

NOVEN PHARMACEUTICALS INC

Form 10-Q

May 07, 2007

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

**Quarterly Report Pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934  
For the quarterly period ended March 31, 2007  
Commission file number 0-17254  
NOVEN PHARMACEUTICALS, INC.  
(Exact name of registrant as specified in its charter)**

STATE OF DELAWARE

59-2767632

(State or other jurisdiction of  
incorporation or organization)

(I.R.S. Employer  
Identification Number)

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

(Address of principal executive offices) (Zip Code)

(305) 253-5099

(Registrant's telephone number, including area code)

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

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

| Class                          | Outstanding at April 30, 2007 |
|--------------------------------|-------------------------------|
| Common stock \$.0001 par value | 24,837,695                    |

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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, 2006 as supplemented by Part II Item 1A Risk Factors of the quarterly reports on Form 10-Q filed in 2007, as well as other reports filed from time to time with the Securities and Exchange Commission. |          |
| <b><u>Trademark Information:</u></b> Vivelle®, Vivelle-Dot®, Estradot® and Menorest are trademarks of Novartis AG or its affiliated companies; CombiPatch® and Estalis® are registered trademarks of Vivelle Ventures LLC; and Daytrana is a trademark of Shire Pharmaceuticals Ireland Limited.   |          |



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## PART I. FINANCIAL INFORMATION

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

Condensed Statements of Operations  
 Three Months Ended March 31,  
 (in thousands, except per share amounts)  
 (unaudited)

|                                       | 2007     | 2006     |
|---------------------------------------|----------|----------|
| Revenues:                             |          |          |
| Product revenues Novogyne:            |          |          |
| Product sales                         | \$ 5,369 | \$ 3,087 |
| Royalties                             | 1,765    | 1,689    |
| Total product revenues Novogyne       | 7,134    | 4,776    |
| Product revenues third parties        | 8,472    | 3,871    |
| Total product revenues                | 15,606   | 8,647    |
| Contract and license revenues:        |          |          |
| Contract                              | (130)    | 664      |
| License                               | 3,839    | 881      |
| Contract and license revenues         | 3,709    | 1,545    |
| Net revenues                          | 19,315   | 10,192   |
| Expenses:                             |          |          |
| Cost of products sold Novogyne        | 2,959    | 2,143    |
| Cost of products sold third parties   | 5,968    | 3,997    |
| Total cost of products sold           | 8,927    | 6,140    |
| Research and development              | 3,466    | 3,482    |
| Marketing, general and administrative | 5,421    | 4,738    |
| Total expenses                        | 17,814   | 14,360   |
| Income (loss) from operations         | 1,501    | (4,168)  |
| Equity in earnings of Novogyne        | 4,903    | 4,327    |
| Interest income, net                  | 1,632    | 611      |
| Income before income taxes            | 8,036    | 770      |

|   |          |         |
|---|----------|---------|
| Provision for income taxes                            | 3,000    | 266     |
| Net income  | \$ 5,036 | \$ 504  |
| Basic earnings per share                              | \$ 0.20  | \$ 0.02 |
| Diluted earnings per share                            | \$ 0.20  | \$ 0.02 |
| Weighted average number of common shares outstanding: |          |         |
| Basic   | 24,738   | 23,657  |
| Diluted   | 25,384   | 23,774  |

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

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**NOVEN PHARMACEUTICALS, INC.**  
 Condensed Balance Sheets  
 (in thousands, except share data)  
 (unaudited)

|  | March 31,<br>2007 | December 31,<br>2006 |
|--|-------------------|----------------------|
| <u>Assets</u>  |                   |                      |
| Current Assets:  |                   |                      |
| Cash and cash equivalents  | \$ 34,625         | \$ 9,144             |
| Short-term investments available-for-sale, at fair value                                 | 149,869           | 144,455              |
| Trade receivable (less allowance for doubtful accounts of \$52 in 2007 and \$67 in 2006) | 4,693             | 5,038                |
| Milestone payment receivable - Shire   |                   | 25,000               |
| Accounts receivable - Novogyne, net  | 8,109             | 7,693                |
| Inventories  | 9,660             | 8,651                |
| Net deferred income tax asset, current portion   | 6,900             | 4,400                |
| Prepaid income taxes   | 11                | 3,416                |
| Prepaid and other current assets   | 2,784             | 2,410                |
|  | 216,651           | 210,207              |
| Property, plant and equipment, net   | 36,605            | 37,010               |
| Other Assets:  |                   |                      |
| Investment in Novogyne   | 18,439            | 23,296               |
| Net deferred income tax asset  | 9,195             | 8,308                |
| Patent development costs, net  | 2,253             | 2,317                |
| Deposits and other assets  | 501               | 227                  |
|  | 30,388            | 34,148               |
|  | \$ 283,644        | \$ 281,365           |
| <u>Liabilities and Stockholders' Equity</u>  |                   |                      |
| Current Liabilities:   |                   |                      |
| Accounts payable and accrued expenses  | \$ 4,572          | \$ 5,184             |
| Capital lease obligation - current portion   | 122               | 109                  |
| Accrued compensation and related liabilities   | 2,895             | 5,308                |
| Other accrued liabilities  | 3,899             | 2,085                |
| Deferred rent credit   | 89                | 89                   |
| Deferred contract revenues   | 1,477             | 1,527                |
| Deferred license revenues - current portion  | 14,994            | 15,084               |
|  | 28,048            | 29,386               |
| Long-Term Liabilities:   |                   |                      |
| Capital lease obligation   | 247               | 279                  |
| Deferred license revenues  | 70,439            | 74,188               |
| Other liabilities  | 1,076             | 837                  |

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|   |            |            |
|---|------------|------------|
|   | 99,810     | 104,690    |
| Commitments and Contingencies (Note 12)   |            |            |
| Stockholders' Equity:   |            |            |
| Preferred stock authorized 100,000 shares of \$.01 par value; no shares issued or outstanding   |            |            |
| Common stock authorized 80,000,000 shares, par value \$.0001 per share; issued and outstanding 24,770,532 at March 31, 2007 and 24,661,169 at December 31, 2006 | 2          | 2          |
| Additional paid-in capital  | 112,565    | 109,912    |
| Retained earnings   | 71,267     | 66,761     |
| Common stock held in trust  | (375)      |            |
| Deferred compensation obligation  | 375        |            |
|   | 183,834    | 176,675    |
|   | \$ 283,644 | \$ 281,365 |

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



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**NOVEN PHARMACEUTICALS, INC.**  
Condensed Statements of Cash Flows  
Three Months Ended March 31,  
(in thousands)  
(unaudited)

|   | 2007      | 2006      |
|---|-----------|-----------|
| Cash flows from operating activities:   |           |           |
| Net income  | \$ 5,036  | \$ 504    |
| Adjustments to reconcile net income to net cash flows provided by (used in) operating activities:       |           |           |
| Depreciation, amortization and certain other noncash items  | 1,301     | 1,012     |
| Stock-based compensation expense  | 988       | 549       |
| Income tax benefits on exercise of stock options  | 253       | 137       |
| Excess tax deduction from exercise of stock options   | (195)     | (137)     |
| Deferred income tax benefit   | (3,387)   | (9)       |
| Recognition of deferred license revenues  | (3,839)   | (881)     |
| Equity in earnings of Novogyne  | (4,903)   | (4,327)   |
| Distributions from Novogyne   | 9,760     | 7,318     |
| Changes in operating assets and liabilities:  |           |           |
| Decrease (increase) in trade receivable, net  | 345       | (1,181)   |
| Decrease in milestone payment receivable Shire  | 25,000    |           |
| (Increase) decrease in accounts receivable Novogyne, net  | (416)     | 3,488     |
| Increase in inventories   | (1,009)   | (2,537)   |
| Decrease in prepaid income taxes  | 3,405     | 135       |
| Increase in prepaid and other current assets  | (374)     | (657)     |
| Increase in deposits and other assets   | (1)       | (15)      |
| Decrease in accounts payable and accrued expenses   | (612)     | (1,410)   |
| Decrease in accrued compensation and related liabilities  | (2,413)   | (3,314)   |
| Increase in other accrued liabilities   | 1,284     | 188       |
| Decrease in deferred contract revenue, net  | (50)      | (231)     |
| Increase in deferred license revenue  |           | 1,000     |
| Increase in other liabilities   | 252       | 31        |
| Amounts recoverable from Shire and offset against deferred license revenue related to Daytrana approval |           | 61        |
| Cash flows provided by (used in) operating activities   | 30,425    | (276)     |
| Cash flows from investing activities:   |           |           |
| Purchases of property, plant and equipment, net   | (689)     | (2,429)   |
| Payments for patent development costs, net  | (66)      | (182)     |
| Purchase of company-owned life insurance  | (260)     | (185)     |
| Purchases of short-term investments   | (226,470) | (285,375) |
| Proceeds from sale of short-term investments  | 220,953   | 252,350   |
| Cash flows used in investing activities   | (6,532)   | (35,821)  |
| Cash flows from financing activities:   |           |           |
| Issuance of common stock from exercise of stock options   | 1,412     | 444       |
| Excess tax benefit from exercise of stock options   | 195       | 137       |
| Payments under capital leases   | (19)      | (30)      |

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|  |           |           |
|--|-----------|-----------|
| Cash flows provided by financing activities          | 1,588     | 551       |
| Net increase (decrease) in cash and cash equivalents | 25,481    | (35,546)  |
| Cash and cash equivalents, beginning of period       | 9,144     | 66,964    |
| Cash and cash equivalents, end of period             | \$ 34,625 | \$ 31,418 |

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

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**NOVEN PHARMACEUTICALS, INC.**

**Notes to Unaudited Condensed Financial Statements**

**1. DESCRIPTION OF BUSINESS:**

Noven Pharmaceuticals, Inc. ( Noven ) was incorporated in Delaware in 1987 and is engaged in the research, development, manufacture and marketing of advanced transdermal drug delivery technologies and prescription transdermal products.

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

**2. BASIS OF PRESENTATION:**

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

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

**3. RECLASSIFICATIONS:**

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

**4. CASH FLOW INFORMATION:**

Cash payments for income taxes, net of refunds, were \$1.5 million and \$0.1 million for the three months ended March 31, 2007 and 2006, respectively. Cash payments for interest were not material for the three months ended March 31, 2007 and 2006.

**Table of Contents****5. RECENT ACCOUNTING PRONOUNCEMENTS:**

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

**6. INVENTORIES:**

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

|                 | March 31,<br>2007 | December<br>31,<br>2006 |
|-----------------|-------------------|-------------------------|
| Finished goods  | \$ 2,132          | \$ 893                  |
| Work in process | 2,256             | 2,851                   |
| Raw materials   | 5,272             | 4,907                   |
| <br>            |                   |                         |
| Total           | \$ 9,660          | \$ 8,651                |

The Drug Enforcement Administration ( DEA ) controls access to controlled substances, including methylphenidate, the active ingredient in Daytrana. Shire plc ( Shire ) retains title to the active methylphenidate ingredient ( AMI ) in Daytrana. AMI is not included in Daytrana product revenues or in Noven's cost of products sold. Noven records AMI maintained at its manufacturing facility as consignment inventory and bears certain manufacturing risks of loss related to the AMI. These risks include the contractual obligation of Noven to reimburse Shire for the cost of AMI if Noven does not meet certain yield requirements of the finished product. Shire has a reciprocal obligation to pay Noven if the yield requirements are exceeded. Noven slightly exceeded the yield requirements for the three months ended March 31, 2007, resulting in an immaterial payment from Shire to Noven. During the three months ended March 31, 2007, Noven used \$1.8 million of AMI in the finished product. Noven had \$2.0 million and \$1.0 million of consignment AMI inventory on hand at March 31, 2007 and December 31, 2006, respectively, which is not reflected in the table above.

**7. EMPLOYEE STOCK PLANS:**

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

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Share-Based Payment . At March 31, 2007, there were 2,773,540 stock options and 403,041 SSARs issued and outstanding under the 1999 Plan.

In May 2006, Noven issued a total of 34,344 shares of restricted stock to its non-employee directors. The shares vest over each director's one-year service period at the end of each calendar quarter beginning with the quarter ended June 30, 2006. As the shares vest, those shares that have been deferred by non-employee directors under Noven's deferred compensation plan are transferred into a rabbi trust maintained by Noven. In accordance with Emerging Issues Task Force 97-14, Accounting for Compensation Arrangements Where Amounts Earned are Held in a Rabbi Trust and Invested, the deferred shares were recorded at its fair value and classified as common stock held in trust. Since the deferral relates to Noven common stock, an offsetting amount was recorded as deferred compensation obligation in the stockholders' equity section of the balance sheet. As of March 31, 2007, there were a total of 21,465 shares of common stock in the rabbi trust. As of March 31, 2007, there was no restricted stock outstanding as all shares of restricted stock previously issued were fully vested.

There were no stock-based compensation grants in the three months ended March 31, 2007. The assumptions used to value option grants for the three months ended March 31, 2006 were as follows:

|                         |       |
|-------------------------|-------|
| Volatility              | 52.2% |
| Risk free interest rate | 4.94% |
| Expected life (years)   | 5     |

Total stock-based compensation recognized in Noven's statements of operations for the three months ended March 31, 2007 and 2006 was as follows (in thousands):

|  | 2007   | 2006   |
|--|--------|--------|
| Marketing, general and administrative                  | \$ 739 | \$ 397 |
| Research and development                               | 127    | 91     |
| Cost of products sold                                  | 122    | 61     |
|  | \$ 988 | \$ 549 |
| Tax benefit recognized related to compensation expense | \$ 309 | \$ 119 |

There were no stock-based compensation costs capitalized as part of inventory or fixed assets for the three months ended March 31, 2007 or 2006.

Cash received from options exercised under all share-based payment arrangements for the three months ended March 31, 2007 and 2006 was \$1.4 million and \$0.4 million, respectively. The tax benefit realized on the tax deductions from option exercises under stock-based compensation arrangements totaled \$0.3 million and \$0.1 million for the three months ended March 31, 2007 and 2006, of which \$0.2 million and \$0.1 million was reported as cash flow from financing activities for the three months ended March 31, 2007 and 2006, respectively.

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Stock option and SSARs transactions related to the 1999 Plan are summarized as follows for the three months ended March 31, 2007 (options/SSARs and aggregate intrinsic value in thousands):

|  | Options/<br>SSARs | Weighted<br>Average<br>Exercise<br>Price | Aggregate<br>Intrinsic<br>Value | Weighted<br>Average<br>Remaining<br>Contractual<br>Term |
|--|-------------------|--|---------------------------------|---|
| Outstanding at beginning of the period       | 3,275             | \$ 19.26                                 |                                 |   |
| Granted                                      |                   |  |                                 |   |
| Exercised                                    | (88)              | 16.42                                    | \$ 853                          |   |
| Canceled and expired                         | (10)              | 17.33                                    |                                 |   |
| Outstanding at end of the period             | 3,177             | \$ 19.35                                 | \$ 16,142                       | 3.8   |
| Outstanding and exercisable at end of period | 2,059             | \$ 21.12                                 | \$ 8,179                        | 3.0   |
| Vested or expected to vest at end of period  | 2,775             | \$ 19.52                                 | \$ 13,803                       | 3.8   |

As of March 31, 2007, the unamortized compensation expense that Noven expects to record in future periods related to currently outstanding unvested stock options, SSARs and restricted stock is approximately \$7.3 million before the effect of income taxes, of which \$2.5 million, \$2.4 million, \$1.6 million and \$0.8 million is expected to be incurred in the remainder of 2007 and in 2008, 2009 and 2010, respectively. The weighted-average period over which this compensation cost is expected to be recognized is 2 years.

#### 8. ACCOUNTING FOR UNCERTAINTY IN INCOME TAXES:

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

Upon adoption of FIN 48, and as a result of the recognition and measurement of Noven's tax positions as of January 1, 2007, Noven recognized a charge of approximately \$0.5 million to the January 1, 2007 retained earnings balance. The gross amount of unrecognized tax benefits as of the date of adoption, January 1, 2007, was \$1.2 million, including \$0.3 million in interest and penalties. If the \$1.2 million were ultimately recognized, only \$0.9 million would affect the effective tax rate due to approximately \$0.3 million in federal benefit. As of March 31, 2007 the gross amount of unrecognized tax benefits was approximately \$1.4 million. Interest and penalties related to income taxes are classified as a component of income tax expense. It is reasonably possible that the gross amount of unrecognized tax benefits may increase by approximately \$0.6 million within 12 months of March 31, 2007.

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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 years 2004–2006 remain open and subject to examination by the Internal Revenue Service. Noven files and remits state income taxes in various states where Noven has determined it is required to file state income taxes, and those states remain open for audit, inclusively, for the years 2002–2006. 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.

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

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

*Amphetamine Transdermal System*

In addition to Noven's agreements with Shire related to Daytrana in June 2004 Noven entered into an agreement with Shire for the development of a transdermal amphetamine patch for ADHD, and in July 2006, Noven and Shire amended this agreement. Under the amended agreement, Shire paid Noven a non-refundable \$1.0 million in August 2006, in exchange for the option of purchasing, for an additional \$5.9 million, the exclusive developmental rights to the product. The amended agreement further provided that Noven would perform certain early-stage development activities which were previously to be performed by Shire. Noven completed a Phase I clinical study for the product in March 2007, and Shire is currently reviewing the results of this study to determine whether it will exercise its option to acquire the exclusive development rights to the product. If Shire does not exercise this option, rights to further develop the product will revert to Noven. The \$1.0 million was included in deferred contract revenues on Noven's balance sheet as of March 31, 2007.

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

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

During the three months ended March 31, 2007 and 2006, Noven had the following transactions with Novogyne (in thousands):

|                     | 2007     | 2006     |
|---------------------|----------|----------|
| Revenues:           |          |          |
| Product sales       | \$ 5,369 | \$ 3,087 |
| Royalties           | 1,765    | 1,689    |
|                     | \$ 7,134 | \$ 4,776 |
| Reimbursed expenses | \$ 7,085 | \$ 7,269 |

As of March 31, 2007 and December 31, 2006, Noven had amounts due from Novogyne of \$8.1 million and \$7.7 million, respectively.

The unaudited condensed statements of operations of Novogyne for the three months ended March 31, 2007 and 2006 are as follows (in thousands):

|  | 2007      | 2006      |
|--|-----------|-----------|
| Gross revenues                               | \$ 37,293 | \$ 37,269 |
| Sales allowances                             | 4,162     | 3,793     |
| Sales return allowances                      | 51        | 1,896     |
| Sales allowances and returns                 | 4,213     | 5,689     |
| Net revenues                                 | 33,080    | 31,580    |
| Cost of sales                                | 7,047     | 7,521     |
| Selling, general and administrative expenses | 10,133    | 9,157     |
| Income from operations                       | 15,900    | 14,902    |
| Interest income                              | 332       | 152       |
| Net income                                   | \$ 16,232 | \$ 15,054 |
| Noven's equity in earnings of Novogyne       | \$ 4,903  | \$ 4,327  |

The activity in the Investment in Novogyne account for the three months ended March 31, 2007 is as follows (in thousands):

|   |           |
|---|-----------|
| Investment in Novogyne, beginning of period | \$ 23,296 |
| Equity in earnings of Novogyne              | 4,903     |
| Cash distributions from Novogyne            | (9,760)   |
| Investment in Novogyne, end of period       | \$ 18,439 |





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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 months ended March 31, 2007 and 2006, Noven received cash distributions representing return on investment of \$9.8 million and \$7.3 million from Novogyne, respectively. These amounts were recorded as reductions in the investment in Novogyne when received.

**11. SHARE REPURCHASE PROGRAM:**

In the first quarter of 2003, Noven's Board of Directors authorized a share repurchase program under which Noven may have acquired up to \$25.0 million of its common stock. In March 2007, Noven's Board of Directors approved the termination of this program. No shares were repurchased during the three months ended March 31, 2007 or 2006.

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

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

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

Since the July 2002 publication of the WHI and other study data, total United States prescriptions have declined for substantially all HT products, including Noven's products in the aggregate. Prescriptions for CombiPatch®, Noven's combination estrogen/progestin patch, continue to decline in the post-WHI environment. Novogyne recorded the acquisition of the marketing rights for Noven's CombiPatch® product at cost and Novogyne tests this asset for impairment on a periodic basis. Further adverse change in the market for HT products could have a material adverse impact on the ability of Novogyne to recover its investment in these rights, which could require Novogyne to record an impairment loss on the CombiPatch® intangible asset. Impairment of the CombiPatch® intangible asset would adversely affect Novogyne's and Noven's financial results. Management cannot predict whether these or other studies will have additional adverse effects on Noven's liquidity and results of operations, or Novogyne's ability to recover the net carrying value of the CombiPatch® intangible asset.

*Supply Agreement*

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 commercial 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

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require the affirmative vote of four of the five members of Novogyne's Management Committee. Accordingly, both Novartis and Noven must agree on Novogyne's supplier.

*Litigation, Claims and Assessments*

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

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

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

Novartis has advised Noven that Novartis has been named as a defendant in at least 28 lawsuits that include approximately 30 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-D®, 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 March 31, 2007 was \$10.0 million. Novogyne has established reserves in the amount of \$9.6 million with an offsetting insurance recovery of \$7.3 million for expected defense and settlement expenses as well as for estimated future cases alleging use of Noven's HT products. This accrual represents Novartis management's best estimate as of March 31, 2007.

Noven intends to defend all of the foregoing lawsuits vigorously, but the outcome of these product liability 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 financial position, results of operations or cash flows.

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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 financial condition at March 31, 2007, and our results of operations for the three months ended March 31, 2007 (the 2007 Quarter ) and March 31, 2006 (the 2006 Quarter ). The contents of this section include:

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

An overview of Noven and our Novogyne joint venture;

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

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

A discussion of how we apply our critical accounting estimates;

A discussion of recently-issued accounting standards; and

An outlook that includes our current financial guidance.

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

**Executive Summary**

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

The highlights of the 2007 Quarter included sales growth for our lead products, significant improvement in our overall gross margin, and receipt of the first of three potential \$25.0 million sales milestones related to Shire's sales of Daytrana.

For the 2007 Quarter, we reported net income of \$5.0 million (\$0.20 diluted earnings per share), compared to \$0.5 million (\$0.02 diluted earnings per share) for the 2006 Quarter. Net revenues for the 2007 Quarter increased 90% to \$19.3 million, primarily reflecting \$4.4 million in Daytrana product sales to Shire, \$3.0 million in Daytrana license revenues, and higher HT product sales to our Novogyne joint venture.

Our gross margin percentage in the 2007 Quarter was 43% compared to 29% in the 2006 Quarter. Gross margin in the 2006 Quarter was negatively affected by start-up and other expenses associated with initial production of Daytrana, which was launched by Shire in the second quarter of 2006. Gross margin in the 2007 Quarter benefited from significantly higher product revenues, primarily due to Daytrana sales; higher production volumes, which contributed to improved overhead absorption; cost savings associated with our cost reduction program implemented in the third quarter of 2006; and a \$0.5 million increase in price reconciliation payments relating to international sales of our HT products, which payments increase product revenues without increasing costs. We continue to expect our gross margin percentage for full-year 2007 to be in the 35% range.

Research and development expenses, at \$3.5 million, were largely unchanged from the 2006 Quarter. Marketing, general and administrative expenses increased \$0.7 million or 14% to \$5.4 million, primarily reflecting higher compensation costs due to additional personnel.

Noven recognized \$4.9 million in earnings from Novogyne in the 2007 Quarter, 13% higher than the \$4.3 million recognized in the 2006 Quarter. Interest income increased \$1.0 million or

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167% compared to the 2006 Quarter, largely reflecting an increase in cash available for investment due to the receipt of a \$50.0 million Daytrana approval milestone in April 2006 and a \$25.0 million Daytrana sales milestone in February 2007.

Novogyne's net income for the 2007 Quarter was \$16.2 million, an 8% increase over the 2006 Quarter. Novogyne's net revenues for the 2007 Quarter were \$33.1 million, up 5% from the 2006 Quarter, reflecting lower sales and returns allowances and increased sales of Vivelle-Dot®. Novogyne's gross margin for the 2007 Quarter increased to 79% from 76% in the 2006 Quarter due to lower sales and returns allowances and increased Vivelle-Dot® sales, which have a higher margin than sales of Novogyne's other products. Novogyne's selling, general and administrative expenses increased 11% to \$10.1 million, primarily reflecting the timing of the purchase of samples from Noven. In the 2007 Quarter, Novogyne satisfied the \$6.1 million annual preferred profit distribution to Novartis required by the joint venture agreements, as it did in the 2006 Quarter. The earnings that Noven recognizes from Novogyne are typically lower in the first quarter of each year due to satisfaction of this required annual preferred return.

At March 31, 2007, we had an aggregate \$184.5 million in cash and cash equivalents and short-term investments, compared to \$153.6 million at year-end 2006. This increase primarily reflected receipt of the Daytrana milestones referenced above, as well as \$9.8 million in distributions from Novogyne.

Prescription demand for our two lead products increased for the 2007 Quarter. Total prescriptions for Vivelle-Dot® increased 4% in 2007 Quarter compared to the 2006 Quarter, and total prescriptions for Novogyne's products, taken as a whole, increased 2%. By comparison, the overall U.S. HT market declined 7% over the same period. Total prescriptions for Daytrana increased 14% in the 2007 Quarter compared to the quarter ended December 31, 2006, while prescriptions for ADHD stimulant therapies as a class increased 5% for the same period.

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

We develop and manufacture advanced transdermal patches and presently derive the majority of our revenues from sales of transdermal patches for use in menopausal HT. In the United States, our HT products are marketed and sold by Novogyne Pharmaceuticals, the joint venture that we formed with Novartis in 1998. Our business, financial position and results of operations currently depend on Novogyne and its marketing of our HT products in the United States. A discussion of Novogyne's results of operations and their impact on our results can be found under the caption

Results of Operations Equity in Earnings of Novogyne.

In all countries other than the United States, Canada and Japan, we have licensed the marketing rights to these products to Novartis Pharma, which is an affiliate of Novartis. In most of these markets, Vivelle® is marketed under the brand name Menorest, Vivelle-Dot® is marketed under the brand name Estradot® and CombiPatch® is marketed under the brand name Estalis®.

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

Novartis is entitled to an annual \$6.1 million preferred return from Novogyne, which has the effect of reducing our share of Novogyne's income in the first quarter of each year. After the annual preferred return to Novartis, our share of Novogyne's income increases as product sales increase, subject to a maximum of 49%. Our share of Novogyne's income was \$4.9 million and \$4.3 million

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for the 2007 Quarter and the 2006 Quarter, respectively. The income we recognize from Novogyne is a non-cash item. Any cash we receive from Novogyne is in the form of cash distributions declared by Novogyne's Management Committee. Accordingly, the amount of cash that we receive from Novogyne in any period is typically not the same as the amount of income we recognize from Novogyne for that period. For the 2007 Quarter and the 2006 Quarter, we received \$9.8 million and \$7.3 million, respectively, in distributions from Novogyne, which, excluding the \$25.0 million received from Shire in 2007, accounted for all of our net cash flows generated by operating activities for these periods. We expect that a significant portion of our earnings and cash flow for the next several years will be generated through our interest in Novogyne, as well as any additional milestone payments we may receive from Shire. Any failure by Novogyne to remain profitable or to continue to make distributions would have a material adverse effect on our results of operations and financial condition.

The market for HT products, including transdermals, significantly declined in the years following the July 2002 publication of the WHI study that found adverse health risks associated with HT, and in current periods the market continues to decline. Comparing the 2006 Quarter to the 2007 Quarter, total prescriptions dispensed in the HT market in the United States decreased 7%. Comparing the same periods, aggregate prescriptions for our United States HT products increased 2%. Total prescriptions in the estrogen segment of the HT market in the United States decreased 7% comparing the same periods, while prescriptions for our Vivelle® line of products increased 3%. Vivelle-Dot®, which represented 88% of our total United States HT prescriptions in the 2007 Quarter, increased 4% from the 2006 Quarter. We believe that Vivelle-Dot® patch prescriptions have benefited from patient conversions from the original Vivelle® product (the predecessor product to Vivelle-Dot®), which represented 3% of our total United States prescriptions in the 2007 Quarter. Vivelle® is in the process of being discontinued in several jurisdictions where our advanced Vivelle-Dot® ET patch has gained acceptance. We ceased manufacturing of Vivelle® for the United States market at the end of 2006.

United States prescriptions for our CombiPatch® product (which represented approximately 9% of our total United States HT prescriptions in the first quarter of 2007) decreased 13% from the 2006 Quarter to the 2007 Quarter, while prescriptions for the total United States market for fixed combination hormone therapy decreased 9%. The combination therapy arm of the WHI studies involved an oral combination estrogen/progestin product and, accordingly, the combination therapy segment of the HT market has experienced the most significant decline. Further decreases above expectations for our CombiPatch® product (whether as a result of the WHI studies, competition in the category or otherwise) could require Novogyne (which holds the CombiPatch® marketing rights) to record an impairment loss related to these marketing rights, which would adversely affect the results of operations of both Noven and Novogyne. See *Critical Accounting Estimates* Investment in Novogyne.

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

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

*Daytrana*

The DEA controls access to controlled substances, including methylphenidate, the active ingredient in Daytrana. Manufacturers of products containing controlled substances must annually

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apply to the DEA for procurement quota in order to obtain these substances for manufacturing. In 2006, we received an initial grant of methylphenidate quota from the DEA. We submitted supplemental applications for additional quota to fulfill 2006 product orders received from Shire. The DEA granted additional 2006 quota in November 2006, but less than we had requested, and later than required to fulfill all 2006 product orders. As a result, we ended 2006 with approximately \$1.0 million in Daytrana product backorders that we fulfilled in the first quarter of 2007.

In January 2007, we received a portion of our requested methylphenidate quota for 2007 and subsequently received a portion of a supplemental request for additional methylphenidate quota. Given the DEA's current approach to awarding controlled substance quota, we expect at any given time to have applications pending with the DEA for procurement quota (either annual or supplemental) that are likely to be critical to continued Daytrana production. Any shortage, delay or stoppage in the supply of the active methylphenidate ingredient could cause us to lose revenues or incur additional costs (including those related to expedited production), which could have an adverse effect on our results of operations in general and our gross margin in particular.

We have received reports concerning difficulty removing the release liner from a small percentage of Daytrana patches. Although the product meets specifications, during the first quarter of 2007, we implemented enhancements intended to make Daytrana easier to use. If Daytrana sales are materially impacted because of this issue, then Noven's results of operations and financial condition would likely be adversely affected.

*Amphetamine Transdermal System*

In addition to our agreements with Shire related to Daytrana, in June 2004 we entered into an agreement with Shire for the development of a transdermal amphetamine patch for ADHD, and in July 2006, Noven and Shire amended this agreement. Under the amended agreement, Shire paid us a non-refundable \$1.0 million in August 2006, in exchange for the option of purchasing, for an additional \$5.9 million, the exclusive developmental rights to the product. The amended agreement further provided that we would perform certain early-stage development activities which were previously to be performed by Shire. We completed a Phase I clinical study for the product in March 2007, and Shire is currently reviewing the results of this study to determine whether it will exercise its option to acquire the exclusive development rights to the product. If Shire does not exercise this option, rights to further develop the product will revert to us. The \$1.0 million was included in deferred contract revenues on our balance sheet as of March 31, 2007.

**Table of Contents****Results of Operations****2007 Quarter compared to the 2006 Quarter*****Revenues***

Total revenues for the 2007 Quarter and the 2006 Quarter are summarized as follows (dollar amounts in thousands):

|                                 | 2007      | 2006      | %<br>Change |
|---------------------------------|-----------|-----------|-------------|
| Product revenues Novogyne:      |           |           |             |
| Product sales                   | \$ 5,369  | \$ 3,087  | 74%         |
| Royalties                       | 1,765     | 1,689     | 4%          |
|                                 | 7,134     | 4,776     | 49%         |
| Product revenues third parties: |           |           |             |
| Product sales                   | 8,413     | 3,800     | 121%        |
| Royalties                       | 59        | 71        | (17%)       |
|                                 | 8,472     | 3,871     | 119%        |
| Total product revenues          | 15,606    | 8,647     | 80%         |
| Contract and license revenues:  |           |           |             |
| Contract                        | (130)     | 664       | (120%)      |
| License                         | 3,839     | 881       | 336%        |
|                                 | 3,709     | 1,545     | 140%        |
| Net revenues                    | \$ 19,315 | \$ 10,192 | 90%         |

**Net Revenues**

As described in more detail below, the 90% increase in net revenues for the 2007 Quarter as compared to the 2006 Quarter was primarily attributable to sales of Daytrana and an increase in license revenue associated with that product. In addition, aggregate sales to Novogyne increased due to increased sales of Vivelle-Dot®.

**Product Revenues Novogyne**

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

The \$2.4 million increase in product revenues from Novogyne for the 2007 Quarter as compared to the 2006 Quarter primarily related to a \$2.7 million increase in unit sales of Vivelle-Dot®. This increase reflects a \$1.4 million increase in trade product orders due to increasing prescriptions trends and a \$1.3 million increase in samples attributable to the timing of orders from Novogyne.

**Product Revenues Third Parties**

Product revenues third parties consists of sales of Estradot®, Estalis® and Menorest to Novartis Pharma at a price based on a percentage of Novartis Pharma's net selling price (subject to certain minima) for resale primarily outside the United States and Japan, together with royalties generated from Novartis Pharma's sales of Vivelle® and Estradot® in Canada. Product revenues third parties for the 2007 Quarter also includes sales of Daytrana to Shire for commercial resale in the United States, which commenced in the second quarter of 2006.



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The \$4.6 million increase in product revenues from third parties for the 2007 Quarter as compared to the 2006 Quarter primarily related to \$4.4 million in unit sales of Daytrana and a \$0.5 million increase related to pricing with Novartis Pharma. The Daytrana product was initially launched in the second quarter of 2006 and no Daytrana revenue is included in product revenues for the 2006 Quarter, while the increase related to pricing was primarily due to the recognition of a higher price adjustment payment received from Novartis Pharma in the 2007 Quarter compared to the 2006 Quarter.

**Contract and License Revenues**

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

Contract revenues declined \$0.8 million for the 2007 Quarter as compared to the 2006 Quarter reflecting a decline in contract work performed and a \$0.3 million reversal of contract revenues previously recognized relating to a change in estimate of work to be completed on a contract. License revenues increased due to the recognition in the 2007 Quarter of \$3.0 million in deferred license revenues related to Daytrana.

***Gross Margin***

This section discusses our gross margin percentages relating to our product revenues (i) across all of our products ( Overall Gross Margin ), (ii) on our product revenues from Novogyne ( Gross Margin Novogyne ), which for accounting purposes is considered a related party, and (iii) on our product revenues from third parties ( Gross Margin Third Parties ). Product revenues from third parties primarily include HT product sales to Novartis Pharma for resale primarily outside the U.S. and Japan, as well as Daytrana product sales to Shire.

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

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Our gross margins for the 2007 Quarter and the 2006 Quarter are summarized as follows (dollar amounts in thousands):

|   | 2007      | 2006     |
|---|-----------|----------|
| <b>Overall Gross Margin:</b>                                    |           |          |
| Product revenues  | \$ 15,606 | \$ 8,647 |
| Cost of products sold   | 8,927     | 6,140    |
| Gross profit (product revenues less cost of products sold)      | 6,679     | 2,507    |
| Gross margin (gross profit as a percentage of product revenues) | 43%       | 29%      |
|   | 2007      | 2006     |
| <b>Gross Margin Novogyne:</b>                                   |           |          |
| Product revenues  | \$ 7,134  | \$ 4,776 |
| Cost of products sold   | 2,959     | 2,143    |
| Gross profit (product revenues less cost of products sold)      | 4,175     | 2,633    |
| Gross margin (gross profit as a percentage of product revenues) | 59%       | 55%      |
|   | 2007      | 2006     |
| <b>Gross Margin Third Parties:</b>                              |           |          |
| Product revenues  | \$ 8,472  | \$ 3,871 |
| Cost of products sold   | 5,968     | 3,997    |
| Gross profit (product revenues less cost of products sold)      | 2,504     | (126)    |
| Gross margin (gross profit as a percentage of product revenues) | 30%       | (3%)     |

In general, our sales of HT products to Novogyne for resale in the U.S. have a higher gross margin than our other products, reflecting favorable pricing, larger production orders and other factors. Our sales of HT products to Novartis Pharma for resale in international markets generally have a lower gross margin than sales of HT products sold to Novogyne due to, among other things, unfavorable pricing environments in foreign markets, and smaller production orders. Our gross margin on product sales of Daytrana to Shire has improved since launch of the product in the 2006 second quarter, reflecting our efforts to reduce production costs and inefficiencies and the impact of our cost reduction program initiated in the third quarter of 2006.

Overall Gross Margin improved from 29% in the 2006 Quarter to 43% in the 2007 Quarter. During the 2006 Quarter, we incurred start-up Daytrana manufacturing costs in preparation for a 2006 second quarter launch, but we did not recognize any Daytrana product revenues, which

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negatively affected Overall Gross Margin in that quarter. To a lesser extent, Overall Gross Margin in the 2006 quarter was also negatively affected by a shift in product mix to lower margin international HT product sales. Overall Gross Margin in the 2007 quarter benefited from significantly higher product revenues, primarily due to Daytrana sales; higher facility utilization, which contributed to improved overhead absorption and increased finished goods inventory balances; and cost savings associated with our cost reduction program that we implemented in the third quarter of 2006 to reduce costs and improve operating efficiency. It also benefited from a \$0.5 million increase in price reconciliation payments relating to international sales of our HT products, which payments increase product revenues without increasing costs.

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. For the 2007 quarter, Daytrana product revenues were \$4.4 million, and cost of products sold related to Daytrana was \$3.5 million, resulting in a gross margin on Daytrana production of 20%. We continue to work to improve the profitability of Daytrana production, but we cannot assure that we will be successful.

In light of the several factors discussed above which benefited our 2007 Quarter Overall Gross Margin, we do not believe that our reported gross margin for the 2007 Quarter is predictive of our expected gross margin for the remaining quarters in 2007. In particular, variations in product revenues and production volumes, as well as the timing and amount of methylphenidate quota that we may receive, could materially affect our gross margin in future periods. Our expectations for future gross margin performance are addressed under **Outlook** below.

**Operating Expenses**

Operating expenses for the 2007 Quarter and the 2006 Quarter are summarized as follows (dollar amounts in thousands):

|                                       | 2007     | 2006     | %<br>Change |
|---------------------------------------|----------|----------|-------------|
| Research and development              | \$ 3,466 | \$ 3,482 | 0%          |
| Marketing, general and administrative | 5,421    | 4,738    | 14%         |

**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. In the aggregate, these costs were consistent for the 2007 Quarter as compared to the 2006 Quarter. Development engineering related to Daytrana and other products decreased \$0.4 million for the 2007 Quarter as compared to the 2006 Quarter while clinical studies and personnel costs increased \$0.3 million and \$0.1 million, respectively.

**Marketing, General and Administrative**

The \$0.7 million increase in marketing, general and administrative expenses for the 2007 Quarter as compared to the 2006 Quarter was primarily attributable to a \$0.4 million increase in salary and related benefits and a \$0.3 million increase in stock-based compensation expense.

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**Other Income and Expenses**

*Interest Income*

Interest income increased \$1.0 million for the 2007 Quarter as compared to the 2006 Quarter. This increase was primarily attributable to an increase in cash available for investment due to the receipt of Shire milestone payments of \$50.0 million in April 2006 and \$25.0 million in March 2007.

*Income Taxes*

Our effective tax rate was approximately 37% and 35% for the 2007 Quarter and the 2006 Quarter, respectively. The increase in our effective tax rate for the 2007 Quarter as compared to the 2006 Quarter related primarily to a higher percentage of our income that was subject to state income taxes. This percentage is expected to decrease in the remainder of 2007.

The provision for income taxes is based on the Federal statutory and state income tax rates. Net deferred income tax assets are measured using the average graduated tax rate for the estimated amount of annual taxable income in the years that the liability is expected to be settled or the asset recovered. The effect of adjusting the expected tax rate related to the net deferred income tax assets is included in the provision for income taxes. As of March 31, 2007, we had a net deferred tax asset of \$16.1 million. Realization of this deferred tax asset depends upon the generation of sufficient future taxable income. Although realization is not assured, we believe it is more likely than not that the deferred income tax asset will be realized based upon estimated future taxable income.

*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 2007 Quarter and the 2006 Quarter to meet Novartis' annual preferred return for those periods and for us to recognize earnings from Novogyne under the formula. We report our share of Novogyne's earnings as Equity in earnings of Novogyne in our unaudited statements of operations.

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The financial results of Novogyne for the 2007 Quarter and the 2006 Quarter are summarized as follows (dollar amounts in thousands):

|  | 2007      | 2006      | %<br>Change |
|--|-----------|-----------|-------------|
| Gross revenues <sup>1</sup>                  | \$ 37,293 | \$ 37,269 | 0%          |
| Sales allowances                             | 4,162     | 3,793     | 10%         |
| Sales returns allowances                     | 51        | 1,896     | (97%)       |
| Sales and returns allowances                 | 4,213     | 5,689     | (26%)       |
| Net revenues                                 | 33,080    | 31,580    | 5%          |
| Cost of sales                                | 7,047     | 7,521     | (6%)        |
| Gross profit                                 | 26,033    | 24,059    | 8%          |
| Gross margin percentage                      | 79%       | 76%       |             |
| Selling, general and administrative expenses | 10,133    | 9,157     | 11%         |
| Income from operations                       | 15,900    | 14,902    | 7%          |
| Interest income                              | 332       | 152       | 118%        |
| Net income                                   | \$ 16,232 | \$ 15,054 | 8%          |
| Noven's equity in earnings of Novogyne       | \$ 4,903  | \$ 4,327  | 13%         |

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

fluctuations in  
Novogyne's  
sales allowances  
and returns.

Novogyne Net Revenues

Novogyne sells its products to trade customers, including wholesalers, distributors and chain pharmacies. As has historically been the case, the timing of purchases by trade customers is driven by the inventory needs of each customer and other factors, and does not necessarily track underlying 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 was consistent for the 2007 Quarter compared to the 2006 Quarter. By product, Vivelle-Dot® increased \$1.4 million while Estradot® and CombiPatch® declined \$0.8 million and \$0.5 million, respectively. The \$1.4 million Vivelle-Dot® increase consisted of a \$1.7 million increase related to pricing partially offset by a \$0.3 million decline in unit sales due to the timing of orders from trade customers as prescriptions have increased for the 2007 Quarter compared to the 2006 Quarter. The decline in Estradot® sales to an affiliate of Novartis Pharma in Canada was attributable to the timing of orders. The decline in CombiPatch® was attributable to a \$0.7 million decline in unit sales as a result of the continuing decline in the market for combination therapies as well as the impact of a competitive product. This CombiPatch® decline was partially offset by a \$0.2 million increase related to pricing.

Sales allowances consist of chargebacks, Medicaid rebates, managed healthcare rebates, cash discounts and other allowances, which tend to fluctuate based on changes in gross revenues. These sales allowances were 11% and 10% of gross revenues for the 2007 Quarter and the 2006 Quarter, respectively.

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Sales returns allowances consist of allowances for returns of expiring product and were \$0.1 million and \$1.9 million for the 2007 Quarter and the 2006 Quarter, respectively. The \$1.8 million decrease was primarily related to lower sales and lower actual returns of CombiPatch® as compared to the same period in the prior year. Actual returns for expiring product were \$0.8 million and \$1.2 million for the 2007 Quarter and the 2006 Quarter, respectively.

**Novogyne Gross Margin**

The 3% gross margin increase for the 2007 Quarter as compared to the 2006 Quarter was primarily related to the decrease in sales returns allowances as discussed above and higher sales of Vivelle-Dot®, which has a higher gross margin than the other products sold by Novogyne.

**Novogyne Selling, General and Administrative Expenses**

Novogyne's selling, general and administrative expenses increased \$1.0 million for the 2007 Quarter as compared to the 2006 Quarter primarily due to a \$1.3 million increase in sample expenses due to the timing of shipments by Noven to Novogyne. Novogyne's policy is to immediately expense samples when shipped from Noven.

**Liquidity and Capital Resources**

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

|                           | March 31,<br>2007 | December 31,<br>2006 |
|---------------------------|-------------------|----------------------|
| Cash and cash equivalents | \$ 34,625         | \$ 9,144             |
| Short-term investments    | 149,869           | 144,455              |
| Working capital           | 188,603           | 180,821              |

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

|                      | 2007      | 2006     |
|----------------------|-----------|----------|
| Cash flows:          |           |          |
| Operating activities | \$ 30,425 | \$ (276) |
| Investing activities | (6,532)   | (35,821) |
| Financing activities | 1,588     | 551      |

***Operating Activities***

Net cash provided by operating activities for the 2007 Quarter primarily resulted from the receipt of a \$25.0 million milestone payment from Shire and the receipt of \$9.8 million in distributions from Novogyne. These receipts were offset by changes in working capital due to the timing of certain payments, including \$2.6 million in compensation and related liabilities, \$1.5 million in tax payments and \$1.3 million related to insurance.

Net cash used in operating activities for the 2006 Quarter primarily resulted from changes in working capital due to the timing of certain payments, including those related to insurance, compensation and related liabilities, and purchases of inventory. These payments were offset by \$7.3 million in distributions from Novogyne.

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***Investing Activities***

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

Net cash used in investing activities for the 2007 Quarter was primarily attributable to \$5.5 million in net purchases of short-term investments, as well as \$0.7 million in equipment purchases to support operations and expansion of administrative offices.

Net cash used in investing activities for the 2006 Quarter was primarily attributable to \$33.0 million in net purchases of short-term investments, as well as the purchase of \$2.4 million in fixed assets to expand production capacity for future products.

***Financing Activities***

Net cash provided by financing activities for the 2007 Quarter and the 2006 Quarter was primarily attributable to \$1.4 million and \$0.4 million, respectively, received in connection with the issuance of common stock from the exercise of stock options. In addition, the 2007 Quarter and the 2006 Quarter benefited from \$0.2 million and \$0.1 million in excess tax deductions from the exercise of stock options, respectively.

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

Our principal sources of short-term liquidity are existing cash, cash generated from product sales, fees and royalties under development and license agreements and distributions from Novogyne. For the 2007 Quarter, a significant portion of our income before income taxes was comprised of equity in earnings of Novogyne and the recognition of deferred license revenue, both of which are non-cash items. Accordingly, our net income may not be reflective of our short-term liquidity. Although we expect to receive distributions from Novogyne, there can be no assurance that Novogyne will have sufficient profits or cash flow to pay distributions or that Novogyne's Management Committee will authorize such distributions.

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

In April 2006, Noven received a \$50.0 million milestone payment from Shire as a result of the final marketing approval of Daytrana by the FDA. Shire's net sales of Daytrana exceeded the threshold for the first sales milestone in the fourth quarter of 2006 and, accordingly, we received a \$25.0 million payment from Shire in the 2007 Quarter. Noven may also earn up to two additional \$25.0 million milestone payments upon Shire's achievement of \$50.0 million and \$75.0 million in annual net sales of Daytrana, respectively. Shire commercially launched the product in June 2006. The majority of the income taxes related to the \$50.0 million milestone are expected to be paid throughout 2007 and into early 2008 and the majority of the income taxes related to the first \$25.0 million milestone are expected to be paid in 2008 and into early 2009.

Our liquidity for the 2007 Quarter benefited from \$1.4 million received as the exercise price paid by option holders in connection with their exercise of employee stock options. This amount can



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be expected to fluctuate from year to year depending on the performance of Noven's stock and equity award exercises.

Capital expenditures were \$0.7 million for the 2007 Quarter. We expect to fund any capital expenditures from our existing cash balances. As a general matter, we believe that we have sufficient liquidity available to meet our operating needs and anticipated short-term capital requirements.

If our products under development are successful, we expect that our cash requirements will increase to fund plant and equipment purchases to expand production capacity. For our long-term operating needs, we intend to utilize funds derived from the above sources, as well as funds generated through sales of products under development or products that we may license or acquire from others. We expect that such funds will be comprised of payments received pursuant to future development and licensing arrangements, as well as direct sales of our own products.

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 may be produced in commercial quantities, at reasonable costs, and be successfully marketed, or that we will successfully negotiate future licensing or product acquisition arrangements. Because much of the cost associated with product development and expansion of manufacturing facilities is incurred prior to product launch, if we are unsuccessful in out-licensing, or if we are unable to launch additional commercially-viable products that we develop or that we license or acquire from others, we will have incurred the up-front costs associated with product development or acquisition without the benefit of the liquidity generated by sales of those products, which could adversely affect our long-term liquidity needs. Factors that could impact our ability to develop or acquire and launch additional commercially-viable products are discussed in Part I Item 1A of our Form 10-K, as supplemented by Part II Item 1A "Risk Factors" of the quarterly reports on Form 10-Q filed in 2007, as well as other reports filed from time to time with the Securities and Exchange Commission.

Our strategic plan includes the acquisition of one or more technologies, products or businesses that we believe may be complementary to our existing business. We expect to draw upon our cash and short-term investments to fund all or a portion of these potential strategic acquisitions. We may also consider issuing equity securities to fund potential acquisitions. To the extent our existing cash and short-term investments are insufficient to fund any large-scale acquisitions, we may be required to seek debt financing or to issue equity or debt securities. If a material acquisition is completed, our results of operations and financial condition could change materially in future periods. If we finance all or any portion of an acquisition through debt financing or debt securities we would be required to devote funds to service and ultimately repay such debt and could be subject to financial or operational covenants that could limit or hinder our ability to conduct our business.

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

**Aggregate Contractual Obligations**

There have been no material changes outside of the ordinary course of our business since December 31, 2006 to our aggregate contractual obligations previously disclosed in our Form 10-K.

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**Critical Accounting Estimates**

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

*Accounting for Uncertainty in Income Taxes*

On January 1, 2007, we adopted the provisions of, and began accounting for uncertainty in income taxes in accordance with FIN 48. This interpretation requires companies to determine whether it is more likely than not that a tax position will be sustained upon examination by the appropriate taxing authorities before any part of the benefit can be recorded in the financial statements. Under FIN 48 an enterprise cannot recognize a tax benefit for a tax position that is not likely to be sustained. The application of income tax law is inherently complex. Laws and regulations in this area are voluminous and are often ambiguous. As such, we are required to make many subjective assumptions and judgments regarding our income tax exposures. Interpretations and guidance surrounding income tax laws and regulations change over time. As a result, changes in our subjective assumptions, estimates and judgments can materially affect amounts recognized in the balance sheets and statements of operations. See Note 8 to the condensed financial statements, Accounting for Uncertainty in Income Taxes for additional information on our uncertain tax positions.

**Recent Accounting Pronouncements**

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

**Outlook**

A summary of our current financial guidance is provided below. This forward-looking information is based on our current assumptions and expectations, many of which are beyond our control to achieve. In particular, for purposes of this guidance we have assumed, among other things, that during the remainder of 2007 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, or new study results);

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

- changes in our business relationships/collaborations; or

- changes in the economy or the health care sector generally.

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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, readers should carefully consider the risks, uncertainties and cautionary factors discussed in Part I Item 1A of our Form 10-K, as supplemented by Part II Item 1A Risk Factors of the quarterly reports on Form 10-Q filed in 2007, as well as other reports filed from time to time with the Securities and Exchange Commission.

*Daytrana.* During 2006, we received a \$50.0 million milestone payment from Shire relating to the final marketing approval of Daytrana by the FDA. In the fourth quarter of 2006, the first of three potential \$25.0 million Daytrana sales milestones was met, resulting in the payment of \$25.0 million from Shire to us in the first quarter of 2007. We expect the second \$25.0 million milestone to be met in 2007, and it is possible that the third milestone will also be met in 2007, in each case depending on the level of Shire's net sales of the product. We expect to defer and recognize the approval milestone and all sales milestones as license revenues on a straight-line basis, beginning on the date the milestone is achieved through the first quarter of 2013, which is our current best estimate of the end of the useful economic life of the product. Reflecting the impact of this recognition schedule, we expect license revenues to increase substantially in 2007 compared to 2006. We expect our product sales of Daytrana to Shire for full-year 2007 to be between \$16.0 million and \$20.0 million, subject to, among other things, demand for the product and the availability and timing of DEA quota.

*HT Product Revenues.* Given customer orders, prescription trends and other factors, we expect Noven's global HT product revenues for full-year 2007 to approximate 2006 levels.

*Gross Margin.* Since the launch of Daytrana in the second quarter of 2006, we have worked to reduce costs and improve yields, and we reported significant improvement in our quarterly overall gross margin since the second quarter of 2006. For full-year 2007, we are targeting an overall gross margin in the 35% range, subject to a variety of factors, some of which are not within our control. These factors include Daytrana production volumes, the availability and timing of methylphenidate quota and our ability to effectively coordinate production between Daytrana and our HT products to improve facility utilization, and our ability to improve yields. These same factors could cause our overall gross margin in any particular quarter to vary significantly from other quarters in 2007.

*Research and Development Expense.* We expect our research and development expense in 2007 to approach \$16.0 million, depending on our ability to advance certain development projects into human clinical studies during 2007.

*Marketing, General and Administrative Expense.* We expect our marketing, general and administrative expense in 2007 to increase in the 5% range over 2006 levels.

*Stock-Based Compensation Expenses.* Based on the expense associated with stock-based compensation previously awarded, and our estimate of the expense associated with such compensation that may be awarded in the course of 2007, we estimate that our total stock-based compensation expenses for full-year 2007 will be approximately \$4.1 million, compared to \$3.3

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million for full-year 2006. The other financial guidance provided in this Outlook includes the effect of our estimate of anticipated stock-based compensation expenses.

*Novogyne.* Based on current prescription trends and other factors, we expect Novogyne's full year 2007 net revenues to increase in the 5% range compared to 2006 levels, and we expect Novogyne's net income and profit contribution to Noven for 2007 to increase by close to 10% compared to 2006 levels.

*Tax Matters.* We estimate that our effective tax rate for full-year 2007 will be in the 33% to 35% range. Throughout 2007 and into early 2008, we expect to pay taxes in the \$18.0 million range associated with the \$50.0 million cash milestone payment received from Shire in 2006. Throughout 2008 and into early 2009, we expect to pay taxes in the \$9.0 million range associated with the \$25.0 million sales milestone payment received from Shire in the first quarter of 2007.

*Capital Expenditures.* We expect our capital expenditures for full-year 2007 to be approximately in line with 2006 levels.

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

Not Applicable.

**Item 4. Controls and Procedures**

*Disclosure Controls and Procedures*

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

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sales deductions functions are performed by Novartis, our disclosure controls and procedures with respect to our equity investment in Novogyne are necessarily more limited than those we maintain with respect to ourself.

*Changes in Internal Control over Financial Reporting*

No changes were made in our internal control over financial reporting subsequent to the date of our Chief Executive Officer's and Chief Financial Officer's evaluation that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

*Certificates*

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

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

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

In addition to the HT cases previously disclosed in our filings with the Securities and Exchange Commission, Novartis has advised us that Novartis has been named as a defendant in at least 28 lawsuits that include approximately 30 plaintiffs that allege liability in connection with personal injury claims allegedly arising from the use of HT patches distributed and sold by Novartis and Novogyne, including our Vivelle-Dot<sup>®</sup>, Vivelle<sup>®</sup>, and CombiPatch<sup>®</sup> products. Novartis has indicated that it will seek indemnification from Noven and Novogyne to the extent permitted by the agreements between and among Novartis, Novogyne and Noven.

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

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

**Item 1A. Risk Factors**

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 or on our behalf. The risk factors are not listed in order of priority and are not the only ones we face. If any of these risks actually occurs, our business, financial condition and results of operations would suffer. Additional risks not presently known to us or other factors not perceived by us to present significant 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.

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

|                                       | Total<br>Number of<br>Shares<br>Purchased | Average<br>Price<br>Paid<br>Per Share | Total<br>Number of<br>Shares<br>Purchased<br>as<br>Part of<br>Publicly<br>Announced<br>Program | Approximate<br>Dollar Value<br>That May Yet<br>be Purchased<br>under the<br>Program <sup>(1)</sup> |
|---------------------------------------|---|---------------------------------------|--|--|
| January 1, 2007 to January 31, 2007   |   |                                       |  | \$ 23,711,040  |
| February 1, 2007 to February 28, 2007 |   |                                       |  | \$ 23,711,040  |
| March 1, 2007 to March 31, 2007       |   |                                       |  | \$ 0   |
| Totals                                |   |                                       |  | \$ 0   |

(1) In March 2007, our Board of Directors terminated the previously announced \$25.0 million stock repurchase program.

**Item 5. Other Information**

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

**Item 6. Exhibits**

31.1 Certification of Robert C. Strauss, President, Chief Executive Officer and Chairman of the Board, pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2 Certification of Diane M. Barrett, Vice President and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

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32.1 Certification of Robert C. Strauss, President, Chief Executive Officer and Chairman of the Board, pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.\*

32.2 Certification of Diane M. Barrett, Vice President and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.\*

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

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**Signatures**

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

NOVEN PHARMACEUTICALS, INC.

Date: May 7, 2007

By: /s/ Diane M. Barrett

Diane M. Barrett  
Vice President and  
Chief Financial Officer

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