 13,837    |
| Product revenues, net third parties | 11,641                  | 8,359    | 23,226                | 16,831    |
| Total net product revenues          | 19,543                  | 15,062   | 35,739                | 30,668    |
| License and contract revenues       | 5,060                   | 3,777    | 10,346                | 7,486     |
| Total net revenues                  | 24,603                  | 18,839   | 46,085                | 38,154    |
| Costs and Expenses:                 |                         |          |                       |           |
| Cost of products sold Novogyne      | 3,463                   | 3,285    | 6,789                 | 6,244     |
| Cost of products sold third parties | 9,320                   | 6,029    | 17,303                | 11,997    |
| Total cost of products sold         | 12,783                  | 9,314    | 24,092                | 18,241    |
| Research and development            | 3,293                   | 3,185    | 6,612                 | 6,651     |
| Selling and marketing               | 5,336                   | 221      | 10,159                | 461       |
| General and administrative          | 8,906                   | 5,488    | 15,928                | 10,669    |
| Total costs and expenses            | 30,318                  | 18,208   | 56,791                | 36,022    |
| Income (loss) from operations       | (5,715)                 | 631      | (10,706)              | 2,132     |
| Equity in earnings of Novogyne      | 12,429                  | 9,174    | 20,696                | 14,077    |
| Interest income, net                | 500                     | 1,813    | 1,122                 | 3,445     |
| Income before income taxes          | 7,214                   | 11,618   | 11,112                | 19,654    |
| Provision for income taxes          | 2,704                   | 4,042    | 4,010                 | 7,042     |
| Net income                          | \$ 4,510                | \$ 7,576 | \$ 7,102              | \$ 12,612 |
| Basic earnings per share            | \$ 0.18                 | \$ 0.31  | \$ 0.29               | \$ 0.51   |

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|  |         |         |         |         |
|--|---------|---------|---------|---------|
| Diluted earnings per share                               | \$ 0.18 | \$ 0.30 | \$ 0.29 | \$ 0.50 |
| Weighted average number of common shares<br>outstanding: |         |         |         |         |
| Basic  | 24,603  | 24,832  | 24,582  | 24,785  |
| Diluted  | 24,754  | 25,379  | 24,710  | 25,381  |

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

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## Condensed Consolidated Statement of Changes in Stockholders' Equity and Comprehensive Income

(in thousands)

(unaudited)

|   | Common Stock |        | Additional | Retained  | Accumulated   | Treasury   | Other | Total      |
|---|--------------|--------|------------|-----------|---------------|------------|-------|------------|
|   | Shares       | Amount | Paid-in    | Earnings  | Comprehensive | Stock      |       |            |
|   |              |        | Capital    |           | Loss          |            |       |            |
| Balance at December 31, 2007  | 24,560       | \$ 2   | \$ 118,561 | \$ 20,855 | \$            | \$ (5,124) | \$    | \$ 134,294 |
| Issuance of shares pursuant to employee equity plan                                       | 1            |        | 10         |           |               |            |       | 10         |
| Stock-based compensation expense and issuance of shares to officers and outside directors | 334          |        | 2,345      |           |               |            |       | 2,345      |
| Common stock held in trust  | (19)         |        |            |           |               |            | (306) | (306)      |
| Deferred compensation obligation  | 19           |        |            |           |               |            | 306   | 306        |
| Comprehensive income:   |              |        |            |           |               |            |       |            |
| Net income  |              |        |            | 7,102     |               |            |       | 7,102      |
| Other comprehensive income:   |              |        |            |           |               |            |       |            |
| Unrealized loss on investments in auction rate securities                                 |              |        |            |           | (515)         |            |       | (515)      |
| Comprehensive income  |              |        |            |           |               |            |       | \$ 6,587   |
| Balance at June 30, 2008  | 24,895       | \$ 2   | \$ 120,916 | \$ 27,957 | \$ (515)      | \$ (5,124) | \$    | \$ 143,236 |

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

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## Condensed Consolidated Statements of Cash Flows

(in thousands)

(unaudited)

|   | <b>Six Months ended June 30,</b> |             |
|---|----------------------------------|-------------|
|   | <b>2008</b>                      | <b>2007</b> |
| Cash flows from operating activities:   |                                  |             |
| Net income  | \$ 7,102                         | \$ 12,612   |
| Adjustments to reconcile net income to net cash flows (used in) provided by operating activities: |                                  |             |
| Depreciation, amortization and certain other noncash items  | 4,568                            | 2,539       |
| Inventory write-offs  | 3,871                            | 682         |
| Stock-based compensation expense  | 2,345                            | 1,976       |
| Income tax benefits on exercise of stock options  |                                  | 462         |
| Excess tax benefit from exercise of stock options   |                                  | (392)       |
| Deferred income tax benefit   | (6,946)                          | (6,661)     |
| Recognition of deferred license and contract revenues   | (10,346)                         | (7,486)     |
| Equity in earnings of Novogyne  | (20,696)                         | (14,077)    |
| Distributions from Novogyne   | 17,247                           | 10,975      |
| Changes in operating assets and liabilities:  |                                  |             |
| (Increase) decrease in accounts receivable trade, net   | (1,346)                          | 1,493       |
| Increase in milestone payment receivable Shire  | (25,000)                         |             |
| Decrease in accounts receivable Novogyne, net   | 2,091                            | 1,619       |
| Increase in inventories   | (8,013)                          | (1,595)     |
| Decrease in prepaid income taxes  | 3,129                            | 243         |
| Decrease (increase) in prepaid and other current assets   | 113                              | (830)       |
| Increase in deposits and other assets   | (176)                            |             |
| Decrease in accounts payable and accrued expenses   | (1,897)                          | (494)       |
| Decrease in accrued compensation and related liabilities  | (4,324)                          | (932)       |
| Increase in other accrued liabilities   | 1,923                            | 2,128       |
| Increase in deferred license and contract revenues  | 26,345                           | 30,975      |
| Increase in other liabilities   | 97                               | 342         |
| Cash flows (used in) provided by operating activities   | (9,913)                          | 33,579      |
| Cash flows from investing activities:   |                                  |             |
| Purchases of property, plant and equipment  | (1,205)                          | (1,421)     |
| Payments for intangible assets  | (152)                            | (348)       |
| Payments for deferred acquisition costs   |                                  | (1,241)     |
| Purchase of company-owned life insurance  | (335)                            | (260)       |
| Purchases of investments  | (62,800)                         | (767,769)   |
| Proceeds from sale of investments   | 99,175                           | 730,864     |
| Cash flows provided by (used in) investing activities   | 34,683                           | (40,175)    |
| Cash flows from financing activities:   |                                  |             |
| Issuance of common stock from exercise of stock options   | 10                               | 2,521       |
| Excess tax benefit from exercise of stock options   |                                  | 392         |

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|   |           |          |
|---|-----------|----------|
| Payments of long-term obligations                     | (3,348)   | (58)     |
| Cash flows (used in) provided by financing activities | (3,338)   | 2,855    |
| Net increase in cash and cash equivalents             | 21,432    | (3,741)  |
| Cash and cash equivalents, beginning of period        | 13,973    | 9,144    |
| Cash and cash equivalents, end of period              | \$ 35,405 | \$ 5,403 |

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

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**NOVEN PHARMACEUTICALS, INC.**

**Notes to Unaudited Condensed Consolidated Financial Statements**

**1. DESCRIPTION OF BUSINESS AND BASIS OF PRESENTATION:**

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

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

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

In management s opinion, the accompanying unaudited condensed consolidated financial statements of Noven contain all adjustments (consisting of only normal recurring adjustments) necessary to present fairly, in all material respects, the consolidated financial position of Noven, the results of its operations, and its cash flows for the periods presented. Noven s business is subject to numerous risks and uncertainties including, but not limited to, those set forth in Part I Item 1A of Noven s Annual Report on Form 10-K for the year ended December 31, 2007 ( Form 10-K ), and as supplemented by Part II Item 1A Risk Factors of this quarterly report on Form 10-Q. Accordingly, the results of operations and cash flows for the periods presented are not, and should not be construed as, necessarily indicative of the results of operations or cash flows which may be reported for the remainder of 2008 or for periods thereafter.

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

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

**Table of Contents****2. RECENT ACCOUNTING PRONOUNCEMENTS:**

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

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

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

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

Cash payments for income taxes were \$7.5 million and \$16.5 million for the six months ended June 30, 2008 and 2007, respectively. In 2002, the State of New Jersey enacted legislation that requires Novogyne to remit estimated state income tax payments on behalf of its owners, Noven and Novartis. For the six months ended June 30, 2008 and 2007, Novogyne paid \$1.8 million and \$4.4 million, respectively, to the New Jersey Department of Revenue, representing Noven's portion of Novogyne's estimated state income tax payment. These payments were deemed distributions to Noven from Novogyne. Noven received tax refunds directly from the State of New Jersey of \$2.7 million and \$2.4 million during the six months ended June 30, 2008 and 2007, respectively, related to these state income tax payments made on Noven's behalf. Cash payments for interest were not material for the six months ended June 30, 2008 and 2007.

*Non-cash Operating Activities*

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

*Non-cash Investing Activities*

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 (loss).

**Table of Contents****4. INVESTMENTS AVAILABLE-FOR-SALE:**

At June 30, 2008, Noven held investments in auction rate securities (classified as available-for-sale) with a par value and fair value of \$18.0 and \$17.5 million, respectively. Auction rate securities are floating rate debt securities with long-term nominal maturities, the interest rates of which are reset periodically (typically every seven to thirty-five days) through a Dutch auction process. These periodic auctions have historically provided a liquid market for auction rate securities, as this mechanism generally allowed existing investors to rollover their holdings and continue to own their respective securities at then-existing market rates or to liquidate their holdings by selling their securities at par value. Beginning in February 2008, as part of the ongoing credit market crisis, several auction rate securities from various issuers have failed to receive sufficient order interest from potential investors to clear successfully, resulting in auction failures. Historically, when investor demand was insufficient, the banks running the auctions would step in and purchase the remaining securities in order to prevent an auction failure. However, the banks have recently been allowing these auctions to fail. As a result of failed auctions, these investments now pay interest as defined by the governing documents or indenture.

Noven liquidated \$36.9 million of auction rate securities at par value during the six months ended June 30, 2008. During the three months ended March 31, 2008, Noven recorded an unrealized loss of \$0.5 million to reduce the investments to fair value. During the three months ended June 30, 2008, Noven determined that no additional loss was required to be recorded. The unrealized loss has been recorded as a reduction of stockholders' equity through other comprehensive income (loss). Because the investments are tax-exempt, there is no related tax effect.

Noven's auction rate security investments are collateralized primarily by tax-exempt municipal bonds and, to a lesser extent, guaranteed student loans. Noven does not hold any auction rate securities collateralized by mortgages or collateralized debt obligations. Noven believes these investments are of high credit quality, as all are investment grade and the majority are rated AA or higher. Furthermore, management currently has the intent and believes it has the ability to hold these investments until the anticipated recovery in fair value occurs. Based on these factors, Noven believes the decline in fair value of these investments is due to general market conditions and is temporary in nature. Noven will continue to monitor the market for its auction rate investments. If management determines in a future period that a decline in fair value is other than temporary, then in accordance with SFAS No. 115, Noven would be required to recognize a realized loss in operations in the period when such determination is made.

**5. FAIR VALUE MEASUREMENTS:**

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

- (i) Level 1 – observable inputs such as quoted prices in active markets;
- (ii) Level 2 – inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and
- (iii) Level 3 – unobservable inputs for which there is little or no market data, which require the reporting entity to develop its own assumptions.

During the six months ended June 30, 2008, Noven recorded a \$0.5 million unrealized loss on its investments in auction rate securities which are classified as available-for-sale under SFAS No. 115. As of June 30, 2008, the total par value and fair value of Noven's investments was \$18.0 million and \$17.5 million, respectively. Due to continuing auction failures beginning in February 2008, Noven utilized valuation models to determine the fair values of its investments in auction rate securities. The fair values of the investments were calculated based on the following:

(i) the underlying structure of each security; (ii) the present value of future principal and interest payments discounted at rates considered to reflect current market conditions; (iii) consideration of the probabilities of default, auction failure, or repurchase at par for each period; and (iv) consideration of third party credit enhancement. These estimated fair values could change significantly based on future market conditions.

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

|  |           |
|--|-----------|
| Balance at December 31, 2007                           | \$ 54,400 |
| Purchases of investments                               | 550       |
| Sales of investments at par                            | (36,925)  |
| Unrealized losses recorded as other comprehensive loss | (515)     |
| Balance at June 30, 2008                               | \$ 17,510 |

**6. INVENTORIES:**

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

|                 | <b>June 30,<br/>2008</b> | <b>December<br/>31,<br/>2007</b> |
|-----------------|--------------------------|----------------------------------|
| Finished goods  | \$ 4,105                 | \$ 3,171                         |
| Work in process | 2,903                    | 1,532                            |
| Raw materials   | 9,270                    | 7,433                            |
| Total           | \$ 16,278                | \$ 12,136                        |

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 due primarily to Daytrana® product that exhibited high peel force characteristics.

Shire plc (Shire) retains title to the active methylphenidate ingredient (AMI) in Daytrana®. The value of the AMI is neither included in Daytrana® product revenues nor in Noven's cost of products sold. Noven records AMI maintained at its manufacturing facility as consignment inventory and bears certain manufacturing risks of loss related to the AMI. These risks include the contractual obligation of Noven to reimburse Shire for the cost of AMI if Noven does not meet certain minimum yields of the finished product. Shire has a reciprocal obligation to pay Noven if the yield requirements are exceeded. Noven slightly exceeded the yield requirements for the six months ended June 30, 2008 for product shipped to Shire, resulting in an immaterial payment from Shire to Noven. During the six months ended June 30, 2008, Noven used \$2.7 million of AMI in the finished product. Noven had \$4.6 million and \$2.6 million of consignment AMI inventory on hand at June 30, 2008 and December 31, 2007, respectively, for which Noven owed Shire approximately \$0.6 million and \$0.5 million as of such respective dates, primarily as a result of product that did not meet the product's release liner removal specification. AMI is not reflected in the inventory table above.



**Table of Contents****7. GOODWILL AND INTANGIBLE ASSETS:**

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

During the six months ended June 30, 2008, Noven took certain actions related to the JDS acquisition, resulting in a \$0.3 million net reduction in goodwill as follows:

As part of the JDS acquisition, a portion of the purchase price was placed in escrow to be distributed upon final determination of the amount of net working capital purchased by Noven. During the three months ended June 30, 2008, Noven reached a final agreement with the JDS sellers on the net working capital, which agreement resulted in a \$1.1 million payment to Noven from the escrow account (which was paid subsequent to June 30, 2008). As a result of the working capital adjustment, Noven adjusted the amount due from escrow by \$1.0 million during the six months ended June 30, 2008 and recorded a corresponding increase of \$1.0 million to goodwill.

Also as part of the JDS acquisition, Noven recognized a favorable lease asset related to office space in New York and a liability for employee relocation costs, based on a tentative determination that Noven would exit the New York location by May 2008. During the three months ended June 30, 2008, management decided to retain the New York office space through its remaining contractual term and to not require relocation of the remaining personnel based in New York. As a result of these decisions, Noven revised the value of the acquired favorable lease asset and reversed the unused relocation liability, resulting in a \$1.3 million reduction in goodwill.

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

|                              | <b>Gross<br/>Carrying<br/>Amount</b> | <b>Accumulated<br/>Amortization</b> | <b>Net<br/>Carrying<br/>Amount</b> | <b>Amortization<br/>Period<br/>(years)</b> |
|------------------------------|--------------------------------------|-------------------------------------|------------------------------------|--|
| As of June 30, 2008          |                                      |                                     |                                    |  |
| Patent development costs     | \$ 4,694                             | \$ (2,814)                          | \$ 1,880                           | 7 - 13                                     |
| Acquired product intangibles | 37,790                               | (3,361)                             | 34,429                             | 10   |
| Non-competition agreements   | 530                                  | (193)                               | 337                                | 2 - 3                                      |
| Favorable lease              | 790                                  | (246)                               | 544                                | 2  |
|                              | \$ 43,804                            | \$ (6,614)                          | \$ 37,190                          |  |
| As of December 31, 2007      |                                      |                                     |                                    |  |
| Patent development costs     | \$ 4,542                             | \$ (2,573)                          | \$ 1,969                           | 8 - 14                                     |
| Acquired product intangibles | 37,790                               | (1,549)                             | 36,241                             | 10   |
| Non-competition agreements   | 530                                  | (82)                                | 448                                | 2 - 3                                      |
| Favorable lease              | 227                                  | (112)                               | 115                                | 10 months                                  |
|                              | \$ 43,089                            | \$ (4,316)                          | \$ 38,773                          |  |



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All intangible assets above, with the exception of patent development costs with a net carrying amount of approximately \$1.9 million and \$2.0 million at June 30, 2008 and December 31, 2007, respectively, were acquired on the Closing Date as part of the JDS acquisition. Amortization expense was \$1.2 million and \$0.1 million for the three months ended June 30, 2008 and 2007, respectively. Amortization expense was \$2.3 million and \$0.3 million for the six months ended June 30, 2008 and 2007, respectively.

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

|  | <b>Remainder<br/>of 2008</b> | <b>2009</b> | <b>Years Ending December 31,</b> |             |             | <b>2013</b> |
|--|------------------------------|-------------|----------------------------------|-------------|-------------|-------------|
|  |                              |             | <b>2010</b>                      | <b>2011</b> | <b>2012</b> |             |
| Cost of goods sold:                              |                              |             |                                  |             |             |             |
| Intellectual property                            | \$ 2,053                     | \$ 4,032    | \$ 3,985                         | \$ 3,924    | \$ 3,908    | \$ 3,847    |
| General and<br>administrative:                   |                              |             |                                  |             |             |             |
| Non-compete and<br>favorable lease<br>agreements | 231                          | 413         | 237                              |             |             |             |
| Total  | \$ 2,284                     | \$ 4,445    | \$ 4,222                         | \$ 3,924    | \$ 3,908    | \$ 3,847    |

**8. OTHER ACCRUED LIABILITIES:**

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

|                                    | <b>June 30,<br/>2008</b> | <b>December 31,<br/>2007</b> |
|------------------------------------|--------------------------|------------------------------|
| Income taxes payable               | \$ 5,437                 | \$ 2,414                     |
| Accrued Medicaid and other rebates | 2,834                    | 4,065                        |
| Accrued market withdrawal costs    | 1,950                    | 3,300                        |
| Allowance for product returns      | 2,416                    | 1,875                        |
| Other accrued liabilities          | 4,556                    | 3,616                        |
| Total other accrued liabilities    | \$ 17,193                | \$ 15,270                    |

**9. EQUITY PLANS:**

Prior to January 1, 2006, all awards granted to employees under Noven's 1999 Long-Term Incentive Plan (the "1999 Plan") were stock options. In 2006, Noven began granting stock-settled stock appreciation rights ("SSARs") and nonvested shares of common stock ("restricted stock"). Noven accounts for these awards in accordance with SFAS No. 123 (revised 2004), "Share-Based Payment". At June 30, 2008, there were 2,114,197 stock options and 1,543,360 SSARs issued and outstanding under the 1999 Plan.

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

|                                | <b>Shares</b> | <b>Weighted<br/>Average<br/>Grant-Date<br/>Fair Value</b> |
|--------------------------------|---------------|---|
| Nonvested at December 31, 2007 | 6             | \$ 22.86  |
| Granted                        | 328           | 9.90  |
| Vested                         | (76)          | 11.15   |
| Nonvested at June 30, 2008     | 258           | \$ 9.86   |

Noven granted 70,847 and 26,244 shares of restricted stock to Noven's non-employee directors in June 2008 and May 2007, respectively, as compensation for Board services. The shares vest over each director's one-year service period at the end of each calendar quarter beginning with the end of the second quarter. As the shares vest, those shares that have been deferred by non-employee directors under Noven's deferred compensation plan are transferred into a rabbi trust maintained by Noven. In accordance with EITF Issue No. 97-14, Accounting for Compensation Arrangements Where Amounts Earned are Held in a Rabbi Trust and Invested, the deferred shares were recorded at their fair value and classified as common stock held in trust. Since the deferral relates to Noven common stock, an offsetting amount was recorded as deferred compensation obligation in the stockholders' equity section of the consolidated balance sheets. At June 30, 2008 and December 31, 2007 there were a total of 67,515 and 48,300 shares of common stock in the rabbi trust, respectively. Restricted stock grants during the six months ended June 30, 2008 include an aggregate 257,345 shares of restricted stock granted to certain executive officers in 2008.

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

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

|                         | <b>2008</b> | <b>2007</b> |
|-------------------------|-------------|-------------|
| Volatility              | 50.5%       | 45.8%       |
| Risk free interest rate | 3.22%       | 4.59%       |
| Expected life (years)   | 4.8         | 5.0         |
| Dividend yield          | 0.0%        | 0.0%        |

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

|   | <b>Three Months Ended<br/>June 30,</b> |             | <b>Six Months Ended June<br/>30,</b> |             |
|---|--|-------------|--------------------------------------|-------------|
|   | <b>2008</b>                            | <b>2007</b> | <b>2008</b>                          | <b>2007</b> |
| Selling and marketing                                     | \$ 169                                 | \$ 111      | \$ 323                               | \$ 222      |
| General and administrative                                | 1,159                                  | 628         | 1,627                                | 1,256       |
| Research and development                                  | 85                                     | 127         | 176                                  | 254         |
| Total cost of products sold                               | 74                                     | 122         | 219                                  | 244         |
|   | \$ 1,487                               | \$ 988      | \$ 2,345                             | \$ 1,976    |
| <br>  |  |             |                                      |             |
| Tax benefit recognized related to<br>compensation expense | \$ 511                                 | \$ 302      | \$ 804                               | \$ 661      |

Stock-based compensation costs of \$0.1 million for the three months ended June 30, 2008 and 2007, respectively, and \$0.2 million for the six months ended June 30, 2008 and 2007, respectively, were included in manufacturing expenses, which are included in the determination of inventory costs. In any given period, the amount of stock-based compensation costs included in ending inventory is not material. There were no stock-based compensation costs capitalized as part of fixed assets for the three and six months ended June 30, 2008 or 2007.

Cash received from options exercised under all share-based payment arrangements for the six months ended June 30, 2008 and 2007 was \$10,000 and \$2.5 million, respectively. There was no tax benefit realized on the tax deductions from option exercises under stock-based compensation arrangements for the six months ended June 30, 2008 as an immaterial amount of stock options/SSARs were exercised during this period. The tax benefit realized on the tax deductions from option exercises under stock-based compensation arrangements was \$0.5 million for the six months ended June 30, 2007, of which \$0.4 million was reported as cash flow from financing activities for the six months ended June 30, 2007.

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

|   | <b>Options/<br/>SSARs</b> | <b>Weighted<br/>Average<br/>Exercise<br/>Price</b> | <b>Aggregate<br/>Intrinsic<br/>Value</b> | <b>Weighted<br/>Average<br/>Remaining<br/>Contractual<br/>Term</b> |
|---|---------------------------|--|--|--|
| Outstanding at December 31, 2007                    | 3,511                     | \$ 16.83   |  |  |
| Granted   | 476                       | 9.87   |  |  |
| Exercised   | (1)                       | 10.89  | \$ 3                                     |  |
| Canceled and expired                                | (329)                     | 18.73  |  |  |
| Outstanding at June 30, 2008                        | 3,657                     | \$ 15.94   | \$ 581                                   | 4.1  |
| Outstanding and exercisable at end of the<br>period | 2,062                     | \$ 17.30   | \$ 185                                   | 2.7  |



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As of June 30, 2008, the unamortized compensation expense that Noven expects to record in future periods related to currently outstanding unvested stock options, SSARs and restricted stock is approximately \$11.7 million before the effect of income taxes, of which \$2.7 million, \$4.0 million, \$2.9 million, \$1.8 million and \$0.3 million is expected to be incurred in the remainder of 2008 and in 2009, 2010, 2011 and 2012, respectively. The weighted-average period over which this compensation cost is expected to be recognized is 2.5 years. As of June 30, 2008, approximately 3,368,362 outstanding options/SSARs are vested or expected to vest. Such options have a weighted average exercise price of \$16.13, \$0.5 million aggregate intrinsic value and a weighted average remaining life of 5.95 years as of June 30, 2008.

**10. INCOME TAXES:**

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

Upon adoption of FIN 48, and as a result of the recognition and measurement of Noven's tax positions as of January 1, 2007, Noven recognized a charge of approximately \$0.5 million to the January 1, 2007 retained earnings balance. The gross amount of unrecognized tax benefits as of the date of adoption, January 1, 2007, was \$0.9 million. If the \$0.9 million were ultimately recognized, approximately \$0.6 million would affect the effective tax rate due to approximately \$0.3 million in related federal tax benefit. As of June 30, 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 affect the effective tax rate due to approximately \$0.4 million in related federal tax benefit. Interest and penalties related to income taxes are classified as a component of income tax expense. Approximately \$0.4 million and \$0.5 million were accrued for interest and penalties as of June 30, 2008 and December 31, 2007, respectively. Noven does not expect the gross amount of unrecognized tax benefits to significantly increase or decrease within twelve months after June 30, 2008. All of Noven's unrecognized tax benefits pertain to state tax positions.

Noven is periodically audited by federal and state taxing authorities. The outcome of these audits may result in Noven being assessed taxes in addition to amounts previously paid. The accruals are determined based upon Noven's best estimate of possible assessments by the Internal Revenue Service ( IRS ) or other taxing authorities and are adjusted, from time to time, based upon changing facts and circumstances. Federal returns for years 2004-2006 remain open and subject to examination by the IRS. Noven files and remits state income taxes in various states where Noven has determined it is required to file state income taxes. Noven's filings with those states remain open for audit for the years 2003-2006. Other than routine state tax inquiries, there are no 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, 2008 and December 31, 2007, net deferred tax assets were \$72.6 million and \$65.7 million, respectively. Realization of these deferred tax assets depends upon the generation of sufficient future taxable income. A valuation allowance is established if it is more likely than not that all or a portion of the deferred tax asset will not be realized. Noven Therapeutics files separate state income tax returns in states where Noven Therapeutics has determined that it is required to file state income taxes. As a result, state deferred tax assets relating to Noven Therapeutics are evaluated separately in determining whether the state deferred tax assets are realizable. Noven expects that Noven Therapeutics will incur taxable losses in the next few years due to future expected clinical trial expenditures related to product development and selling and marketing costs required to commercialize its products. These expected taxable losses create negative evidence indicating the need for a valuation allowance at June 30, 2008 and December 31, 2007. Noven's valuation allowance for state deferred tax assets was \$3.3 million and \$3.2 million as

of June 30, 2008 and December 31, 2007, respectively, due to uncertainties in realizing these state deferred tax assets based on Noven's projection of future state taxable income relating to Noven Therapeutics. If Noven determines, based on future Noven Therapeutics profitability that these state deferred tax assets will more likely than not be realized, a release of all, or part, of the related valuation allowance could result in an immediate income tax benefit in the period the valuation allowance is released.



**Table of Contents****11. CONTRACT AND LICENSE AGREEMENTS:****SHIRE COLLABORATION**

Noven has developed a once-daily transdermal methylphenidate patch for Attention Deficit Hyperactivity Disorder (ADHD) called Daytrana®. In the first quarter of 2003 Noven licensed to Shire the exclusive global rights to market Daytrana® for payments by Shire of up to \$150.0 million. In consideration for this licensing transaction, Shire agreed to pay Noven as follows: (i) \$25.0 million was paid upon closing of the transaction in April 2003; (ii) \$50.0 million was paid in April 2006 upon receipt of final marketing approval by the United States Food and Drug Administration (FDA); and (iii) three installments of \$25.0 million each payable upon Shire's achievement of \$25.0 million, \$50.0 million and \$75.0 million in annual Daytrana® net sales, respectively. Noven received the first \$25.0 million sales milestone in the first quarter of 2007 and the second \$25.0 million sales milestone in the third quarter of 2007. Noven has been advised by Shire that Shire's net sales of Daytrana® during the 12 months ended June 30, 2008 have triggered the third and final \$25.0 million sales milestone due to be paid to Noven during the third quarter of 2008. As a result, Noven's balance sheet reflects a milestone payment receivable from Shire of \$25.0 million as of June 30, 2008. Noven is currently deferring and recognizing approval and sales milestones as license revenues on a straight-line basis, beginning on the date the milestone is achieved through the first quarter of 2013, which is Noven's current best estimate of the end of the useful economic life of the product.

**SYNTHON PHARMACEUTICALS COLLABORATION**

In November 2005, JDS 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 the JDS acquisition, Noven became responsible for the possible future contingent payments of up to \$11.5 million under the asset purchase agreement with Synthon. As of June 30, 2008 and December 31, 2007, \$8.2 million and \$11.5 million of these milestones were reflected as liabilities on Noven's consolidated balance sheets. In April 2008, Noven made a milestone payment of \$3.3 million to Synthon as a result of Pexeva® achieving certain sales levels in 2007.

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

Noven shares in the earnings of Novogyne, after satisfaction of an annual preferred return of \$6.1 million to Novartis, according to an established formula. Noven's share of Novogyne's earnings increases as Novogyne's product sales increase, subject to a cap of 49%. Novogyne earned sufficient income in the first quarter of 2008 and 2007 to meet Novartis' annual preferred return for those years and for Noven to recognize earnings from Novogyne under the formula.

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

|                     | <b>Three Months</b> |             | <b>Six Months</b> |             |
|---------------------|---------------------|-------------|-------------------|-------------|
|                     | <b>2008</b>         | <b>2007</b> | <b>2008</b>       | <b>2007</b> |
| Revenues:           |                     |             |                   |             |
| Product sales       | \$ 5,553            | \$ 4,804    | \$ 7,984          | \$ 10,173   |
| Royalties           | 2,349               | 1,899       | 4,529             | 3,664       |
|                     | \$ 7,902            | \$ 6,703    | \$ 12,513         | \$ 13,837   |
| Reimbursed expenses | \$ 7,381            | \$ 7,021    | \$ 14,653         | \$ 14,106   |

Reimbursed expenses are primarily comprised of selling and marketing expenses paid by Noven on behalf of Novogyne. As of June 30, 2008 and December 31, 2007, Noven had amounts due from Novogyne of \$6.6 million and \$8.7 million, respectively.

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

|  | <b>Three Months</b> |             | <b>Six Months</b> |             |
|--|---------------------|-------------|-------------------|-------------|
|  | <b>2008</b>         | <b>2007</b> | <b>2008</b>       | <b>2007</b> |
| Gross revenues                               | \$ 50,054           | \$ 42,915   | \$ 95,348         | \$ 80,208   |
| Sales allowances                             | 5,702               | 6,837       | 11,555            | 10,999      |
| Sales return allowances                      | 585                 | (60)        | 500               | (9)         |
| Sales allowances and returns                 | 6,287               | 6,777       | 12,055            | 10,990      |
| Net revenues                                 | 43,767              | 36,138      | 83,293            | 69,218      |
| Cost of sales                                | 8,788               | 7,795       | 16,596            | 14,842      |
| Selling, general and administrative expenses | 9,798               | 9,579       | 18,810            | 19,712      |
| Income from operations                       | 25,181              | 18,764      | 47,887            | 34,664      |
| Interest income                              | 174                 | 165         | 441               | 497         |
| Net income                                   | \$ 25,355           | \$ 18,929   | \$ 48,328         | \$ 35,161   |
| Noven's equity in earnings of Novogyne       | \$ 12,429           | \$ 9,174    | \$ 20,696         | \$ 14,077   |

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

|  |           |
|--|-----------|
| Investment in Novogyne, beginning of period                  | \$ 24,310 |
| Equity in earnings of Novogyne                               | 20,696    |
| Cash distributions from Novogyne                             | (17,247)  |
| Deemed distribution by Novogyne for state income tax payment | (1,800)   |
| Investment in Novogyne, end of period                        | \$ 25,959 |



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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, 2008, Noven received cash distributions representing return on investment of \$6.3 million and \$17.2 million, respectively, from Novogyne. For the three and six months ended June 30, 2007, Noven received cash distributions representing return on investment of \$1.2 million and \$11.0 million, respectively, from Novogyne. In addition, as discussed in Note 3, tax payments of \$1.8 million and \$4.4 million were made by Novogyne on Noven's behalf to the New Jersey Department of Revenue during the six months ended June 30, 2008 and 2007, respectively. These amounts were recorded as reductions in the investment in Novogyne when received (or in the case of tax payments, when paid).

**13. SHARE REPURCHASE PROGRAM:**

In September 2007, Noven's Board of Directors authorized a share repurchase program under which Noven may acquire up to \$25.0 million of its common stock. As of December 31, 2007, Noven had repurchased 322,345 shares of its common stock at an aggregate price of approximately \$5.1 million. These shares remained in treasury as of June 30, 2008 and December 31, 2007. No shares were repurchased under the program during the six months ended June 30, 2008.

**14. COMMITMENTS AND CONTINGENCIES:****HORMONE THERAPY ( HT ) STUDIES:**

Since 2002, several studies, including the Women's Health Initiative ( WHI ) study performed by the National Institutes of Health ( NIH ) and a study performed by the National Cancer Institute ( NCI ), have identified increased risks from the use of HT, including increased risks of invasive breast cancer, ovarian cancer, stroke, heart attacks and blood clots. As a result of the findings from these and other studies, the FDA has required that "black box" labeling be included on all HT products marketed in the United States to warn, among other things, that these products have been associated with increased risks for heart disease, heart attacks, strokes and breast cancer and that they are not approved for heart disease prevention. Since the July 2002 publication of the WHI and NCI study data, total United States prescriptions have declined for substantially all HT products, including our HT products in the aggregate. Researchers continue to analyze data from the WHI study and other studies. Other studies evaluating HT are currently underway or in the planning stage. In particular, a private foundation has commenced a clinical study aimed at determining whether estrogen therapy ( ET ) use, by women aged 42 to 58, reduces the risk of heart disease. The study also seeks to determine if transdermal estrogen patches are more or less beneficial than an oral HT product. While our HT products are not being used in the study, the market for our 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 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, 2008 and 2007, Noven's product sales of Daytrana® to Shire were \$2.7 million and \$5.2 million, respectively. During the six months ended June 30, 2008 and 2007, Noven's product sales of Daytrana® to Shire were \$5.7 million and \$9.6 million, respectively. The supply agreement gives Shire the right to qualify a second manufacturing source and purchase a portion of its requirements from that source. If Shire were to exercise this right, Noven's financial results from sales of Daytrana® would be adversely affected.

**LITIGATION, CLAIMS AND ASSESSMENTS:**

In September 2005, Noven, Novogyne and Novartis were served with a summons and complaint from an individual plaintiff in Superior Court of New Jersey Law Division, Atlantic County in which the plaintiff claims personal injury allegedly arising from the use of HT products, including Vivelle®. The plaintiff claims compensatory, punitive and other damages in an unspecified amount. Noven does not expect any activity in this case in the near future, as the court has entered an order to stay proceedings in all its pending and future HT cases except for cases where Wyeth Pharmaceuticals and its affiliates and Pfizer Inc. are the defendants.

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

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

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

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

Novartis has advised Noven that Novartis is currently named as a defendant in at least 31 additional lawsuits that include approximately 32 plaintiffs that allege liability in connection with personal injury claims allegedly arising from the use of HT patches distributed and sold by Novartis and Novogyne, including Noven's Vivelle-Dot®, Vivelle®, and CombiPatch® products. Novogyne has been named as a defendant in one lawsuit in addition to the four lawsuits referenced above. Novartis has indicated that it will seek indemnification from Noven and Novogyne to the extent permitted by the agreements between and among Novartis, Novogyne and Noven. Novogyne's aggregate limit under its claims-made insurance policy as of June 30, 2008 was \$10.0 million. Novogyne has established reserves in the amount of \$9.1 million with an offsetting insurance recovery of \$7.0 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, 2008.

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In June 2007, Johnson-Matthey Inc. filed a complaint in the United States District Court, Eastern District of Texas against Noven alleging that Noven was infringing one of its patents through Noven's manufacture and sale of Daytrana®. The plaintiff is seeking injunctions from further infringement and claiming compensatory and other damages in an unspecified amount. In July 2007, Johnson-Matthey added Shire as a defendant in this lawsuit.

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

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

**FDA WARNING LETTER:**

Noven and Shire have received reports from some consumers concerning the difficulty of removing the release liner from Daytrana® patches. In the first quarter of 2007, Noven, together with Shire, implemented enhancements to the Daytrana® release liner. While the enhanced release liner has reduced the level of consumer reports, some patients and caregivers continue to have difficulty in removing the release liner from some Daytrana® patches. Noven and Shire continue to monitor and review release liner complaints and the manufacturing process to determine whether modifications to the product or process can improve the long-term ease of use and address the issues raised by the FDA in the warning letter described below. Daytrana's market share based on total prescriptions declined in the three months ended June 30, 2008.

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

In the third quarter of 2007, Shire initiated two voluntary market withdrawals of a portion of the Daytrana® product on the market primarily in response to feedback from patients and caregivers who experienced difficulty removing the release liner from some Daytrana® patches. Noven paid Shire \$3.3 million in February 2008 related to the withdrawals. These costs were charged to operations in 2007.

In January 2008, Noven received a warning letter from the FDA in connection with the FDA's July 2007 inspection of its manufacturing facilities. In the warning letter, which is posted at the FDA's website, the FDA cited Current Good Manufacturing Practice deficiencies related to: (i) peel force specifications for removal of Daytrana'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. In March 2008, the Florida District Office of the FDA indicated that Noven's response appears to be satisfactory and stated that Noven's response had been forwarded to the FDA's Center for Drug Evaluation and Research for further review. In April 2008, a Noven stability protocol identified certain Daytrana® lots exhibiting high peel force characteristics. In June 2008, Shire initiated the voluntary recall of two lots of Daytrana® that did not meet the product's release liner removal specification. Noven has agreed to pay Shire \$1.95 million related to this recall, of which \$0.25 million and \$1.7 million were charged to operations in the first and second quarters of 2008, respectively.

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

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**CONTRACT AND LICENSE AGREEMENTS:**

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

**NOVEN THERAPEUTICS COMMITMENTS:**

Noven Therapeutics has certain commitments and contingencies related to contractual arrangements, primarily related to milestone payments for development, FDA submission, FDA approval and commercial sales of current and developmental products. As of June 30, 2008 and December 31, 2007, Noven Therapeutics was responsible for up to \$20.2 million and \$23.5 million in such contingent milestones, respectively. As of June 30, 2008 and December 31, 2007, \$8.2 million and \$11.5 million of these milestones, respectively, were reflected as liabilities in Noven's consolidated balance sheets and, as discussed in Note 11, in April 2008, Noven made a milestone payment of \$3.3 million to Synthon.

**EMPLOYMENT AGREEMENT AND BONUS PLAN:**

Effective April 29, 2008, Peter Brandt was appointed to the offices of President and Chief Executive Officer and to Noven's Board of Directors. In connection with Mr. Brandt's appointment as an executive officer, Noven and Mr. Brandt entered into an employment agreement, dated April 29, 2008 (the "Agreement"). The initial two-year term of the Agreement expires on April 28, 2010 and will continue for consecutive one-year terms unless it is terminated by either party under certain conditions. Mr. Brandt's base salary under the Agreement is approximately \$0.7 million, subject to further increases at the discretion of the Board of Directors. Mr. Brandt's annual target incentive bonus under Noven's annual incentive plan during the term will be at least 75% of his base salary.

In connection with the Agreement, Mr. Brandt was granted the following equity awards under the 1999 Plan: (i) SSARs with an aggregate fair value of \$1.3 million to acquire 311,529 shares of Noven's common stock at an exercise price of \$9.10 per share (the market price on the grant date) which vest at a rate of 25% per year on each anniversary of the grant date; and (ii) 250,000 shares of restricted stock. The shares of restricted stock vest as follows: (a) 50,000 shares immediately upon grant; (b) 16,667 shares on the first anniversary of the grant date; (c) 16,666 shares on the second anniversary of the grant date; (d) 16,666 shares on the third anniversary of the grant date; (e) 50,000 shares upon Noven attaining pre-tax income of \$50.0 million or more over any four consecutive quarterly periods; (f) 50,000 shares upon Noven attaining pre-tax income of \$75.0 million or more over any four consecutive quarterly periods; and (g) 50,000 shares upon Noven attaining pre-tax income of \$100.0 million or more over any four consecutive quarterly periods. On the grant date, the restricted shares had an aggregate fair value of \$2.3 million, of which \$455,000 related to the vested shares was immediately charged to operations and \$455,000 pertaining to 50,000 shares is being amortized ratably over the 3-year vesting period. The balance of \$1.4 million is and will be amortized over periods which reflect management's current best estimate of when the specified performance targets will be achieved.

Noven has a formula bonus plan that includes company and individual performance goals. Under the plan, a fixed percentage of each eligible employee's base salary is established as a target incentive bonus award for such employee. To the extent that actual company performance is equal to, exceeds or is less than the company performance targets, an employee's bonus award may be equal to, greater than or less than his or her target award. An employee's non-financial goals are then considered in determining his or her final bonus award. Management's estimate of the bonus accrual is expensed over the year in which it is earned.

**Table of Contents****15. SEGMENT AND CUSTOMER DATA:**

The accounting policies of the segments are the same as those described in Note 2 of the notes to the financial statements included in Noven's Form 10-K. The table below presents segment information for the periods identified and reconciles segment information to the applicable consolidated amounts. There are no inter-segment revenues. The results of the Noven Therapeutics segment are included in Noven's consolidated results beginning on the date of acquisition (August 14, 2007). Consequently, Noven's results for the three and six month period ended June 30, 2007 do not include the results of the Noven Therapeutics segment. Prior year comparative data is provided for the Noven Transdermals segment:

|                                | <b>Three Months<br/>Ended June 30,</b> |             | <b>Six Months<br/>Ended June 30,</b> |             |
|--------------------------------|--|-------------|--------------------------------------|-------------|
|                                | <b>2008</b>                            | <b>2007</b> | <b>2008</b>                          | <b>2007</b> |
| (in thousands):                |  |             |                                      |             |
| Noven Transdermals:            |  |             |                                      |             |
| Product revenues               | \$ 12,968                              | \$ 15,062   | \$ 23,459                            | \$ 30,668   |
| License and contract revenues  | 5,060                                  | 3,777       | 10,346                               | 7,486       |
| Net revenues                   | 18,028                                 | 18,839      | 33,805                               | 38,154      |
| Cost of products sold          | (10,761)                               | (9,314)     | (20,034)                             | (18,241)    |
| Research and development       | (2,436)                                | (3,185)     | (4,814)                              | (6,651)     |
| Selling and marketing          | (213)                                  | (221)       | (407)                                | (461)       |
| Equity in earnings of Novogyne | 12,429                                 | 9,174       | 20,696                               | 14,077      |
| Segment contribution           | 17,047                                 | 15,293      | 29,246                               | 26,878      |
| Noven Therapeutics:            |  |             |                                      |             |
| Product revenues               | 6,575                                  |             | 12,280                               |             |
| Cost of products sold          | (2,022)                                |             | (4,058)                              |             |
| Research and development       | (857)                                  |             | (1,798)                              |             |
| Selling and marketing          | (5,123)                                |             | (9,752)                              |             |
| Segment contribution           | (1,427)                                |             | (3,328)                              |             |
| Unallocated income (expense):  |  |             |                                      |             |
| General and administrative     | (8,906)                                | (5,488)     | (15,928)                             | (10,669)    |
| Interest income, net           | 500                                    | 1,813       | 1,122                                | 3,445       |
| Income before income taxes     | \$ 7,214                               | \$ 11,618   | \$ 11,112                            | \$ 19,654   |

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

|                    | <b>June 30,<br/>2008</b> | <b>December<br/>31,<br/>2007</b> |
|--------------------|--------------------------|----------------------------------|
| Noven Transdermals | \$ 113,295               | \$ 83,912                        |
| Noven Therapeutics | 55,848                   | 57,893                           |



|                                  |            |            |
|----------------------------------|------------|------------|
| Assets not allocated to segments | 134,454    | 144,893    |
| Total Assets                     | \$ 303,597 | \$ 286,698 |

**16. SUBSEQUENT EVENT NEW CREDIT FACILITY**

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

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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, 2008, and our consolidated results of operations for the three months ended June 30, 2008 (the 2008 Quarter ) and June 30, 2007 (the 2007 Quarter ), and the six months ended June 30, 2008 (the 2008 Period ) and June 30, 2007 (the 2007 Period ). The contents of this section include:

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

An overview of Noven and our Novogyne joint venture;

An overview of Noven Therapeutics;

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

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

An outlook that includes our current financial guidance;

A discussion of how we apply our critical accounting estimates; and

A discussion of recently-issued accounting standards.

This discussion should be read in conjunction with Noven's consolidated financial statements for the three and six months ended June 30, 2008 and 2007 and the related notes included elsewhere in this Form 10-Q, as well as the section Management's Discussion and Analysis of Financial Condition and Results of Operations from our Form 10-K.

**Executive Summary**

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

Our financial results for the 2008 Quarter include the results of operations of Noven Therapeutics, a specialty pharmaceutical company that we acquired in August 2007. The 2008 Quarter also included a \$1.7 million charge related to reimbursements to Shire in connection with the voluntary recall of two lots of Daytrana<sup>®</sup> product initiated in the 2008 Quarter (the Recall Charge ).

Including the impact of the Recall Charge, we reported net income of \$4.5 million (\$0.18 diluted earnings per share) for the 2008 Quarter, compared to net income of \$7.6 million (\$0.30 diluted earnings per share) for the 2007 Quarter.

Our net revenues in the 2008 Quarter were \$24.6 million, 31% higher than the \$18.8 million reported in the 2007 Quarter. This increase reflects the recognition of \$6.6 million in net revenues associated with Noven Therapeutics sales of Pexeva<sup>®</sup> and Lithobid<sup>®</sup> products and increased license and contract revenues, primarily due to amortization of additional Daytrana<sup>®</sup> milestones received in 2007.

Gross margin, as a percentage of net product revenues, was 35% in the 2008 Quarter compared to 38% in the 2007 Quarter. Gross margin in the 2008 Quarter was adversely affected by increased quality assurance activities and expenses, primarily related to Daytrana<sup>®</sup> production. This decrease in gross margin was partially offset by sales of Pexeva<sup>®</sup> and Lithobid<sup>®</sup> in 2008, which have a higher gross margin than the products that we manufacture and sell to partners.

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Research and development expenses for the 2008 Quarter were \$3.3 million, relatively unchanged from the \$3.2 million reported in the 2007 Quarter. Selling and marketing expenses for the 2008 Quarter increased to \$5.3 million from \$0.2 million for the 2007 Quarter due to the addition of Noven Therapeutics. General and administrative expenses increased \$3.4 million, or 62%, due to a \$1.7 million charge related to reimbursements due to Shire in connection with the voluntary recall of two lots of Daytrana<sup>®</sup>, an increase in professional fees and the addition of Noven Therapeutics.

We recognized \$12.4 million in earnings from Novogyne in the 2008 Quarter, an increase of 35% compared to the 2007 Quarter. Net revenues at Novogyne increased 21% to \$43.8 million in the 2008 Quarter, primarily due to increased sales of Vivelle-Dot<sup>®</sup>. Novogyne's gross margin percentage for the 2008 Quarter increased slightly to 80%. Novogyne's selling, general and administrative expenses for the 2008 Quarter were \$9.8 million, largely unchanged from the 2007 Quarter. Novogyne's net income for the 2008 Quarter increased 34% to \$25.4 million compared to \$18.9 million in the 2007 Quarter.

At June 30, 2008, Noven had \$52.9 million in cash and cash equivalents and other non-current investments (\$35.4 million and \$17.5 million, respectively). This compares with \$68.4 million in cash and cash equivalents, short-term investments and other non-current investments (\$14.0 million, \$21.6 million and \$32.8 million, respectively) at December 31, 2007. Noven's investments at June 30, 2008 consisted of auction rate securities with a fair value of \$17.5 million, all of which have been classified as non-current on Noven's consolidated balance sheet following failed auctions occurring since February 2008. Noven's auction rate securities are collateralized primarily by tax-exempt municipal bonds, and to a lesser extent, guaranteed student loans. As of June 30, 2008, Noven had recorded unrealized losses totaling \$0.5 million relating to its investments in auction rate securities.

Total prescriptions for Vivelle-Dot<sup>®</sup> increased 6% in the 2008 Quarter compared to the 2007 Quarter, and total prescriptions for Novogyne's products, taken as a whole, increased 2%. By comparison, the overall U.S. HT market declined 6% for the same period. Total prescriptions for Daytrana<sup>®</sup> (launched in June 2006) decreased 11% in the 2008 Quarter compared to the 2007 Quarter, while prescriptions for ADHD stimulant therapies as a class increased 8% over the same period. Total prescriptions for Pexeva<sup>®</sup> decreased 6% in the 2008 Quarter compared to the 2007 Quarter, while for the same period prescriptions for the selective serotonin re-uptake inhibitor (SSRI) class were largely unchanged. Reflecting ongoing generic substitution, total prescriptions for Lithobid<sup>®</sup> decreased 32% in the 2008 Quarter compared to the 2007 Quarter.

In July 2008, Noven received final FDA approval of Stavzor (valproic acid delayed release capsules) in the treatment of manic episodes associated with bipolar disorder, adjunctive therapy in multiple seizure types (including epilepsy), and prophylaxis of migraine headaches. Stavzor is expected to be launched by the Noven Therapeutics sales force in August 2008. In addition, sales of Daytrana<sup>®</sup> by Shire during the 12 months ended June 30, 2008 were sufficient to trigger the third and final \$25.0 million sales milestone.

**Overview of Noven and our Novogyne Joint Venture**

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

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

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Novartis is entitled to an annual \$6.1 million preferred return from Novogyne, which has the effect of reducing our share of Novogyne's income in the first quarter of each year. After the annual preferred return to Novartis, our share of Novogyne's income increases as product sales increase, subject to a maximum of 49%. Our share of Novogyne's income was \$12.4 million and \$9.2 million for the 2008 Quarter and the 2007 Quarter, respectively. The income we recognize from Novogyne is a non-cash item. Any cash we receive from Novogyne is in the form of cash distributions declared by Novogyne's Management Committee. Accordingly, the amount of cash that we receive from Novogyne in any period is typically not the same as the amount of income we recognize from Novogyne for that period. For the 2008 Period and the 2007 Period, we received \$17.2 million and \$11.0 million, respectively, in distributions from Novogyne, which accounted for a substantial portion of our net operating cash flows for these periods. We expect that for the next several years a substantial portion of our earnings will be generated through our interest in Novogyne and a substantial portion of our cash flow will also be generated through our interest in Novogyne. Any failure by Novogyne to remain profitable or to continue to make distributions would have a material adverse effect on our consolidated results of operations and financial condition.

**Overview of Noven Therapeutics**

Noven Therapeutics is a specialty pharmaceutical company that currently markets three branded prescription psychiatry products (Stavzor, Pexeva<sup>®</sup> and Lithobid<sup>®</sup>) and is advancing developmental products in psychiatry and women's health including Mesafem, a non-hormonal therapy for the treatment of vasomotor symptoms associated with menopause. We will seek to leverage Noven Therapeutics' marketing and sales infrastructure with next-generation psychiatry/CNS products, and with complementary products that we will seek to develop and/or acquire. To bring Noven Therapeutics' pipeline of products under development to market, we plan to increase our research and development expenses significantly over the next several years. See Management's Discussion and Analysis of Financial Condition and Results of Operations - Outlook.

**Certain Items that May Affect Historical or Future Comparability**

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

*Acquisition of JDS Pharmaceuticals, LLC in 2007*

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

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We acquired \$39.1 million in identifiable intangible assets in the JDS acquisition, which relate to: (i) intellectual property rights associated with Noven Therapeutics' products approved by the FDA; (ii) a favorable lease intangible asset; and (iii) non-competition agreements with two former executives of JDS. At June 30, 2008, the carrying amount of Noven's intangible assets (excluding goodwill, but including certain patent development costs unrelated to the JDS acquisition) totaled \$37.2 million. Noven estimates that the annual amortization expense for intangible assets held at June 30, 2008 for each of the five years through 2013 will be as follows (amounts in thousands):

|   | <b>Remainder<br/>of 2008</b> | <b>2009</b>     | <b>Years Ending December 31,</b> |                 |                 | <b>2013</b>     |
|---|------------------------------|-----------------|----------------------------------|-----------------|-----------------|-----------------|
|   |                              |                 | <b>2010</b>                      | <b>2011</b>     | <b>2012</b>     |                 |
| Cost of goods sold:                           |                              |                 |                                  |                 |                 |                 |
| Intellectual property                         | \$ 2,053                     | \$ 4,032        | \$ 3,985                         | \$ 3,924        | \$ 3,908        | \$ 3,847        |
| General and administrative:                   |                              |                 |                                  |                 |                 |                 |
| Non-compete and favorable<br>lease agreements | 231                          | 413             | 237                              |                 |                 |                 |
| <b>Total</b>                                  | <b>\$ 2,284</b>              | <b>\$ 4,445</b> | <b>\$ 4,222</b>                  | <b>\$ 3,924</b> | <b>\$ 3,908</b> | <b>\$ 3,847</b> |

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

**Daytrana®**

Daytrana® is Noven's transdermal methylphenidate system for the treatment of ADHD, which we have 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. Noven and Shire continue to monitor and review release liner complaints and the manufacturing process to determine whether modifications to the product or process can improve the long-term ease of use and address the issues raised by the FDA in the warning letter described below. Daytrana®'s market share based on total prescriptions declined in the 2008 Quarter.

In July 2007, Noven 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, Noven submitted to the FDA its response to the Form 483.

In the third quarter of 2007, Shire initiated two voluntary market withdrawals of a portion of the Daytrana® product on the market primarily in response to feedback from patients and caregivers who experienced difficulty removing the release liner from some Daytrana® patches. Noven paid Shire \$3.3 million in February 2008 related to the withdrawals. 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. We submitted our response to the warning letter on January 30, 2008. In March 2008, the Florida District Office

of the FDA indicated that our response appears to be satisfactory and stated that our response had been forwarded to the FDA's Center for Drug Evaluation and Research for further review. In April 2008, a Noven stability protocol identified certain Daytrana<sup>®</sup> lots exhibiting high peel force characteristics. In June 2008, Shire initiated the voluntary recall of two lots of Daytrana<sup>®</sup> that did not meet the product's release liner removal specification. We have agreed to pay Shire \$1.95 million related to this recall, of which \$0.25 million and \$1.7 million was charged to operations in the first and second quarters of 2008, respectively.

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

**Results of Operations**

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

We evaluate segment performance based on segment contribution, which consists of segment gross margin less direct research and development expenses and direct selling and marketing expenses, plus (in the case of Noven Transdermals) our equity in earnings of Novogyne. Shared corporate general and administrative expenses and interest income are not allocated to our operating segments. The contribution of our Noven Transdermals segment includes \$12.4 million and \$20.7 million of equity in earnings of Novogyne recognized in the 2008 Quarter and Period, respectively. We acquired the Noven Therapeutics business on August 14, 2007. Consequently, the results of the Noven Therapeutics segment are not included in the 2007 Quarter or Period. The negative contribution of our Noven Therapeutics segment in the 2008 Quarter and Period reflects the impact of \$5.1 million and \$9.8 million, respectively, in selling and marketing expenses in support of Noven Therapeutics currently marketed products, including approximately \$0.9 million in the 2008 Period of expenses in connection with the Stavzor launch.

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|                                | <b>Three Months<br/>Ended June 30,</b> |             | <b>Six Months<br/>Ended June 30,</b> |             |
|--------------------------------|--|-------------|--------------------------------------|-------------|
|                                | <b>2008</b>                            | <b>2007</b> | <b>2008</b>                          | <b>2007</b> |
| (in thousands):                |  |             |                                      |             |
| Noven Transdermals:            |  |             |                                      |             |
| Product revenues               | \$ 12,968                              | \$ 15,062   | \$ 23,459                            | \$ 30,668   |
| License and contract revenues  | 5,060                                  | 3,777       | 10,346                               | 7,486       |
| Net revenues                   | 18,028                                 | 18,839      | 33,805                               | 38,154      |
| Cost of products sold          | (10,761)                               | (9,314)     | (20,034)                             | (18,241)    |
| Research and development       | (2,436)                                | (3,185)     | (4,814)                              | (6,651)     |
| Selling and marketing          | (213)                                  | (221)       | (407)                                | (461)       |
| Equity in earnings of Novogyne | 12,429                                 | 9,174       | 20,696                               | 14,077      |
| Segment contribution           | 17,047                                 | 15,293      | 29,246                               | 26,878      |
| Noven Therapeutics:            |  |             |                                      |             |
| Product revenues               | 6,575                                  |             | 12,280                               |             |
| Cost of products sold          | (2,022)                                |             | (4,058)                              |             |
| Research and development       | (857)                                  |             | (1,798)                              |             |
| Selling and marketing          | (5,123)                                |             | (9,752)                              |             |
| Segment contribution           | (1,427)                                |             | (3,328)                              |             |
| Unallocated income (expense):  |  |             |                                      |             |
| General and administrative     | (8,906)                                | (5,488)     | (15,928)                             | (10,669)    |
| Interest income, net           | 500                                    | 1,813       | 1,122                                | 3,445       |
| Income before income taxes     | \$ 7,214                               | \$ 11,618   | \$ 11,112                            | \$ 19,654   |



**Table of Contents****Three and Six months ended June 30, 2008 compared to the Three and Six months ended June 30, 2007  
Revenues**

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

|                                | Three Months<br>Ended June 30, |           |             | Six Months<br>Ended June 30, |           |             |
|--------------------------------|--------------------------------|-----------|-------------|------------------------------|-----------|-------------|
|                                | 2008                           | 2007      | %<br>Change | 2008                         | 2007      | %<br>Change |
| Noven Transdermals             |                                |           |             |                              |           |             |
| Novogyne:                      |                                |           |             |                              |           |             |
| Product sales                  | \$ 5,553                       | \$ 4,804  | 16%         | \$ 7,984                     | \$ 10,173 | -22%        |
| Royalties                      | 2,349                          | 1,899     | 24%         | 4,529                        | 3,664     | 24%         |
| Product revenues               |                                |           |             |                              |           |             |
| Novogyne                       | 7,902                          | 6,703     | 18%         | 12,513                       | 13,837    | -10%        |
| Third Parties:                 |                                |           |             |                              |           |             |
| Product sales                  | 4,978                          | 8,271     | -40%        | 10,779                       | 16,684    | -35%        |
| Royalties                      | 88                             | 88        | 0%          | 167                          | 147       | 14%         |
| Product revenues third parties | 5,066                          | 8,359     | -39%        | 10,946                       | 16,831    | -35%        |
| Total product revenues         | 12,968                         | 15,062    | -14%        | 23,459                       | 30,668    | -24%        |
| License and contract revenues  | 5,060                          | 3,777     | 34%         | 10,346                       | 7,486     | 38%         |
| Total Transdermals             | 18,028                         | 18,839    | -4%         | 33,805                       | 38,154    | -11%        |
| Noven Therapeutics             |                                |           |             |                              |           |             |
| Third Parties:                 |                                |           |             |                              |           |             |
| Product sales                  | 6,575                          |           | N/A         | 12,280                       |           | N/A         |
| Net Revenues                   | \$ 24,603                      | \$ 18,839 | 31%         | \$ 46,085                    | \$ 38,154 | 21%         |

**Net Revenues**

As described in more detail below, our net revenues in the 2008 Quarter were \$24.6 million, an increase of 31% compared to \$18.8 million reported in the 2007 Quarter. This increase reflects the addition of \$6.6 million in net revenues associated with our sales of Pexeva® and Lithobid® products through Noven Therapeutics, which was acquired in August 2007. We also realized a \$1.3 million, or 34%, increase in license and contract revenues compared to the 2007 Quarter. In addition, the 2008 Quarter benefited from the fulfillment of backorders that resulted from production issues related to our Noven Transdermals segment in the prior quarter. These increases were partially offset by a \$2.5 million decrease in Daytrana® sales in the 2008 Quarter.

As described in more detail below, our net revenues in the 2008 Period were \$46.1 million, an increase of 21% compared to \$38.2 million reported in the 2007 Period. This increase reflects the addition of \$12.3 million in net revenues associated with our sales of Pexeva® and Lithobid® products through Noven Therapeutics. We also realized a \$2.9 million, or 38%, increase in license and contract revenues compared to the 2007 Period. These increases were offset by a \$7.2 million decrease in product revenues from our Noven Transdermals segment comprised of a

\$4.0 million decrease in sales of Daytrana and a \$3.2 million decrease in the sale of HT products in the 2008 Period.

Product Revenues - Novogyne

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

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The \$1.2 million increase in Novogyne product revenues for the 2008 Quarter primarily resulted from the timing of orders from Novogyne. By product, Vivelle-Dot® increased \$0.4 million, Combipatch® increased \$0.5 million, and royalties increased \$0.4 million due to increased sales by Novogyne to its customers for the 2008 Quarter.

The \$1.3 million decrease in Novogyne product revenues for the 2008 Period primarily resulted from a \$2.7 million decline of Vivelle-Dot® product revenues, partially offset by a \$0.6 million increase in unit sales of CombiPatch® due to the timing of orders from Novogyne, as well as an increase of \$0.9 million in royalties due to increased sales by Novogyne to their customers for the 2008 Period. The decline in Vivelle-Dot® product revenues is attributable to the timing of orders and shipments primarily as a result of order backlogs originating in the first quarter of 2008. During the first quarter of 2008, production issues (discussed further below under Gross Margin) primarily related to an equipment failure in transdermal manufacturing resulted in write-offs of inventory representing approximately \$1.6 million of potential first quarter revenue, creating a backlog of unfilled orders as of the end of the first quarter. 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's revenues were approximately \$2.6 million lower than expected for the 2008 Period. We expect to fill the remaining orders during the remainder of 2008. Our expectations for aggregate HT product revenues in future periods are addressed under Outlook below.

**Product Revenues – Third Parties**

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

The \$3.3 million decrease in product revenues – third parties in our Noven Transdermals segment for the 2008 Quarter compared to the 2007 Quarter consisted of a \$2.5 million decline in sales of Daytrana®, a \$0.6 million decline in sales of Estradot® and a \$0.3 million decline related to pricing. The decline in Daytrana® sales was primarily due to the timing of orders and delays in the release of product due to additional quality control procedures that were implemented in 2008. The decline in Estradot® sales relates to a timing of orders from Novartis Pharma. With respect to pricing, we recognize the benefit from price increases for our third party HT product through periodic price reconciliation payments received from Novartis Pharma. We receive such payments from time to time upon Novartis Pharma's determination that its actual sales price of our product entitles us to receive amounts in excess of the minimum transfer price at which we initially sold the product to Novartis Pharma. We recognized \$0.3 million of such payments in the 2007 Quarter. There were no such payments in the 2008 Quarter.

The \$5.9 million decrease in product revenues – third parties in our Noven Transdermals segment for the 2008 Period compared to the 2007 Period consisted of a \$4.0 million decline in unit sales of Daytrana®, a \$1.5 million decline in third-party revenues from our HT products and a \$0.4 million decline due to pricing. The decrease in Daytrana® product revenues was largely attributable to delays in the release of product at the end of the 2008 Quarter, the timing of orders and, to a lesser extent, decreased demand. The decline in third-party HT product revenues is attributable to the timing of orders and shipments primarily as a result of order backlogs originating in the first quarter of 2008. In addition, Noven realized a lower benefit from price increases for our third party HT product through periodic price reconciliation payments received from Novartis as discussed above. We recognized \$1.2 million and \$1.6 million of such payments in the 2008 Period and 2007 Period, respectively.

Noven Therapeutics, which was acquired in August 2007, generated \$6.6 million and \$12.3 million of net revenues in the 2008 Quarter and 2008 Period, respectively, from sales of Pexeva® and Lithobid®.

**Table of Contents****License and Contract Revenues**

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

License and contract revenues increased \$1.3 million for the 2008 Quarter compared to the 2007 Quarter, primarily attributable to an increase in license revenues due to an increase in amortization of milestone payments received from Shire related to the license of Daytrana®.

License and contract revenues increased \$2.9 million for the 2008 Period compared to the 2007 Period, attributable to a \$2.1 million increase in license revenues primarily due to an increase in amortization of milestone payments received from Shire related to the license of Daytrana®. In addition, contract revenues increased \$0.8 million due to \$0.5 million in additional work performed on developmental products and a \$0.3 million reversal in the 2007 Period of contract revenues resulting from a change in the estimate of the amount of work to be completed on a contract.

**Gross to Net Revenues**

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

|   | <b>Three Months Ended June 30,</b> |                                    |             |                                    | <b>Six Months Ended June 30,</b> |                                    |             |                                    |
|---|------------------------------------|------------------------------------|-------------|------------------------------------|----------------------------------|------------------------------------|-------------|------------------------------------|
|   | <b>2008</b>                        | <b>% of<br/>gross<br/>revenues</b> | <b>2007</b> | <b>% of<br/>gross<br/>revenues</b> | <b>2008</b>                      | <b>% of<br/>gross<br/>revenues</b> | <b>2007</b> | <b>% of<br/>gross<br/>revenues</b> |
| Noven<br>Transdermals:  |                                    |                                    |             |                                    |                                  |                                    |             |                                    |
| Gross revenues  | \$ 18,386                          | 100%                               | \$ 18,898   | 100%                               | \$ 34,399                        | 100%                               | \$ 38,213   | 100%                               |
| Sales returns<br>allowances   | 358                                | 2%                                 | 59          | 0%                                 | 594                              | 2%                                 | 59          | 0%                                 |
| Net revenues  | \$ 18,028                          | 98%                                | \$ 18,839   | 100%                               | \$ 33,805                        | 98%                                | \$ 38,154   | 100%                               |
| Noven<br>Therapeutics:  |                                    |                                    |             |                                    |                                  |                                    |             |                                    |
| Gross revenues  | \$ 10,133                          | 100%                               |             |                                    | \$ 19,641                        | 100%                               |             |                                    |
| Cash discounts  | 193                                | 2%                                 |             |                                    | 385                              | 2%                                 |             |                                    |
| Medicaid, Medicare<br>& State program<br>rebates and credits<br>including |                                    |                                    |             |                                    |                                  |                                    |             |                                    |
| redemption offers   | 1,289                              | 13%                                |             |                                    | 3,578                            | 18%                                |             |                                    |
| Chargebacks   | 365                                | 4%                                 |             |                                    | 632                              | 3%                                 |             |                                    |
| Wholesaler fees   | 608                                | 6%                                 |             |                                    | 1,202                            | 6%                                 |             |                                    |
| Sales returns   | 1,103                              | 11%                                |             |                                    | 1,564                            | 8%                                 |             |                                    |
| Sales and returns<br>allowances   | 3,558                              | 35%                                |             |                                    | 7,361                            | 37%                                |             |                                    |

|              |          |     |           |     |
|--------------|----------|-----|-----------|-----|
| Net revenues | \$ 6,575 | 65% | \$ 12,280 | 63% |
|--------------|----------|-----|-----------|-----|

**Table of Contents****Gross Margin:**

This section discusses gross margins relating to our product revenues: (i) across all of our products ( Overall Gross Margin ); (ii) on our transdermal product revenues from Novogyne ( Gross Margin Novogyne ), which for accounting purposes is considered a related party; (iii) on our transdermal product revenues from third parties ( Gross Margin Third Parties ); and (iv) on our Noven Therapeutics products. Product revenues from third parties include HT product sales to Novartis Pharma for resale primarily outside the United States and Japan, as well as Daytrana® product sales to Shire. Noven Therapeutics product revenues include sales of Pexev® and Lithobid® to trade customers for the 2008 Quarter and Period.

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 \$8.6 million and \$16.5 million in the 2008 Quarter and the 2008 Period, respectively, include compensation and benefits, supplies and tools, equipment costs, depreciation and amortization, and insurance costs and represent a substantial portion of our inventory production costs. Manufacturing expenses for the 2007 Quarter and the 2007 Period were \$6.5 million and \$13.1 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):

|                                  | <b>Three Months Ended June 30,</b> |             | <b>Six Months Ended June 30,</b> |             |
|----------------------------------|------------------------------------|-------------|----------------------------------|-------------|
|                                  | <b>2008</b>                        | <b>2007</b> | <b>2008</b>                      | <b>2007</b> |
| <b><u>Noven Transdermals</u></b> |                                    |             |                                  |             |
| Novogyne:                        |                                    |             |                                  |             |
| Product revenues                 | \$ 7,902                           | \$ 6,703    | \$ 12,513                        | \$ 13,837   |
| Cost of products sold            | 3,463                              | 3,285       | 6,789                            | 6,244       |
| Gross profit                     | 4,439                              | 3,418       | 5,724                            | 7,593       |
|                                  | 56%                                | 51%         | 46%                              | 55%         |
| Third parties:                   |                                    |             |                                  |             |
| Product revenues                 | 5,066                              | 8,359       | 10,946                           | 16,831      |
| Cost of products sold            | 7,298                              | 6,029       | 13,245                           | 11,997      |
| Gross profit (loss)              | (2,232)                            | 2,330       | (2,299)                          | 4,834       |
|                                  | -44%                               | 28%         | -21%                             | 29%         |
| Total Noven Transdermals:        |                                    |             |                                  |             |
| Product revenues                 | 12,968                             | 15,062      | 23,459                           | 30,668      |
| Cost of products sold            | 10,761                             | 9,314       | 20,034                           | 18,241      |
| Gross profit                     | 2,207                              | 5,748       | 3,425                            | 12,427      |
|                                  | 17%                                | 38%         | 15%                              | 41%         |
| <b><u>Noven Therapeutics</u></b> |                                    |             |                                  |             |
| Product revenues                 | 6,575                              |             | 12,280                           |             |
| Cost of products sold            | 2,022                              |             | 4,058                            |             |
| Gross profit                     | 4,553                              |             | 8,222                            |             |
|                                  | 69%                                |             | 67%                              |             |

Total Company

|                       |          |     |          |     |           |     |           |     |
|-----------------------|----------|-----|----------|-----|-----------|-----|-----------|-----|
| Product revenues      | 19,543   |     | 15,062   |     | 35,739    |     | 30,668    |     |
| Cost of products sold | 12,783   |     | 9,314    |     | 24,092    |     | 18,241    |     |
| Gross profit          | \$ 6,760 | 35% | \$ 5,748 | 38% | \$ 11,647 | 33% | \$ 12,427 | 41% |

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

As noted in the tables above, Overall Gross Margin declined in the 2008 Quarter compared to the 2007 Quarter. Overall Gross Margin in the 2008 Quarter was negatively affected by: (i) the addition of \$2.1 million in manufacturing costs over the 2007 Quarter, primarily in the quality area, of which, \$1.0 million related to costs associated with the Daytrana® peel force issue; and (ii) inventory write-offs of \$0.8 million due to Daytrana® product exhibiting high peel force characteristics. Overall Gross Margin in the 2008 Quarter benefited from the addition of our Pexeva® and Lithobid® products, which had net sales of \$6.6 million and related cost of products sold of \$2.0 million, resulting in a gross margin of 69% for those products.

As noted in the tables above, Overall Gross Margin declined in the 2008 Period compared to the 2007 Period. Overall Gross Margin in the 2008 Period was negatively affected by: (i) inventory write-offs of \$2.8 million, primarily related to an equipment failure in transdermal manufacturing (comprised of \$1.8 million of Novogyne product write-offs and \$1.0 million of third party HT product write-offs), as well as additional manufacturing costs incurred in the 2008 Quarter to address this issue; (ii) inventory write-offs of approximately \$0.8 million due to Daytrana® product exhibiting high peel force characteristics; (iii) the addition of approximately \$3.4 million in manufacturing costs over the 2007 Period, primarily in the quality assurance area, of which, approximately \$1.2 million related to costs associated with the Daytrana® peel force issue; and (iv) significantly lower product revenues in our Noven Transdermals segment, primarily related to the timing of shipments, delays in the release of Daytrana® product at the end of the 2008 Quarter and the production issues for our HT product. Overall Gross Margin in the 2008 Period benefited from the addition of our Pexeva® and Lithobid® products, which had net sales of \$12.3 million and related cost of products sold of \$4.1 million, resulting in a gross margin of 67% for those products and a decrease product inventory at Novogyne which resulted in approximately \$0.7 million of recognized deferred profit on product sold to Novogyne.

We sell Daytrana® finished product to Shire at a fixed cost, so our profit on product sales of Daytrana® depends on our ability to manufacture the product efficiently and to fully utilize our facilities. For the 2008 Quarter, Daytrana® product revenues were \$2.7 million and cost of products sold related to Daytrana® was \$5.2 million, resulting in negative gross margin for the product. This compares with a gross profit of \$1.3 million and gross margin of 25% for the 2007 Quarter. For the 2008 Period, Daytrana® product revenues were \$5.7 million and cost of products sold related to Daytrana® was \$8.5 million, resulting in negative gross margin for the product. This compares with a gross profit of \$2.1 million and gross margin of 22% for the 2007 Period. Daytrana® gross margin was negatively affected in the 2008 Quarter and the 2008 Period by increased manufacturing and quality assurance related expenditures, including, as discussed above, approximately \$1.2 million related to costs associated with the Daytrana® peel force issue.

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

Our expectations for gross margins in future periods are addressed under Outlook below.



**Table of Contents****Operating Expenses**

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

|                            | Three Months<br>Ended June 30, |          |             | Six Months<br>Ended June 30, |          |             |
|----------------------------|--------------------------------|----------|-------------|------------------------------|----------|-------------|
|                            | 2008                           | 2007     | %<br>Change | 2008                         | 2007     | %<br>Change |
| Research and development   | \$ 3,293                       | \$ 3,185 | 3%          | \$ 6,612                     | \$ 6,651 | -1%         |
| Selling and marketing      | 5,336                          | 221      | N/M         | 10,159                       | 461      | N/M         |
| General and administrative | 8,906                          | 5,488    | 62%         | 15,928                       | 10,669   | 49%         |

N/M Not Meaningful

**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 \$0.1 million increase in research and development expenses for the 2008 Quarter, compared to the 2007 Quarter, was primarily attributable to the \$0.8 million addition of Noven Therapeutics expenses which were partially offset by a \$0.7 million decrease in pre-clinical testing and clinical research costs in our Noven Transdermals segment. Research and development expenses for the 2008 Period, compared to the 2007 Period, were relatively unchanged as the \$1.8 million decrease in pre-clinical testing and clinical research costs in our Noven Transdermals segment were offset by the addition of \$1.8 million in Noven Therapeutics expenses, primarily related to regulatory and medical affairs expenses.

**Selling and Marketing**

The \$5.1 million and \$9.7 million increases in selling and marketing costs for the 2008 Quarter and 2008 Period, compared to the 2007 Quarter and 2007 Period, respectively, were attributable to the addition of Noven Therapeutics in August 2007.

**General and Administrative**

General and administrative expenses increased \$3.4 million, or 62%, for the 2008 Quarter, compared to the 2007 Quarter. The increase was primarily due to a \$1.7 million charge related to reimbursements owed to Shire in connection with the voluntary recall of two lots of Daytrana®, a \$0.7 million increase in salary and related benefits, including stock-based compensation, and a \$0.4 million increase in professional fees, mostly attributable to recruiting fees, as well as a \$0.6 million increase in other general and administrative expenses, primarily as a result of the addition of Noven Therapeutics.

General and administrative expenses increased \$5.3 million, or 49%, for the 2008 Period, compared to the 2007 Period. The increase was primarily attributable to a \$1.7 million charge related to reimbursements owed to Shire in connection with the voluntary recall of two lots of Daytrana®, a \$1.6 million increase in professional fees, mostly attributable to accounting, auditing and recruiting fees, a \$0.3 million increase in salary and related benefits, a \$0.2 million increase in information management services and supplies, as well as a \$1.3 million increase in other general and administrative expenses areas, primarily as a result of the addition of Noven Therapeutics.

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**Other Income and Expenses**

*Interest Income*

Interest income decreased \$1.3 million and \$2.3 million for the 2008 Quarter and the 2008 Period, compared to the 2007 Quarter and the 2007 Period, respectively. This decrease was primarily attributable to a decrease in cash available for investment as a result of the payment of \$130.4 million in connection with the JDS acquisition in August 2007, as well as additional sales of auction rate securities at par during 2008 and lower interest rates on our remaining investments.

*Income Taxes*

Our effective tax rate was approximately 36% for both the 2008 Period and the 2007 Period. The provision for income taxes is based on the Federal statutory and state income tax rates. Net deferred income tax assets are measured using the average graduated tax rate for the estimated amount of annual taxable income in the years that the liability is expected to be settled or the asset recovered. The effect of adjusting the expected tax rate related to the net deferred income tax assets is included in the provision for income taxes. The acquisition of JDS resulted in a significant increase in our deferred income tax assets, primarily due to the fact that the \$100.2 million expense recognized in 2007 relating to in-process research and development is not immediately deductible for tax purposes. As of June 30, 2008 we had a net deferred tax asset of \$72.6 million compared to \$65.7 million at December 31, 2007. Realization of this deferred tax asset depends upon the generation of sufficient future taxable income. A valuation allowance is established if it is more likely than not that all or a portion of the deferred tax asset will not be realized. Noven Therapeutics files separate state income tax returns in states where it has determined that it is required to file state income taxes. As a result, state deferred tax assets relating to Noven Therapeutics are evaluated separately in determining whether the state deferred tax assets are realizable. We expect that Noven Therapeutics will incur taxable losses in the next few years due to expected clinical trial expenditures related to product development. These expected taxable losses create negative evidence indicating the need for a valuation allowance at June 30, 2008. Our valuation allowance for state deferred tax assets was \$3.3 million and \$3.2 million as of June 30, 2008 and December 31, 2007, respectively, due to uncertainties in realizing these state deferred tax assets based on our projection of future state taxable income. If we determine, based on future profitability of Noven Therapeutics that these state deferred tax assets will more likely than not be realized, a release of all, or part, of the related valuation allowance could result in an immediate income tax benefit in the period the valuation allowance is released.

*Equity in Earnings of Novogyne*

We share in the earnings of Novogyne according to an established formula after satisfaction of an annual preferred return of \$6.1 million to Novartis. Our share of Novogyne's earnings (a non-cash item) increases as Novogyne's product sales increase, subject to a cap of 49%. Novogyne earned sufficient income in each of the first quarters of 2008 and 2007 to meet Novartis' annual preferred return for those periods and for us to recognize earnings from Novogyne under the formula. We report our share of Novogyne's earnings as Equity in earnings of Novogyne in our unaudited 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, 2008 and 2007 are summarized as follows (dollar amounts in thousands):

|  | Three Months Ended June 30, |           |          | Six Months Ended June 30, |           |          |
|--|-----------------------------|-----------|----------|---------------------------|-----------|----------|
|  | 2008                        | 2007      | Change % | 2008                      | 2007      | Change % |
| Gross revenues                               | \$ 50,054                   | \$ 42,915 | 17%      | \$ 95,348                 | \$ 80,208 | 19%      |
| Sales allowances                             | 5,702                       | 6,837     | -17%     | 11,555                    | 10,999    | 5%       |
| Sales returns allowances                     | 585                         | (60)      | N/M      | 500                       | (9)       | N/M      |
| Sales and returns allowances                 | 6,287                       | 6,777     | -7%      | 12,055                    | 10,990    | 10%      |
| Net revenues                                 | 43,767                      | 36,138    | 21%      | 83,293                    | 69,218    | 20%      |
| Cost of sales                                | 8,788                       | 7,795     | 13%      | 16,596                    | 14,842    | 12%      |
| Gross profit                                 | 34,979                      | 28,343    | 23%      | 66,697                    | 54,376    | 23%      |
| Gross margin percentage                      | 80%                         | 78%       |          | 80%                       | 79%       |          |
| Selling, general and administrative expenses | 9,798                       | 9,579     | 2%       | 18,810                    | 19,712    | -5%      |
| Income from operations                       | 25,181                      | 18,764    | 34%      | 47,887                    | 34,664    | 38%      |
| Interest income                              | 174                         | 165       | 5%       | 441                       | 497       | -11%     |
| Net income                                   | \$ 25,355                   | \$ 18,929 | 34%      | \$ 48,328                 | \$ 35,161 | 37%      |
| Noven's equity in earnings of Novogyne       | \$ 12,429                   | \$ 9,174  | 35%      | \$ 20,696                 | \$ 14,077 | 47%      |

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 \$7.1 million for the 2008 Quarter compared to the 2007 Quarter. By product, Vivelle-Dot® and CombiPatch® increased \$8.0 million and \$0.6 million, respectively, while Vivelle® (a discontinued product) decreased \$1.5 million. The \$8.0 million Vivelle-Dot® increase consisted of a \$4.4 million increase related to pricing and a \$3.6 million increase in unit sales which is consistent with increases in prescription trends. The \$0.6 million CombiPatch® increase was primarily attributable to a \$0.4 million increase related to pricing.

Novogyne's gross revenues increased \$15.1 million for the 2008 Period compared to the 2007 Period. By product, Vivelle-Dot® and CombiPatch® increased \$17.3 million and \$0.7 million, respectively, while Vivelle® (a discontinued product) decreased \$2.9 million. The \$17.3 million Vivelle-Dot® increase consisted of a \$10.8 million increase related to pricing and a \$6.5 million increase in unit sales which is consistent with increases in prescription trends. The \$0.7 million CombiPatch® increase was attributable to a \$0.9 million increase related to pricing, partially offset by a \$0.2 million decline in unit sales which resulted from a continued decline in the market for combination therapies, and the impact of a competitive product.

Sales allowances consist of chargebacks, Medicaid rebates, managed healthcare rebates, cash discounts and other allowances, which tend to fluctuate based on changes in gross revenues. These sales allowances were 11% and 16% of gross revenues for the 2008 Quarter and the 2007 Quarter, respectively. For the 2008 Period and the 2007 Period, these sales allowances were 12% and 14% of gross revenues, respectively. The decrease in sales allowances as a percentage of gross revenues for the 2008 Quarter and 2008 Period compared to the corresponding 2007 periods was attributable to decreases in estimated managed healthcare rebate payments.

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

|   | <b>Three Months Ended June</b> |             | <b>Six Months Ended June</b> |             |
|---|--------------------------------|-------------|------------------------------|-------------|
|   | <b>30,</b>                     | <b>30,</b>  | <b>30,</b>                   | <b>30,</b>  |
|   | <b>2008</b>                    | <b>2007</b> | <b>2008</b>                  | <b>2007</b> |
| Sales returns allowances included in net revenues               | \$ 585                         | \$ (60)     | \$ 500                       | \$ (9)      |
| Actual returns primarily for expiring product                   | (889)                          | (645)       | (1,499)                      | (1,474)     |
| Change in allowances for returns primarily for expiring product | \$ (304)                       | \$ (705)    | \$ (999)                     | \$ (1,483)  |

The increase in sales returns allowances for the three and six months ended June 30, 2008 is attributable to the prior periods benefiting from reductions in allowances for returns of expiring product due to lower than expected returns of Vivelle-Dot® and CombiPatch® in the prior periods.

**Novogyne Gross Margin**

The 2% and 1% gross margin increase for the 2008 Quarter and 2008 Period compared to the 2007 Quarter and the 2007 Period, respectively, was primarily related to higher sales of Vivelle-Dot®, which has a higher gross margin than the other products sold by Novogyne, as well as price increases for all products and lower sales deductions as a percentage of revenues.

**Novogyne Selling, General and Administrative Expenses**

Novogyne's selling, general and administrative expenses increased \$0.2 million for the 2008 Quarter compared to the 2007 Quarter, primarily due to a \$0.4 million increase in sales force and marketing and advertising expenses and a \$0.2 million increase in litigation expenses which were partially offset by a \$0.4 million decrease in sample expenses due to the timing of shipments by Noven to Novogyne. Novogyne's policy is to immediately expense samples when shipped from Noven.

Novogyne's selling, general and administrative expenses decreased \$0.9 million for the 2008 Period compared to the 2007 Period, primarily due to a \$1.3 million decrease in sample expenses due to the timing of shipments by Noven to Novogyne as discussed above.

**Table of Contents****Liquidity and Capital Resources**

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

|                           | <b>June 30,<br/>2008</b> | <b>December 31,<br/>2007</b> |
|---------------------------|--------------------------|------------------------------|
| Cash and cash equivalents | \$ 35,405                | \$ 13,973                    |
| Short-term investments    |                          | 21,565                       |
| Working capital           | 49,207                   | 24,024                       |

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

|                      | <b>2008</b> | <b>2007</b> |
|----------------------|-------------|-------------|
| Cash flows:          |             |             |
| Operating activities | \$ (9,913)  | \$ 33,579   |
| Investing activities | 34,683      | (40,175)    |
| Financing activities | (3,338)     | 2,855       |
| Net cash flow        | \$ 21,432   | \$ (3,741)  |

**Operating Activities**

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, payment to Shire of \$3.3 million related to its 2007 withdrawal of Daytrana® product and \$3.1 million in payments related to insurance premiums. In addition, changes in working capital accounts, including an \$8.0 million increase in inventories and a \$4.3 million decrease in accrued compensation and related liabilities also contributed to the net cash used in operating activities. The net operating cash used was partially offset by the receipt of \$17.2 million in distributions from Novogyne.

Net cash provided by operating activities for the 2007 Period primarily resulted from our receipt of a \$25.0 million milestone payment from Shire, our receipt of \$11.0 million in distributions from Novogyne, and our receipt of \$5.9 million in connection with the development agreements with Shire for an amphetamine transdermal patch. These amounts were partially offset by changes in working capital due to the timing of certain payments, including \$14.1 million in tax payments, \$2.6 million in compensation and related liabilities and \$2.4 million related to insurance premiums.

**Investing Activities**

Noven has invested a portion of its cash in short-term investments, which primarily consist of investment grade, auction rate securities, which are categorized as available-for-sale under the provisions of SFAS No. 115 Accounting for Certain Investments in Debt and Equity Securities .

Net cash provided by investing activities for the 2008 Period was primarily attributable to \$36.4 million in net sales of short-term investments at par, partially offset by \$1.2 million in equipment purchases to support operations.

Net cash used in investing activities for the 2007 Period was primarily attributable to \$36.9 million in net purchases of short-term investments, \$1.4 million in equipment purchases to support operations and expansion of administrative offices and \$1.2 million in acquisition costs related to the August 2007 acquisition of JDS.

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***Financing Activities***

Net cash used in financing activities for the 2008 Period was primarily attributable to a \$3.3 million sales milestone payment to Synthron, an obligation recorded as part of the acquisition of JDS. Net cash provided by financing activities for the 2007 Period was primarily attributable to \$2.5 million received in connection with the issuance of common stock from the exercise of stock options. In addition, the 2007 Period benefited from \$0.4 million in excess tax deductions from the exercise of stock options.

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

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

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

During the 2008 Period, our cash, cash equivalents and investments in auction rate securities decreased from \$68.4 million to \$52.9 million. The \$15.5 million used during the 2008 Period included the payment of certain obligations previously charged to operations in 2007 and/or accrued as of December 31, 2007, including (i) \$5.4 million of employee severance, bonus and retention payments, (ii) \$3.3 million of Daytrana<sup>®</sup> voluntary market withdrawal costs, and (iii) a \$3.3 million contingent milestone payment related to sales of Pexeva<sup>®</sup>. We currently expect net cash used in operations to decline in the second half of 2008 relative to the 2008 Period, and 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 have been advised by Shire that Shire's net sales of Daytrana<sup>®</sup> during the 12 months ended June 30, 2008 triggered the third and final \$25.0 million sales milestone due to be paid to Noven during the third quarter of 2008. We expect to pay income taxes related to the Daytrana<sup>®</sup> milestones of approximately \$9.1 million and \$8.5 million during the remainder of 2008 and 2009, respectively.

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

We expect that the increased sales and marketing expenses relating to the operations of Noven Therapeutics, including for the upcoming Stavzor launch, will continue during the remainder of 2008. We expect to fund the additional sales and marketing expenses from our operating cash flows, existing cash and investments as well as the other sources of funds described above.

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We have invested a significant portion of our cash in auction rate securities, which subjects us to the liquidity risk described in Part II Item 7A Quantitative and Qualitative Disclosures About Market Risk in our Form 10-K. During the 2008 Period, we recorded a \$0.5 million unrealized loss on our investments in auction rate securities which are classified as available for sale under SFAS No. 115. As of June 30, 2008, the total par value and fair value of our investments was \$18.0 million and \$17.5 million, respectively. Due to continuing auction failures beginning in February 2008, we utilized valuation models to determine the fair values of our investments in auction rate securities. The fair values of our investments were calculated based on the following: (i) the underlying structure of each security; (ii) the present value of future principal and interest payments discounted at rates considered to reflect current market conditions; (iii) consideration of the probabilities of default, auction failure, or repurchase at par for each period; and (iv) consideration of third party credit enhancement. These estimated fair values could change significantly based on future market conditions.

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

|  |               |
|--|---------------|
| Balance at December 31, 2007                           | \$ 54,400     |
| Purchases of investments                               | 550           |
| Sales of investments at par                            | (36,925)      |
| Unrealized losses recorded as other comprehensive loss | (515)         |
| <br>Balance at June 30, 2008                           | <br>\$ 17,510 |

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

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

We paid approximately \$125.0 million in cash to acquire JDS in August 2007 and incurred approximately \$5.4 million in transaction-related costs. We funded the purchase price and related transaction expenses from our sale of short-term investments. In addition, we assumed approximately \$16.1 million of accrued expenses and other current liabilities and assumed certain contractual arrangements whereby we may be required to pay to third parties up to \$23.5 million in product development and sales milestones. In April 2008, we paid Synthron \$3.3 million in connection with a Pexeva<sup>®</sup> sales milestone.

Our liquidity for the 2007 Period benefited from \$2.5 million received upon the exercise of stock options by employees. During the 2008 Period, proceeds from exercises were not significant. We expect this amount to fluctuate from period to period depending on the performance of our common stock and equity award exercises. Beginning in 2006, we began granting SSARs to employees and restricted stock to non-employee directors in lieu of stock options. These types of awards do not provide cash to us upon their exercise. Accordingly, we expect that funds received from option exercises will become less of a source of funds over time.

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



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

Capital expenditures totaled \$1.2 million for the 2008 Period. We expect to fund our foreseeable capital expenditures from our operating cash flows, existing cash, short-term investments and debt.

If our transdermal products under development are successful, we expect that our cash requirements will increase to fund plant and equipment purchases to expand production capacity. For our long-term operating needs, we intend to utilize funds derived from the sources described above. To the extent available, we may use funds generated through sales of products under development and payments received pursuant to development and licensing arrangements. If such funds are insufficient, we may rely on debt and/or equity financing to fund such expansion. We cannot assure that we will successfully complete the development of such products, that we will obtain regulatory approval for any such products, that any approved product will be produced in commercial quantities, at reasonable costs, and be successfully marketed, or that we will successfully negotiate future licensing or product acquisition arrangements. Because much of the cost associated with product development and expansion of manufacturing facilities is incurred prior to product launch, if we are unsuccessful in out-licensing, or if we are unable to launch additional commercially-viable products that we develop or that we license or acquire from others, we will have incurred the up-front costs associated with product development or acquisition without the benefit of the cash generated by sales of those products, which could adversely affect our long-term liquidity needs. Factors that could impact our ability to develop or acquire and launch additional commercially-viable products are discussed in Part I Item 1A Risk Factors of our Form 10-K.

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

**Aggregate Contractual Obligations**

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

**Critical Accounting Estimates**

For a discussion of our critical accounting estimates, see Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Estimates, which is included in our Form 10-K.

**Recent Accounting Pronouncements**

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

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### **Outlook**

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

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

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

regulatory or technological developments;

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

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

adverse actions by the FDA in connection with the January 2008 warning letter or otherwise;

changes in our business relationships/collaborations; or

changes in the economy or the health care sector generally.

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

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

*Net Revenues.* We expect total net revenues for full year 2008 to be in the \$100 million to \$105 million range, reflecting: (i) a full year of sales of Pexeva<sup>®</sup> and Lithobid<sup>®</sup>; (ii) recognition of nominal revenues associated with the expected launch of Stavzor in the second half of 2008, reflecting the fact that, pursuant to applicable accounting rules, we expect to recognize Stavzor revenues based on prescriptions filled as opposed to upon shipment to trade customers; (iii) Daytrana<sup>®</sup> net sales to Shire for 2008 consistent with 2007 levels; (iv) higher license and contract revenues compared to 2007 due to the amortization of Daytrana<sup>®</sup> sales milestones received in 2007 and 2008; and (v) aggregate HT product sales by Noven for sale in the U.S. and international markets consistent with 2007 levels.

*Gross Margin.* We expect our overall gross margin, as a percentage of product sales, to be in the low 30% range for full year 2008. Among other factors influencing our gross margin in our transdermal manufacturing operations, we expect to incur increased quality assurance costs related to our continued efforts to improve our quality assurance

systems and address the issues raised by the FDA in the July 2007 Form 483 and January 2008 warning letter. A significant portion of these costs will be allocated to Daytrana<sup>®</sup>, which will negatively affect the gross margin on sales of this product in 2008.

*Research and Development Expense.* We expect our consolidated research and development expense for full year 2008 to be, as expressed in millions of dollars, in the low-to-mid teens. Estimates of research and development expenses for future periods are subject to substantial adjustment as each product advances through various stages of development.

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*Selling, General and Administrative Expense.* We expect our consolidated selling, general and administrative expense for full year 2008 to be in the upper \$50 million range, including selling and promotional expenses in support of Noven Therapeutics' existing products and the commercial launch of Stavzor.

*Equity in Earnings of Novogyne.* We expect our equity in earnings of Novogyne to increase in the low 20% range in 2008 compared to 2007.

*Interest Income.* We expect our interest income to decrease in 2008 compared to 2007, primarily reflecting lower cash and investment balances following payment of the JDS acquisition purchase price in August 2007, as well as additional sales of auction rate securities at par during 2008 and lower interest rates on our remaining investments.

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

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

**Table of Contents****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, 2008, our disclosure controls and procedures were effective in ensuring that information relating to Noven, including its consolidated subsidiaries, required to be disclosed in reports that it files or submits under the Exchange Act was: (1) recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms; and (2) accumulated and communicated to our management, including our CEO and CFO, as appropriate to allow timely decisions regarding required disclosure. However, that conclusion should be considered in light of the various limitations described below on the effectiveness of those controls and procedures, some of which pertain to most if not all business enterprises, and some of which arise as a result of the nature of our business. Our management, including our CEO and CFO, does not expect that our disclosure controls and procedures will prevent all errors and all improper conduct. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of improper conduct, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Further, the design of any system of controls also is based in part upon assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. Furthermore, our level of historical and current equity participation in Novogyne may substantially impact the effectiveness of our disclosure controls and procedures. Because we do not control Novogyne, and Novogyne s financial, accounting, inventory, sales and sales deductions functions are performed by Novartis, our disclosure controls and procedures with respect to our equity investment in Novogyne are necessarily more limited than those we maintain with respect to Noven.

*Changes in Internal Control over Financial Reporting*

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

*Certificates*

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

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**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

Certain lawsuits and legal proceedings in which we are involved are described in Part I, Item 3 Legal Proceedings of our Form 10-K for the year ended December 31, 2007. Except as described below, there have been no material developments related to the legal proceedings described in our Form 10-K during the period covered by this Form 10-Q, and through the filing of this Form 10-Q. All proceedings described in our Form 10-K remain outstanding. In addition to the cases in which Noven is a named defendant, Novartis has advised Noven that it has been named as a defendant in a total of 31 cases that include approximately 32 plaintiffs that allege liability in connection with personal injury claims allegedly arising from the use of HT patches distributed and sold by Novartis and Novogyne, including Noven's Vivelle-Dot®, Vivelle® and CombiPatch® products.

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

Each of the HT related federal court cases in which Noven is a named defendant, 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.

**Item 1A. Risk Factors**

There have been no material changes 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 and are not the only ones we face. If any of these risks actually occurs, our business, financial condition and results of operations would suffer. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operation. We do not undertake to update any of these forward-looking statements or to announce the results of any revisions to these forward-looking statements except as required by law.

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

The following table provides information with respect to our stock repurchases during the second quarter of 2008:

|                                    | <b>Total<br/>Number of<br/>Shares<br/>Purchased</b> | <b>Average<br/>Price<br/>Paid<br/>Per Share</b> | <b>Total<br/>Number of<br/>Shares<br/>Purchased<br/>as<br/>Part of<br/>Publicly<br/>Announced<br/>Program</b> | <b>Approximate<br/>Dollar Value<br/>That May<br/>Yet<br/>be Purchased<br/>under the<br/>Program<sup>(1)</sup></b> |
|------------------------------------|---|---|---|---|
| April 1, 2008 to<br>April 30, 2008 |   |   |   | \$ 19,876,238   |
| May 1, 2008 to<br>May 31, 2008     |   |   |   | 19,876,238  |
| June 1, 2008 to<br>June 30, 2008   |   |   |   | 19,876,238  |
| Totals                             |   |   |   | \$ 19,876,238   |

(1) In September 2007, we announced a stock repurchase program authorizing the repurchase of up to \$25.0 million of our common stock. During the third quarter of 2007, we repurchased 322,345 shares of our common stock at an aggregate price of approximately \$5.1 million. There is no expiration date specified for this program.

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

The following proposals were approved at our Annual Meeting of Stockholders held on June 5, 2008:

1. **Election of the Board of Directors:**

|                        | <b>For</b> | <b>Withheld</b> |
|------------------------|------------|-----------------|
| Sidney Braginsky       | 16,224,775 | 5,037,645       |
| Peter Brandt           | 21,110,943 | 151,477         |
| John G. Clarkson, M.D. | 16,970,502 | 4,291,918       |
| Donald A. Denkhaus     | 16,986,592 | 4,275,828       |
| Pedro P. Granadillo    | 16,989,442 | 4,272,978       |
| Phillip M. Satow       | 20,301,501 | 960,919         |
| Robert G. Savage       | 20,173,025 | 1,089,395       |
| Wayne P. Yetter        | 16,715,657 | 4,546,763       |

2. Proposal to ratify and approve the appointment of Deloitte & Touche LLP as Noven's independent registered public accounting firm for 2008:

| For        | Against | Abstained | Broker Non-Vote |
|------------|---------|-----------|-----------------|
| 21,116,342 | 120,537 | 25,538    | 0               |
|            |         | 46        |                 |

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**Item 5. Other Information**

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

**Item 6. Exhibits**

- 10.1 Amended and Restated Restricted Stock Agreement between Peter Brandt and Noven Pharmaceuticals, Inc., dated May 28, 2008 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K of Noven Pharmaceuticals, Inc. filed on June 2, 2008).
- 10.2 Employment Agreement between Peter Brandt and Noven Pharmaceuticals, Inc., dated April 29, 2008 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K of Noven Pharmaceuticals, Inc. filed on May 5, 2008).
- 10.3 Restricted Stock Agreement between Peter Brandt and Noven Pharmaceuticals, Inc., dated April 29, 2008 (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K of Noven Pharmaceuticals, Inc. filed on May 5, 2008).
- 10.4 Stock Appreciation Rights Agreement between Peter Brandt and Noven Pharmaceuticals, Inc., dated April 29, 2008 (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K of Noven Pharmaceuticals, Inc. filed on May 5, 2008).
- 10.5 Letter Agreement between W. Neil Jones and Noven Pharmaceuticals, Inc., dated April 29, 2008 (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K of Noven Pharmaceuticals, Inc. filed on May 5, 2008).
- 31.1 Certification of Peter Brandt, President and Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of Michael D. Price, Vice President and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification of Peter Brandt, President and Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.\*
- 32.2 Certification of Michael D. Price, Vice President and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.\*

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

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**Signatures**

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

NOVEN PHARMACEUTICALS, INC.

Date: August 7, 2008

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

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