

NOVEN PHARMACEUTICALS INC

Form 10-Q

May 10, 2006

Table of Contents

**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, 2006**

**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 28, 2006

Common stock \$.0001 par value

23,680,001

**NOVEN PHARMACEUTICALS, INC.**  
**INDEX**

|  | Page No. |
|--|----------|
| <b><u>PART I FINANCIAL INFORMATION</u></b>   |          |
| <b><u>Item 1 Unaudited Condensed Financial Statements</u></b>  |          |
| <u>Condensed Statements of Operations for the Three Months Ended March 31, 2006 and 2005</u>               | 3        |
| <u>Condensed Balance Sheets as of March 31, 2006 and December 31, 2005</u>                                 | 4        |
| <u>Condensed Statements of Cash Flows for the Three Months Ended March 31, 2006 and 2005</u>               | 5        |
| <u>Notes to Unaudited Condensed Financial Statements</u>   | 6        |
| <b><u>Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b> | 17       |
| <b><u>Item 3 Quantitative and Qualitative Disclosures About Market Risk</u></b>                            | 34       |
| <b><u>Item 4 Controls and Procedures</u></b>   | 34       |
| <b><u>PART II OTHER INFORMATION</u></b>  |          |
| <b><u>Item 1 Legal Proceedings</u></b>   | 36       |
| <b><u>Item 1A Risk Factors</u></b>   | 36       |
| <b><u>Item 2 Unregistered Sales of Equity Securities and Use of Proceeds</u></b>                           | 37       |
| <b><u>Item 6 Exhibits</u></b>  | 37       |
| <b><u>SIGNATURES</u></b>   | 38       |
| <u>Stock Appreciation Rights Agreement</u>   |          |
| <u>Section 302 Certification of CEO</u>  |          |
| <u>Section 302 Certification of CFO</u>  |          |
| <u>Section 906 Certification of CEO</u>  |          |
| <u>Section 906 Certification of CFO</u>  |          |

Cautionary Factors: Statements in this report that are not descriptions of historical facts are forward-looking statements provided under the safe harbor protection of the Private Securities Litigation Reform Act of 1995. Our actual results, performance and achievements may be materially different from those expressed or implied by such statements and readers should consider the risks and uncertainties associated with our business that are discussed in Item 1A of Part I of our Annual Report on Form 10-K for the year ended December 31, 2005 and Item 1A of Part II of this report, as well as other reports filed from time to time with the Securities and Exchange Commission.

Trademark Information: Vivel®e, Vivel®e-Dot, Estradot® and Menorest are trademarks of Novartis AG or its affiliated companies; CombiPatch® and Estalis® are registered trademarks of Vivel®e Ventures LLC; and Daytrana is a trademark of Shire Pharmaceuticals Ireland Limited.

**Table of Contents****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)

|  | Three Months |          |
|--|--------------|----------|
|  | 2006         | 2005     |
| Revenues:                              |              |          |
| Product revenues    Novogyne:          |              |          |
| Product sales                          | \$ 3,087     | \$ 4,978 |
| Royalties                              | 1,689        | 1,114    |
| Total product revenues    Novogyne     | 4,776        | 6,092    |
| Product revenues    third parties      | 3,871        | 4,038    |
| Total product revenues                 | 8,647        | 10,130   |
| Contract and license revenues:         |              |          |
| Contract                               | 664          | 595      |
| License                                | 881          | 1,011    |
| Contract and license revenues          | 1,545        | 1,606    |
| Net revenues                           | 10,192       | 11,736   |
| Expenses:                              |              |          |
| Cost of products sold    Novogyne      | 2,143        | 3,249    |
| Cost of products sold    third parties | 3,997        | 2,625    |
| Total cost of products sold            | 6,140        | 5,874    |
| Research and development               | 3,482        | 2,893    |
| Marketing, general and administrative  | 4,738        | 4,055    |
| Total expenses                         | 14,360       | 12,822   |
| Loss from operations                   | (4,168)      | (1,086)  |
| Equity in earnings of Novogyne         | 4,327        | 912      |
| Interest income, net                   | 611          | 503      |

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|   |         |         |
|---|---------|---------|
| Income before income taxes                            | 770     | 329     |
| Provision for income taxes                            | 266     | 118     |
| Net income  | \$ 504  | \$ 211  |
| Basic earnings per share                              | \$ 0.02 | \$ 0.01 |
| Diluted earnings per share                            | \$ 0.02 | \$ 0.01 |
| Weighted average number of common shares outstanding: |         |         |
| Basic   | 23,657  | 23,509  |
| Diluted   | 23,774  | 23,966  |

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

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

Condensed Balance Sheets  
(in thousands, except share data)  
(unaudited)

|   | March 31,<br>2006 | December<br>31, 2005 |
|---|-------------------|----------------------|
| <b><u>Assets</u></b>  |                   |                      |
| Current Assets:   |                   |                      |
| Cash and cash equivalents   | \$ 31,418         | \$ 66,964            |
| Short-term investments available-for-sale, at fair value  | 50,925            | 17,900               |
| Accounts receivable trade (less allowance for doubtful accounts of \$45 in 2006 and \$53 in 2005) | 4,100             | 2,919                |
| Accounts receivable Novogyne, net   | 5,424             | 8,912                |
| Inventories   | 10,398            | 7,861                |
| Net deferred income tax asset, current portion  | 5,200             | 6,000                |
| Prepaid income taxes  | 7,562             | 7,697                |
| Prepaid and other current assets  | 2,014             | 1,357                |
|   | 117,041           | 119,610              |
| Property, plant and equipment, net  | 35,968            | 34,455               |
| Other Assets:   |                   |                      |
| Investment in Novogyne  | 20,252            | 23,243               |
| Net deferred income tax asset   | 7,182             | 6,373                |
| Patent development costs, net   | 2,271             | 2,211                |
| Deposits and other assets   | 222               | 18                   |
|   | 29,927            | 31,845               |
|   | \$ 182,936        | \$ 185,910           |
| <b><u>Liabilities and Stockholders' Equity</u></b>  |                   |                      |
| Current Liabilities:  |                   |                      |
| Accounts payable and accrued expenses   | \$ 4,402          | \$ 5,812             |
| Capital lease obligation current portion  | 91                | 121                  |
| Accrued liability Shire   | 5,488             | 5,488                |
| Accrued compensation and related liabilities  | 2,457             | 5,771                |
| Other accrued liabilities   | 2,312             | 2,124                |
| Deferred rent credit  | 89                | 89                   |
| Deferred contract revenues  | 1,250             | 1,481                |
| Deferred license revenues current portion   | 4,276             | 7,602                |
|   | 20,365            | 28,488               |
| Long-Term Liabilities:  |                   |                      |
| Deferred rent credit  | 726               | 748                  |
| Deferred license revenues   | 19,559            | 16,053               |

|   |            |            |
|---|------------|------------|
| Deferred compensation liability   | 31         |            |
|   | 40,681     | 45,289     |
| 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 23,678,111 at March 31, 2006 and 23,617,221 at December 31, 2005 | 2          | 2          |
| Additional paid-in capital  | 90,976     | 89,846     |
| Retained earnings   | 51,277     | 50,773     |
|   | 142,255    | 140,621    |
|   | \$ 182,936 | \$ 185,910 |

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

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

## Condensed Statements of Cash Flows

Three Months Ended March 31,

(in thousands)

(unaudited)

|   | 2006      | 2005     |
|---|-----------|----------|
| Cash flows from operating activities:   |           |          |
| Net income  | \$ 504    | \$ 211   |
| Adjustments to reconcile net income to net cash flows provided by operating activities:                                   |           |          |
| Depreciation and amortization   | 916       | 581      |
| Stock-based compensation expense  | 549       |          |
| Amortization of patent costs  | 122       | 108      |
| Increase in cash surrender value of company owned life insurance  | (4)       |          |
| Amortization of deferred rent credit  | (22)      | (8)      |
| Income tax benefits on exercise of stock options  | 137       | 77       |
| Deferred income tax benefit   | (9)       | (12)     |
| Recognition of deferred license revenues  | (881)     | (1,011)  |
| Equity in earnings of Novogyne  | (4,327)   | (912)    |
| Distributions from Novogyne   | 7,318     | 7,444    |
| Changes in operating assets and liabilities:  |           |          |
| (Increase) decrease in accounts receivable trade, net   | (1,181)   | 2,740    |
| Decrease in accounts receivable Novogyne, net   | 3,488     | 3,295    |
| Increase in inventories   | (2,537)   | (2,361)  |
| Decrease (increase) in prepaid income taxes   | 135       | (25)     |
| Increase in prepaid and other current assets  | (657)     | (692)    |
| Increase in deposits and other assets   | (15)      |          |
| Decrease in accounts payable  | (1,410)   | (4,898)  |
| Increase in accrued liability Shire   |           | 4,362    |
| Decrease in accrued compensation and related liabilities  | (3,314)   | (2,514)  |
| Increase (decrease) in other accrued liabilities  | 188       | (150)    |
| Decrease in deferred contract revenue, net  | (231)     | (45)     |
| Increase in deferred license revenue  | 1,000     |          |
| Increase in deferred compensation liability   | 31        |          |
| Amounts recoverable from (reimbursable to) Shire and offset against deferred license revenue related to Daytrana approval | 61        | (4,680)  |
| Cash flows (used in) provided by operating activities   | (139)     | 1,510    |
| Cash flows from investing activities:   |           |          |
| Purchases of property, plant and equipment, net   | (2,429)   | (1,825)  |
| Payments for patent development costs, net  | (182)     | (156)    |
| Purchase of company owned life insurance  | (185)     |          |
| Purchases of short-term investments   | (285,375) | (95,100) |
| Proceeds from sale of short-term investments  | 252,350   | 65,150   |
| Cash flows used in investing activities   | (35,821)  | (31,931) |
| Cash flows from financing activities:   |           |          |
| Issuance of common stock from exercise of stock options   | 444       | 816      |



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|  |           |           |
|--|-----------|-----------|
| Payments under capital leases                  | (30)      | (38)      |
| Cash flows provided by financing activities    | 414       | 778       |
| Net decrease in cash and cash equivalents      | (35,546)  | (29,643)  |
| Cash and cash equivalents, beginning of period | 66,964    | 93,958    |
| Cash and cash equivalents, end of period       | \$ 31,418 | \$ 64,315 |

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

**Table of Contents**

**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 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, 2006, and the results of its operations and its cash flows for the three months ended March 31, 2006 and 2005. 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, 2005 ( Form 10-K ), and in Part II Item 1A Risk Factors of this quarterly report on Form 10-Q. Accordingly, the results of operations and cash flows for the three months ended March 31, 2006 and 2005 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 2006 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, as updated and supplemented by the following:

**VENDOR DISCOUNTS:**

Noven receives purchase-volume-related discounts and rebates from vendors in the normal course of business. Management uses projected purchase volumes to estimate accrual rates, validates those projections based on actual purchase trends and applies those rates to actual purchase volumes to determine the amount of funds accrued by Noven and receivable from the vendor. Amounts accrued could be impacted if actual purchase volumes differ from

**Table of Contents**

projected purchase volumes. Noven treats purchase-volume-related discounts or rebates as a reduction of inventory cost or cost of products sold, depending on whether the related inventory is on-hand or has been previously sold, which is consistent with Emerging Issues Task Force 02-16 Accounting by a Customer (Including a Reseller) for Certain Consideration Received from a Vendor .

### 3. CASH AND CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS:

Cash and cash equivalents includes all highly liquid investments with an original maturity of three months or less at the date of purchase. Cash and cash equivalents as of March 31, 2006, and December 31, 2005, consisted primarily of overnight money market accounts, time deposits, commercial paper and money market funds with original maturities of three months or less at the date of purchase. Noven has 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 Statement of Financial Accounting Standards ( SFAS ) No. 115 Accounting for Certain Investments in Debt and Equity Securities . Despite the long-term nature of their stated contractual maturities, these securities have provisions that allow for liquidation in the short-term. Accordingly, the short-term investments are reported at fair value, with any related unrealized gains and losses included in comprehensive income as a separate component of stockholder s equity, net of applicable taxes. As of March 31, 2006 and December 31, 2005, the cost of all short-term investments approximated fair value. No unrealized gains and losses have been recognized for the quarters ended March 31, 2006 and 2005, respectively. Realized gains and losses and interest and dividends are included in interest income or interest expense, as appropriate.

### 4. RECLASSIFICATIONS:

Certain reclassifications have been made to prior period financial statements to conform to the current period s presentation. Cost of products sold has been revised for the prior period to include certain amounts previously included in research and development expenses.

### 5. CASH FLOW INFORMATION:

Cash payments for income taxes and interest were not material for the three months ended March 31, 2006 and 2005.

#### *Non-cash Investing Activities*

During the three months ended March 31, 2005, Noven recorded approximately \$0.5 million in leasehold improvements as a deferred rent credit as the landlord paid for the applicable leasehold improvements.

### 6. INVENTORIES:

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

|                  | March 31, 2006 |            |           | December 31, 2005 |            |          |
|------------------|----------------|------------|-----------|-------------------|------------|----------|
|                  | Commercial     | Pre-launch | Total     | Commercial        | Pre-launch | Total    |
| Finished goods   | \$ 1,121       | \$         | \$ 1,121  | \$ 760            | \$         | \$ 760   |
| Work in progress | 1,219          | 2,685      | 3,904     | 1,278             | 1,004      | 2,282    |
| Raw materials    | 2,479          | 2,894      | 5,373     | 3,422             | 1,397      | 4,819    |
|                  | \$ 4,819       | \$ 5,579   | \$ 10,398 | \$ 5,460          | \$ 2,401   | \$ 7,861 |

## **Table of Contents**

Pre-launch inventories as of March 31, 2006 and December 31, 2005 consisted of Noven's Daytran<sup>®</sup> product, which received final approval from the United States Food and Drug Administration (FDA) in April 2006 and is expected to be launched in mid-2006. Provisions have been made to reduce inventories to net realizable value. To date, Noven has not experienced any difficulty acquiring materials necessary to manufacture its products. Given that certain materials and compounds, including essential polymers used by Noven, are available from limited sources and, in some cases, a single supplier, no assurance can be given that Noven will not experience such difficulty in the future. Other than products produced for commercial sale, Noven's policy is to immediately recognize as expense all inventory purchased for research and development purposes.

### **7. EMPLOYEE STOCK PLANS:**

Prior to January 1, 2006, all awards granted to employees under the 1999 Long-Term Incentive Plan (the 1999 Plan) were stock options. In 2006, Noven began granting stock-settled stock appreciation rights (SSARs) to employees in lieu of stock options.

At March 31, 2006, there were 3,921,495 stock options and 11,000 SSARs issued and outstanding under the 1999 Plan. Since November 21, 2004, stock options and SSARs granted under the 1999 Plan have had a vesting period of four years, beginning one year after date of grant, and expire seven years after date of grant.

During the first quarter of 2006, Noven adopted the provisions of, and began accounting for stock-based compensation in accordance with, the Financial Accounting Standards Board's Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment (SFAS 123(R)). Under the fair value recognition provisions of this statement, stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period. Noven elected the modified-prospective method, under which prior periods are not revised for comparative purposes. The valuation provisions of SFAS 123(R) apply to new grants and to grants that were outstanding as of the effective date and are subsequently modified. Estimated compensation for grants that were outstanding as of the effective date will be recognized over the remaining service period using the grant date fair value previously calculated for the Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation (SFAS 123) pro forma disclosures requisite.

Noven currently uses the Black-Scholes option pricing model to determine the fair value of stock options and SSARs. The grant date fair value of stock-based payment awards using an option-pricing model is affected by Noven's stock price as well as assumptions regarding a number of complex and subjective variables. These variables include Noven's expected stock price volatility over the term of the awards, actual and projected employee equity award exercise behaviors, risk-free interest rate, estimated forfeitures of awards and expected dividends.

Noven estimates the expected term of options granted by taking the average of the vesting term and the contractual term of the option, as described in the Securities and Exchange Commission's Staff Accounting Bulletin Topic 14: Share-Based Payment (SAB 107) (SAB 107). Noven estimates the volatility of common stock by using a combination of both historical and implied volatility based on an equal weighting of each as management believes it is the expected volatility that marketplace participants would likely use in determining an exchange price for an option. Noven based the risk-free interest rate that Noven uses in the option valuation model on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term on the options. Noven does not anticipate paying any cash dividends in the foreseeable future and therefore uses an expected dividend yield of zero in the option valuation model. Noven is

**Table of Contents**

required to estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. Noven uses historical data to estimate pre-vesting option forfeitures and records stock-based compensation expense only for those awards that are expected to vest. All stock-based payment awards are amortized on a straight-line basis over the requisite service periods of the awards, which are generally the vesting periods.

The assumptions used to value option grants for the quarters ended March 31, 2006 and March 31, 2005 are as follows:

|                         | 2006  | 2005  |
|-------------------------|-------|-------|
| Volatility              | 52.2% | 69.0% |
| Risk free interest rate | 4.94% | 3.49% |
| Expected life (years)   | 5     | 5     |

Total stock-based compensation recognized in Noven's statements of operations for the quarter ended March 31, 2006 was \$0.5 million, of which \$0.4 million was recognized in marketing, general and administrative, \$0.1 million was recognized in research and development and an immaterial amount was recognized in cost of products sold. The total tax benefit recognized related to this compensation expense was \$0.1 million. There were no stock-based compensation costs capitalized as part of inventory and fixed assets for the period ended March 31, 2006.

Prior to the adoption of SFAS 123(R), Noven presented all tax benefits for deductions resulting from the exercise of non-qualified stock options and disqualifying dispositions of incentive stock options as operating cash flows on its statement of cash flows. SFAS 123(R) requires the benefits of tax deductions in excess of recognized compensation expense, determined on an individual award basis, to be reported as a financing cash flow, rather than as an operating cash flow. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. However, under this requirement, total cash flow should remain unchanged from what would have been reported under prior accounting rules. Cash received from options exercised under all share-based payment arrangements for the periods ended March 31, 2006 and 2005 was \$0.4 million and \$0.8 million, respectively. The tax benefit realized for the tax deductions from option exercise of the share-based payment arrangements totaled \$0.1 million for each of the three months ended March 31, 2006 and 2005, respectively. There were no benefits of tax deductions in excess of recognized stock-based compensation expense to be reported as a financing cash flow for the three months ended March 31, 2006.

**Table of Contents**

Stock option transactions related to the plans are summarized as follows for the three months ended March 31, 2006 (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       | 4,004             | \$ 17.23                                 |                                 |   |
| Granted                                      | 11                | 17.34                                    |                                 |   |
| Exercised                                    | (61)              | 7.30                                     | \$ 525                          |   |
| Canceled and expired                         | (9)               | 23.74                                    |                                 |   |
| Outstanding at end of the period             | 3,945             | \$ 17.37                                 | \$ 12,989                       | 4.3   |
| Outstanding and exercisable at end of period | 2,805             | \$ 19.38                                 | \$ 6,619                        | 3.9   |

As of March 31, 2006, the unamortized compensation expense that Noven expects to record in future periods related to currently outstanding unvested stock options and SSARs, as determined in accordance with SFAS 123(R) is approximately \$6.7 million before the effect of income taxes, of which \$2.2 million, \$2.4 million, \$1.5 million and \$0.6 million is expected to be incurred in the remainder of 2006 and in 2007, 2008 and 2009, respectively. The weighted-average period over which this compensation cost is expected to be recognized is 3.7 years.

Prior to 2006, in accordance with the provisions of SFAS 123, as amended by Statement of Financial Accounting Standards No. 148, Accounting for Stock-Based Compensation Transition and Disclosure ( SFAS 148 ), Noven elected to continue to apply the provisions of the Accounting Principles Board's Opinion No. 25, Accounting for Stock Issued to Employees ( APB 25 ), and related interpretations in accounting for its employee stock option plans. Therefore no stock-based employee compensation cost is reflected in net income for the three months ended March 31, 2005, as all options granted under those plans had an exercise price equal to the market value of the underlying common stock on the date of grant.

The following table illustrates the effect on net income and earnings per share for the three months ended March 31, 2005 if Noven had applied the fair value recognition provisions of SFAS 123, as amended by SFAS 148 (in thousands, except per share amounts):

|   |            |
|---|------------|
| Net income:   |            |
| As reported   | \$ 211     |
| Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects | (1,747)    |
| Pro forma   | \$ (1,536) |
| Basic earnings per share:   |            |
| As reported   | \$ 0.01    |
| Pro forma   | \$ (0.07)  |
| Diluted earnings per share:   |            |
| As reported   | \$ 0.01    |
| Pro forma   | \$ (0.07)  |



## **Table of Contents**

In order to eliminate some of the future compensation expense that Noven would otherwise have recognized in its statements of operations under SFAS 123(R), during 2005 Noven accelerated the vesting of certain stock options under the 1999 Plan. As a result of this action, options to purchase approximately 1.1 million shares of Noven's common stock became immediately exercisable, including options held by Noven's executive officers to purchase approximately 455,000 shares. Noven recorded an immaterial charge to compensation expense during the fourth quarter of 2005 due to the acceleration of a nominal amount of in-the-money options. As a result of the acceleration, during 2005, approximately \$10.1 million of compensation expense, net of applicable income taxes, was eliminated from Noven's future statements of operations and included in the pro forma footnote disclosure for the year ended December 31, 2005.

### **8. DEFERRED COMPENSATION PLAN:**

Effective January 1, 2006, Noven established a deferred compensation plan (the Plan) available for members of Noven's Board of Directors and a group of Noven's officers selected by Noven's Employee Benefits Committee. The Plan permits participants to defer receipt of part of their current compensation to a later date as part of their personal retirement or financial planning. Participants may elect to defer, as applicable, portions of their director fees, base salary, bonus, long-term incentive plan awards, and/or restricted stock grants. Benefit security for the Plan is provided by a funded rabbi trust.

The compensation withheld from Plan participants, together with investment income on the Plan, is reflected as a deferred compensation obligation to participants and is classified as a long-term liability in the accompanying condensed balance sheets. The related assets, which are held in the rabbi trust in the form of a company owned life insurance policy that names Noven as the beneficiary, are classified within other assets as a deferred charge in the accompanying condensed balance sheets and are reported at cash surrender value, which was approximately \$0.2 million as of March 31, 2006. At March 31, 2006, the balance of the deferred compensation liability totaled \$31,000.

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

#### *Shire*

On April 6, 2006, Noven's amended New Drug Application (NDA) for Daytrana was approved for marketing by the FDA. In April 2006, Noven received a \$50 million milestone payment from Shire plc (Shire) (the global licensee of the product) as a result of the approval, and Noven may also earn additional milestone payments of up to \$75 million depending on the level of Shire's commercial sales of the product. Noven expects to defer and recognize approval and sales milestones as license revenues on a quarterly basis through the first quarter of 2013, which is Noven's current best estimate of the useful life of the product. Noven expects to begin recognizing the \$50 million milestone payment as well as the balance of the Shire deferred license revenues (\$4.8 million at March 31, 2006) starting in the second quarter of 2006. Noven also expects to earn revenues and gross profit on the finished product it manufactures and supplies to Shire.

As of March 31, 2006 Noven's inventories included \$5.6 million of Daytrana pre-launch inventories. Noven's agreement with Shire provides that if any Daytrana inventory is ultimately not commercially saleable (other than as a result of a failure by Noven to comply with its contractual obligations), Shire would bear the full cost of any inventory write-off.



**Table of Contents****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 produced sufficient income in the first quarter of 2006 and 2005 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, 2006 and 2005, Noven had the following transactions with Novogyne (in thousands):

|                     | Three Months |          |
|---------------------|--------------|----------|
|                     | 2006         | 2005     |
| Revenues:           |              |          |
| Product sales       | \$ 3,087     | \$ 4,978 |
| Royalties           | 1,689        | 1,114    |
|                     | \$ 4,776     | \$ 6,092 |
| Reimbursed expenses | \$ 7,269     | \$ 7,242 |

As of March 31, 2006 and December 31, 2005, Noven had amounts due from Novogyne of \$5.4 million and \$8.9 million, respectively, for products sold to, and marketing expenses reimbursable by, Novogyne.

The unaudited condensed Statements of Operations of Novogyne for the three months ended March 31, 2006 and 2005 are as follows (in thousands):

|  | Three Months |           |
|--|--------------|-----------|
|  | 2006         | 2005      |
| Gross revenues                               | \$ 37,269    | \$ 27,334 |
| Sales allowances                             | 3,793        | 3,395     |
| Sales return allowances                      | 1,896        | 1,266     |
| Sales allowances and returns                 | 5,689        | 4,661     |
| Net revenues                                 | 31,580       | 22,673    |
| Cost of sales <sup>1</sup>                   | 7,521        | 6,100     |
| Selling, general and administrative expenses | 9,157        | 8,670     |
| Income from operations                       | 14,902       | 7,903     |
| Interest income                              | 152          | 93        |
| Net income                                   | \$ 15,054    | \$ 7,996  |
| Noven's equity in earnings of Novogyne       | \$ 4,327     | \$ 912    |

<sup>1</sup> Included in Novogyne's costs of sales is the amortization of the marketing

rights Novogyne  
acquired for  
CombiPatch<sup>®</sup>,  
which in prior  
periods was  
listed as a  
separate  
operating  
expense in  
Novogyne's  
statement of  
operations.

**Table of Contents**

The activity in the Investment in Novogyne account for the three months ended March 31, 2006 is as follows (in thousands):

|   |           |
|---|-----------|
| Investment in Novogyne, beginning of period | \$ 23,243 |
| Equity in earnings of Novogyne              | 4,327     |
| Cash distributions from Novogyne            | (7,318)   |
| Investment in Novogyne, end of period       | \$ 20,252 |

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, 2006 and 2005, Noven received cash distributions representing return on investment of \$7.3 million and \$7.4 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 acquire up to \$25.0 million of its common stock. To date, Noven has repurchased 105,000 shares of its common stock at an aggregate price of approximately \$1.3 million. No shares were repurchased during the three months ended March 31, 2006 and 2005.

**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 our 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 as disclosed in our Form 10-K. 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 two 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 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

## **Table of Contents**

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.

### *Production Issues*

Noven maintains in-house product stability testing for its commercialized products. This process includes, among other things, testing samples from commercial lots under a variety of conditions to confirm that the samples remain within required specifications for the shelf-life of the product.

In 2003, Noven's product stability testing program revealed that certain lots of CombiPatch® and Vivelle-Dot patches did not maintain required specifications throughout the products' shelf-lives, resulting in product recalls of certain lots. As a result, Noven initiated a series of special stability protocols to monitor commercial lots in distribution as well as future production. In the first quarter of 2005, a total of ten lots of Vivelle-Dot manufactured in 2003 were identified for recall when one of Noven's stability protocols revealed that these lots did not meet required specification or were associated with lots that did not meet specification. The recall of these lots in the first quarter of 2005 did not have a material impact on Noven's or Novogyne's results of operations because an immaterial number of patches from these lots remained in distribution. A joint Noven and Novartis task force is working to identify the definitive root cause of the Vivelle-Dot stability failures. Based on testing and analysis to date, Noven believes that the probable cause of the Vivelle-Dot stability failures relates to certain patch backing material that Noven obtained from a raw material supplier. If the root cause determination or additional testing indicates that the production issue affects more product than Noven's current testing and analysis suggests, additional recalls may be required. Noven continues to manufacture and ship Vivelle-Dot to Novogyne.

In October 2004, Noven's product stability testing program indicated that one commercial lot of CombiPatch® product did not maintain required specifications throughout the product's shelf-life due to the formation of crystals. This issue is unrelated to the issue that led to the 2003 CombiPatch® recall referenced above. Novartis recalled the affected lot. The recall of this lot did not have a material impact on Noven's and Novogyne's financial results in either 2004 or 2005. Noven continues to manufacture and ship CombiPatch® to Novogyne.

In the fourth quarter of 2005, Novartis Pharma AG (Novartis Pharma), an affiliate of Novartis, recalled three commercial lots of Estalis® (the form of CombiPatch® manufactured for sale outside the United States) after special stability protocols put in place after the October 2004 CombiPatch® stability failure indicated that certain lots did not maintain required specifications throughout the product's shelf-life due to the formation of crystals. The recall of these lots did not have a material impact on Noven's financial statements for the year ended December 31, 2005. In April 2006, stability testing indicated that one additional lot of Estalis® was not maintaining specifications due to the formation of crystals while another lot, while not out of specification, was trending adversely. Any recall of these two additional lots by Novartis Pharma is not expected to have a material impact on Noven's results of operations. Noven believes that the Estalis® stability failures were caused by the use of certain pouchstock obtained from a third-party vendor. Noven continues to manufacture and ship Estalis® to Novartis Pharma.

Noven continues to maintain stability testing related to the foregoing production issues. If Noven's testing indicates that additional lots of CombiPatch®, Estalis® or Vivelle-Dot or other products do not meet specifications, there could be additional recalls. Although Noven and Novartis work together in assessing production issues related to these products, the decision to recall product resides with Novartis as the holder of the regulatory approvals for these products

## **Table of Contents**

and is not within Noven's control. If Noven's estimate concerning product returns associated with the recall are incorrect, or if Noven's continued testing indicates that additional lots are affected, or if Novartis should initiate additional recalls for any reason, then Noven's and Novogyne's business and results of operations could be materially and adversely impacted. Among other things, any CombiPatch® recalls could have a material adverse impact on the ability of Novogyne to recover its investment in its CombiPatch® marketing rights.

The recent recalls may result in an FDA inspection of Noven's facilities and procedures and Noven cannot assure that the FDA will be satisfied with our operations and procedures, which could result in more frequent and stringent inspections and monitoring. If the FDA were to conclude that Noven's manufacturing controls and procedures are not sufficient, Noven could be required to suspend production until Noven demonstrates to the FDA that Noven's controls and procedures are sufficient.

### *Supply Agreement*

Noven's supply agreement with Novogyne for Vivelle® and Vivelle-Dot patches expired in January 2003. Since expiration, the parties have continued to operate in accordance with the supply agreement's commercial terms. There is no assurance that the agreement's non-commercial terms would be enforceable with respect to post-expiration occurrences. A decision to discontinue operating in accordance with the agreement under the agreement's commercial terms could have a material adverse effect on Noven's financial position and results of operations. Novogyne's designation of a new supplier and approval of a new supply agreement would require the affirmative vote of four of the five members of Novogyne's Management Committee. 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 indicated that it intends 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.

Novartis has advised Noven that Novartis has been named as a defendant in at least 20 pending additional lawsuits that include approximately 27 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, Vivelle®, and CombiPatch® products. Novogyne has been named as a defendant in one lawsuit in addition to the ones 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 has established an accrual for the expected legal fees and settlements of these lawsuits for \$6.3 million with an offsetting insurance recovery of \$4.5 million. This accrual represents Novartis management's best estimate as of March 31, 2006. The outcome of these product liability lawsuits cannot ultimately be predicted.

**Table of Contents**

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.

**Table of Contents**

**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, 2006, and our results of operations for the three months ended March 31, 2006 and 2005. The contents of this section include:

An executive summary of our results of operations for the quarter ended March 31, 2006;

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;

An outlook that includes our current financial guidance;

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

A discussion of recently-issued accounting standards.

This discussion should be read in conjunction with Noven's financial statements for the three months ended March 31, 2006 and 2005 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 Noven's financial statements and the related notes included in this Form 10-Q.*

Our financial results for the three months ended March 31, 2006 were characterized by, among other things, lower HT product sales to our Novogyne joint venture due primarily to the timing of product shipments; gross margin pressure related primarily to the scale-up of manufacturing for our recently-approved Daytrana product; and a strong performance from Novogyne and its principal product, Vivelle-Dot.

Our net revenues for the three months ended March 31, 2006 decreased 13% to \$10.2 million primarily due to the timing of Vivelle-Dot shipments to Novogyne. Our quarterly gross margin was negatively affected by manufacturing scale-up for our Daytrana methylphenidate patch, approved by the FDA on April 6, 2006, and lower production volume in our HT business due to the timing of orders. We expect our gross margin to begin to improve from current levels in the second half of 2006 as Daytrana is expected to move into ongoing commercial production; however, no assurance can be given that gross margin will improve in accordance with these expectations, including as a result of delays or inefficiencies in the launch or manufacture of Daytrana.

Research and development expenses in the three months ended March 31, 2006 increased 20% to \$3.5 million compared to the three months ended March 31, 2005, primarily due to increases in development engineering costs related to Daytrana as well as higher pre-clinical and clinical costs for other projects. Marketing, general and administrative expense increased 17% to \$4.7 million, primarily due to stock-based compensation expense, which commenced in the three months ended March 31, 2006, and increased professional fees.

## **Table of Contents**

We recognized \$4.3 million in earnings from Novogyne in the three months ended March 31, 2006 (after satisfaction by Novogyne of Novartis' annual preferred profit return of \$6.1 million) compared to \$0.9 million recognized in the three months ended March 31, 2005.

Our net income for the three months ended March 31, 2006 was \$0.5 million (or \$0.02 diluted earnings per share), compared to net income of \$0.2 million (or \$0.01 diluted earnings per share) for the three months ended March 31, 2005.

Novogyne's net income for the three months ended March 31, 2006 increased 88% to \$15.1 million. Novogyne's net revenues increased 39% to \$31.6 million, primarily due to a \$9.4 million increase in net sales of Vivelle-Dot. We believe this increase related to trade customers reducing their inventories in the quarter ended March 31, 2005 and, to a lesser extent, increased prescription demand and price increases. Novogyne's selling, general and administrative expense for the quarter increased 6% to \$9.2 million, due primarily to increased litigation expense and higher expenses associated with sales force expansion.

Total prescriptions for Vivelle-Dot increased 8% in the three months ended March 31, 2006 compared to the three months ended March 31, 2005, and total prescriptions for Novogyne's products, taken as a whole, increased 4%. For the same period, the overall U.S. HT market declined 5%.

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

We develop and manufacture advanced transdermal patches and presently derive substantially all 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 three principal HT products Vivelle®, Vivelle-Dot and CombiPatch® 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 Vivelle®, Vivelle-Dot and CombiPatch® 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 \$4.3 million and \$0.9 million for the three months ended March 31, 2006 and 2005, 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 may not be the same as the amount of income we recognize from Novogyne for that period. For the three months ended March 31, 2006 and 2005, we received \$7.3 million and \$7.4 million, respectively, in distributions from Novogyne, which



## **Table of Contents**

accounted for a substantial portion 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, but we cannot assure that Novogyne will continue to be profitable or make cash distributions. 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 our transdermal HT products, has contracted since the July 2002 publication of the WHI study that found adverse health risks associated with HT products. Comparing the second quarter of 2002 (the quarter immediately preceding the publication of initial data from the WHI study) to the first quarter of 2006, total prescriptions dispensed in the HT market in the United States decreased by 54.2%. For the same period, aggregate prescriptions for Noven's United States HT products decreased 10.4%. The estrogen segment of the HT market in the United States declined 49.9%, while our Vivelle® line of products increased 2.4%. Vivelle-Dot, which represented 86.0% of our total United States prescriptions in the first quarter of 2006, increased 29.5% from the second quarter of 2002 to the first quarter of 2006. We believe Vivelle-Dot patch prescriptions have benefited from both increased demand and patient conversions from the original Vivelle® product.

United States prescriptions for our CombiPatch® product (which represented approximately 10.4% of our total United States prescriptions in the first quarter of 2006) declined 56.8% from the second quarter of 2002 to the first quarter of 2006, while prescriptions for the total United States market for fixed combination hormone therapy products decreased 71.9%. The combination therapy arm of WHI involved an oral combination estrogen/progestin product and, accordingly, the combination therapy segment of the HT market has experienced the most significant decrease. Further decreases for our CombiPatch® product (whether as a result of the WHI studies, the production issues discussed below or otherwise) could require Novogyne (which holds the CombiPatch® marketing rights) to record an impairment loss related to this intangible asset, which would adversely affect the results of operations of both Noven and 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.

#### ***Stock-Based Compensation***

Currently, our outstanding stock-based compensation consists of: (i) stock options; (ii) SSARs; and (iii) stock awards granted to non-employee directors. Prior to January 1, 2006, all awards granted to employees under the 1999 Plan were stock options. In 2006, Noven began granting SSARs to employees in lieu of stock options and from time to time we may consider or grant other forms of stock-based compensation.

On January 1, 2006, we adopted the provisions of, and for the quarter ended March 31, 2006, we accounted for stock-based compensation in accordance with, SFAS 123(R). We elected the modified-prospective method, under which prior periods are not revised for comparative purposes. Under the fair value recognition provisions of this statement, stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense on a straight-line basis over the requisite service period, which is typically the vesting period. The

## **Table of Contents**

determination of the fair value of stock-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. See Critical Accounting Estimates.

Total stock-based compensation recognized in our statements of operations for the quarter ended March 31, 2006 was \$0.5 million, of which \$0.4 million was recognized in marketing, general and administrative, \$0.1 million was recognized in research and development and an immaterial amount was recognized in cost of products sold. There were no stock-based compensation costs capitalized as part of inventory and fixed assets for the period ended March 31, 2006.

At March 31, 2006, the unamortized compensation expense that we expect to record in future periods related to currently outstanding unvested stock options and SSARs, as determined in accordance with SFAS 123(R), is approximately \$6.7 million before the effect of income taxes, of which \$2.2 million, \$2.4 million, \$1.5 million and \$0.6 million is expected to be incurred in the remainder of 2006 and in 2007, 2008 and 2009, respectively. The \$1.1 million reduction in future compensation expense (\$8.3 million as of December 31, 2005 minus \$0.5 million incurred for the three months ended March 31, 2006 and \$6.7 million expected to be incurred in the future) related to unvested stock options is mainly attributable to a change in management's estimate of expected forfeitures in connection with the adoption of SFAS123(R). We will also incur additional expense in future years related to new equity awards that may be granted in the future that cannot yet be quantified.

In order to eliminate some of the future compensation expense that we would otherwise have recognized in our statements of operations under SFAS 123(R), during 2005 we accelerated the vesting of certain stock options under the 1999 Plan. As a result of this action, options to purchase approximately 1.1 million shares of our common stock became immediately exercisable, including options held by our executive officers to purchase approximately 455,000 shares. We recorded an immaterial charge to compensation expense during the fourth quarter of 2005 due to the acceleration of a nominal amount of in-the-money options. As a result of the acceleration, during 2005, we eliminated approximately \$10.1 million of compensation expense, net of applicable income taxes, from our future statements of operations and included in the pro forma footnote disclosure for the year ended December 31, 2005.

### *Shire*

On April 6, 2006, our amended NDA for Daytrana was approved for marketing by the FDA. In April 2006, we received a \$50 million milestone payment from Shire (the global licensee of the product) as a result of the approval, and we may also earn additional milestone payments of up to \$75 million depending on the level of Shire's commercial sales of the product. We expect to defer and recognize approval and sales milestones as license revenues on a quarterly basis through the first quarter of 2013, which is our best estimate of the useful life of the product. We expect to begin recognizing the \$50 million milestone payment as well as the balance of the Shire deferred license revenues (\$4.8 million at March 31, 2006) starting in the second quarter of 2006. We also expect to earn a profit on the finished product we manufacture and supply to Shire.

As of March 31, 2006 our inventories included \$5.6 million of Daytrana pre-launch inventories. If any Daytrana inventory is ultimately not commercially saleable (other than as a result of a failure by Noven to comply with its contractual obligations), our agreement with Shire provides that Shire would bear the full cost of any inventory write-off.

**Table of Contents**

*Production Issues*

We maintain in-house product stability testing for our commercialized products. This process includes, among other things, testing samples from commercial lots under a variety of conditions to confirm that the samples remain within required specifications for the shelf-life of the product.

As previously disclosed in our Form 10-K, Novartis Pharma recalled three commercial lots of Estalis® (the form of CombiPatch® manufactured for sale outside the United States) in the fourth quarter of 2005 after special stability protocols indicated that those lots did not maintain required specifications throughout the product's shelf-life due to the formation of crystals. In April 2006, stability testing indicated that one additional lot of Estalis® was not maintaining specifications due to the formation of crystals while another lot, while not out of specification, was trending adversely. Any recall of these two additional lots by Novartis Pharma is not expected to have a material impact on our results of operations. We believe that the Estalis® stability failures were caused by the use of certain pouchstock obtained from a third-party vendor. We continue to manufacture and ship Estalis® to Novartis Pharma.

We continue to maintain stability testing related to the production issues discussed here and in our Form 10-K. If our testing indicates that additional lots of our products or lots of products that have not previously experienced failures do not meet specifications, there could be additional recalls. Although Noven and Novartis work together in assessing production issues related to these products, the decision to recall product resides with Novartis as the holder of the regulatory approvals for these products and is not within our control. If our estimates concerning product returns associated with a recall are incorrect, or if our continued testing indicates that additional lots are affected, or if Novartis should initiate recalls for any reason, then Noven's and Novogyne's business and results of operations could be materially and adversely impacted. Among other things, any CombiPatch® recalls could have a material adverse impact on the ability of Novogyne to recover its investment in its CombiPatch® marketing rights.

The recent recalls may result in an FDA inspection of our facilities and procedures and we cannot assure that the FDA will be satisfied with our operations and procedures, which could result in more frequent and stringent inspections and monitoring. If the FDA were to conclude that our manufacturing controls and procedures are not sufficient, we could be required to suspend production until we demonstrate to the FDA that our controls and procedures are sufficient.

**Table of Contents****Results of Operations****Three months ended March 31, 2006 compared to the three months ended March 31, 2005*****Revenues***

Total revenues for the three months ended March 31, 2006 and 2005 are summarized as follows (dollar amounts in thousands):

|                                 | Three Months |           | %      |
|---------------------------------|--------------|-----------|--------|
|                                 | 2006         | 2005      | Change |
| Product revenues Novogyne:      |              |           |        |
| Product sales                   | \$ 3,087     | \$ 4,978  | (38%)  |
| Royalties                       | 1,689        | 1,114     | 52%    |
|                                 | 4,776        | 6,092     | (22%)  |
| Product revenues third parties: |              |           |        |
| Product sales                   | 3,800        | 3,965     | (4%)   |
| Royalties                       | 71           | 73        | (3%)   |
|                                 | 3,871        | 4,038     | (4%)   |
| Total product revenues          | 8,647        | 10,130    | (15%)  |
| Contract and license revenues:  |              |           |        |
| Contract                        | 664          | 595       | 12%    |
| License                         | 881          | 1,011     | (13%)  |
|                                 | 1,545        | 1,606     | (4%)   |
| Net revenues                    | \$ 10,192    | \$ 11,736 | (13%)  |

**Net Revenues**

As described in more detail below, the 13% decline in net revenues for the three months ended March 31, 2006 as compared to the same period in 2005 was primarily attributable to an aggregate decline in sales to Novogyne due to timing of shipments and an aggregate decline in international product sales, partially offset by an increase in royalties for the three months ended March 31, 2006 as compared to the same period in 2005 as a result of Novogyne's higher sales of Vivelle-Dot.

**Product Revenues Novogyne**

Product revenues Novogyne consists of our sales of Vivelle-Dot<sup>®</sup>, Estradot<sup>®</sup>, and Vivelle<sup>®</sup> to Novogyne at a fixed price for 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<sup>®</sup>.

The \$1.3 million decline in product revenues from Novogyne for the three months ended March 31, 2006 as compared to the same period in the prior year primarily related to a \$1.2 million, \$0.4 million and \$0.2 million decline in unit sales of Vivelle-Dot, Vivelle<sup>®</sup> and Estradot<sup>®</sup>, respectively, partially offset by a \$0.6 million increase in royalties. The decline in sales of Vivelle-Dot to Novogyne for the three months ended March 31, 2006 was primarily

due to the timing of shipments to Novogyne. There were no sales of Vivelle® to Novogyne in the first quarter of 2006 due to the planned discontinuation of the production of this mature product by the end of 2006. The

**Table of Contents**

decline in unit sales of Estradot® was primarily due to the timing of orders. The increase in royalties was attributable to higher sales by Novogyne for the three months ended March 31, 2006.

**Product Revenues – Third Parties**

Product revenues – third parties consists primarily 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.

The \$0.2 million decline in product revenues from third parties for the three months ended March 31, 2006 as compared to the same period in the prior year primarily related to \$0.4 million decline related to pricing and a \$0.2 million decline in unit sales of Menorest, partially offset by \$0.5 million increase in unit sales of Estradot®. The \$0.4 million price decline is primarily related to a \$0.7 million price adjustment payment from Novartis Pharma, which was recorded in the first quarter of 2006, compared to \$1.2 million in the first quarter of 2005. Noven records such price adjustment payments from time to time upon Novartis Pharma's determination that its actual sales price of our product entitles us to receive amounts in excess of the minimum transfer price. The decline in unit sales of Menorest and the increase in Estradot® unit sales are attributable to the continued transition from Menorest to Estradot®.

**Contract and License Revenues**

Contract and license revenues were approximately the same for the three months ended March 31, 2006 as compared to the same period in the prior year.

***Gross Margin***

The following section presents Noven's gross margin on an overall basis and also discusses gross margin for: (i) Novogyne-related product revenues and (ii) third party-related product revenues. The following section includes a discussion of gross margins that excludes the effect of our deferral of profits on products we sell to Novogyne. We believe such non-GAAP presentation is useful to investors in order to meaningfully evaluate Noven's ongoing, underlying business and compare Noven's financial results for the three months ended March 31, 2006 to those in the same period of 2005. For the same reasons, management uses these non-GAAP financial measures to evaluate Noven's ongoing, underlying business. These measures should not be considered alternatives to measures computed in accordance with GAAP, nor should they be considered indicators of our overall financial performance.

**Table of Contents**

Noven's gross margin for the three months ended March 31, 2006 and 2005 are summarized as follows (dollar amounts in thousands):

|   | Three Months |           |
|---|--------------|-----------|
|   | 2006         | 2005      |
| <b>Gross Margin Total:</b>                                      |              |           |
| Product revenues  | \$ 8,647     | \$ 10,130 |
| Cost of products sold   | 6,140        | 5,874     |
| Gross profit (product revenues less cost of products sold)      | 2,507        | 4,256     |
| Gross margin (gross profit as a percentage of product revenues) | 29%          | 42%       |
| Changes in deferred profit on sales of product to Novogyne      | (296)        | 142       |
| Gross profit excluding impact of deferred profit                | 2,211        | 4,398     |
| Gross margin excluding impact of deferred profit                | 26%          | 43%       |

Noven's cost of products sold may be affected in a given period by changes in deferred profit on Noven's sale of product to Novogyne. As a result of our 49% equity investment in Novogyne, we are required to defer 49% of our profit on product that we sell to Novogyne until that product is sold by Novogyne to trade customers. Since our cost of products sold is adjusted to reflect changes in deferred profit, our gross margin can vary from period to period based on the timing of our shipments to Novogyne and Novogyne's sale of our products to trade customers. If Novogyne sells more product than we provide it in a given period (i.e., if Novogyne's inventories decline), we will defer less profit from sales to Novogyne. In light of the significant historic fluctuations in our deferred profit on sales of product to Novogyne, we have included our gross margin net of the changes in deferred profit on sales of product to Novogyne, which, Noven's management believes, is useful to understanding Noven's revenues as they relate to its cost of production.

Our overall gross margin was significantly affected by increased cost of products sold resulting from start-up expenses associated with Daytrana and, to a lesser extent a shift in the product mix as there was a higher percentage of international sales in the three months ended March 31, 2006 in comparison to the three months ended March 31, 2005, which have a lower margin than our sales to Novogyne. In addition, our overall gross margin was adversely affected by lower production volume in our HT business due to the timing of orders.

**Table of Contents****Gross Margin Sales to Novogyne**

|   | Three Months |          |
|---|--------------|----------|
|   | 2006         | 2005     |
| <b>Gross Margin Novogyne:</b>   |              |          |
| Product revenues  | \$ 4,776     | \$ 6,092 |
| Cost of products sold   | 2,143        | 3,249    |
| Gross profit (product revenues less cost of products sold)                        | 2,633        | 2,843    |
| Gross margin (gross profit as a percentage of product revenues)                   | 55%          | 47%      |
| Changes in deferred profit on sales of product to Novogyne                        | (296)        | 142      |
| Gross profit excluding changes in deferred profit on sales of product to Novogyne | 2,337        | 2,985    |
| Gross margin excluding impact of deferred profit                                  | 49%          | 49%      |

Gross margin related to Novogyne excluding the impact of deferred profit was approximately the same for the three months ended March 31, 2006 as compared to the same period in 2005. The decline in the deferred profit on sales to Novogyne for the three months ended March 31, 2006 was a result of a decrease in inventory levels at Novogyne from December 31, 2005 to March 31, 2006.

**Gross Margin Sales to third parties**

|   | Three Months |          |
|---|--------------|----------|
|   | 2006         | 2005     |
| <b>Gross Margin Third Parties:</b>                              |              |          |
| Product revenues  | \$ 3,871     | \$ 4,038 |
| Cost of products sold   | 3,997        | 2,625    |
| Gross profit (product revenues less cost of products sold)      | (126)        | 1,413    |
| Gross margin (gross profit as a percentage of product revenues) | (3%)         | 35%      |

As discussed above, the decline in gross margin related to third party sales was primarily attributable to increased cost of products sold resulting from start-up manufacturing expenses associated with Daytrana.



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

Operating expenses for the three months ended March 31, 2006 and 2005 are summarized as follows (dollar amounts in thousands):

|                                       | Three Months |          | %      |
|---------------------------------------|--------------|----------|--------|
|                                       | 2006         | 2005     | Change |
| Research and development              | \$ 3,482     | \$ 2,893 | 20%    |
| Marketing, general and administrative | 4,738        | 4,055    | 17%    |

**Research and Development**

Research and development expense includes costs associated with, among other things, product formulation, pre-clinical testing, clinical studies, regulatory and medical affairs, production for clinical and regulatory purposes, production related development engineering for developmental products, and the personnel associated with each of these functions.

The \$0.6 million increase in research and development expenses for the three months ended March 31, 2006 as compared to the same period in 2005 was primarily attributable to a \$0.7 million increase in development engineering related to Daytrana, a \$0.3 million increase in pre-clinical testing, a \$0.3 million increase in clinical studies and a \$0.3 million increase in personnel costs, partially offset by a \$1.0 million decline in development engineering related to our fentanyl transdermal system.

**Marketing, General and Administrative**

The \$0.7 million increase in marketing, general and administrative expenses for the three months ended March 31, 2006 as compared to the same period in 2005 was primarily attributable to a \$0.2 million increase in professional fees and a \$0.5 million increase in compensation costs, which were primarily related to stock-based compensation expense.

**Other Income and Expenses*****Interest Income***

The \$0.1 million increase in interest income for the three months ended March 31, 2006 as compared to the same period in 2005 was primarily attributable to investing a higher portion of our cash in short-term investments that yielded higher interest income.

***Income Taxes***

Our effective tax rate was approximately 35% and 36% for the three months ended March 31, 2006 and 2005, respectively. The provision for income taxes is based on the Federal statutory and state income tax rates. Net deferred income tax assets are measured using the average graduated tax rate for the estimated amount of annual taxable income in the years that the liability is expected to be settled or the asset recovered. The effect of adjusting the expected tax rate related to the net deferred income tax assets is included in the provision for income taxes. As of March 31, 2006, we had a net deferred tax asset of \$12.4 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.

**Table of Contents***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 increases as Novogyne's product sales increase, subject to a cap of 49%. Novogyne produced sufficient income in the first quarters of 2006 and 2005 to meet Novartis annual preferred return for those years and for us to recognize earnings from Novogyne under the formula. We report our share of Novogyne's earnings as Equity in earnings of Novogyne in our unaudited Condensed Statements of Operations.

The financial results of Novogyne for the three months ended March 31, 2006 and 2005 are summarized as follows (dollar amounts in thousands):

|  | Three Months |           | %      |
|--|--------------|-----------|--------|
|  | 2006         | 2005      | Change |
| Gross revenues <sup>1</sup>                  | \$ 37,269    | \$ 27,334 | 36%    |
| Sales allowances                             | 3,793        | 3,395     | 12%    |
| Sales returns allowances                     | 1,896        | 1,266     | 50%    |
| Sales and returns allowances                 | 5,689        | 4,661     | 22%    |
| Net revenues                                 | 31,580       | 22,673    | 39%    |
| Cost of sales <sup>2</sup>                   | 7,521        | 6,100     | 23%    |
| Gross profit                                 | 24,059       | 16,573    | 45%    |
| Gross margin percentage                      | 76%          | 73%       |        |
| Selling, general and administrative expenses | 9,157        | 8,670     | 6%     |
| Income from operations                       | 14,902       | 7,903     | 89%    |
| Interest income                              | 152          | 93        | 63%    |
| Net income                                   | \$ 15,054    | \$ 7,996  | 88%    |
| Noven's equity in earnings of Novogyne       | \$ 4,327     | \$ 912    | 374%   |

<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.

- <sup>2</sup> Included in  
Novogyne's  
costs of sales is  
the amortization  
of the marketing  
rights Novogyne  
acquired for  
CombiPatch®,  
which in prior  
periods was  
listed as a  
separate  
operating  
expense in  
Novogyne's  
statement of  
operations.

#### Novogyne Net Revenues

Novogyne's gross revenues increased \$9.9 million for the three months ended March 31, 2006 compared to the same period in the prior year, primarily due to a \$10.2 million increase in sales of Vivelle-Dot and a \$0.3 million increase in sales of CombiPatch®, partially offset by a \$0.4 million decline in sales of Estradot® to Canada. In addition, Vivelle®, our first generation estrogen patch, the production of which is planned to be discontinued by the end of 2006, declined \$0.2 million in unit sales. Approximately \$8.6 million of the Vivelle-Dot increase was due to increased unit sales, of which we believe approximately half of this increase was due to inventory reductions by trade customers in the first quarter of 2005. Increased prescription demand influenced the remaining

## **Table of Contents**

unit increase. Price increases accounted for \$1.6 million of the overall increase in Vivelle-Dot gross sales.

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.

Approximately \$0.1 million of the CombiPatch® increase was due to increased unit sales which we believe is based on the timing of orders and not increased trade demand as there is a continuing decline in the market for combination therapies after the publication of the combination arm of the WHI study as well as the impact of a competitive product. The remaining \$0.2 million CombiPatch® increase related to price increases. The decline in sales to Canada by Novogyne is primarily attributable to the timing of orders.

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 10% and 12% of gross revenues for the three months ended March 31, 2006 and 2005, respectively. The 2% reduction for the three months ended March 31, 2006 as compared to the same period in 2005 was due to price increases that occurred at the start of the prior year period, which allowed customers for a short period of time to purchase product at the new price and subsequently receive a discount to the original price, thereby resulting in an increase in the amount of discount recognized for the 2005 period. There was no such price increase during the first quarter of 2006.

Sales returns allowances consist of allowances for returns of expiring product and were \$1.9 million and \$1.3 million for the three months ended March 31, 2006 and 2005, respectively. The \$0.6 million increase was primarily related to higher sales of Vivelle-Dot and higher actual returns of CombiPatch® as compared to the same period in the prior year. Actual returns for expiring product were \$1.2 million and \$0.9 million for the three months ended March 31, 2006 and 2005, respectively.

### **Novogyne Gross Margin**

The 3% gross margin increase for the three months ended March 31, 2006 as compared to the same period in 2005 was primarily related to increased sales of Vivelle-Dot, which has a higher gross margin than the other products sold by Novogyne, coupled with decreased sales of Estradot® to Canada, which typically has a lower gross margin.

### **Novogyne Selling, General and Administrative Expenses**

Novogyne's selling, general and administrative expenses for the three months ended March 31, 2006 increased \$0.5 million compared to the same period in 2005, due primarily to a \$0.2 million increase in litigation expenses and a \$0.1 million increase in sales force expenses.

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

As of March 31, 2006 and December 31, 2005, we had the following (amounts in thousands):

|                           | March 31,<br>2006 | December 31,<br>2005 |
|---------------------------|-------------------|----------------------|
| Cash and cash equivalents | \$ 31,418         | \$ 66,964            |
| Short-term investments    | 50,925            | 17,900               |
| Working capital           | 96,676            | 91,122               |

Cash provided by (used in) operating, investing and financing activities for the three months ended March 31, 2006 and 2005 is summarized as follows (amounts in thousands):

|                      | Three Months |          |
|----------------------|--------------|----------|
|                      | 2006         | 2005     |
| Cash flows:          |              |          |
| Operating activities | \$ (139)     | \$ 1,510 |
| Investing activities | (35,821)     | (31,931) |
| Financing activities | 414          | 778      |

***Operating Activities***

Net cash used in operating activities for the three months ended March 31, 2006 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.

Net cash provided by operating activities for the three months ended March 31, 2005 primarily resulted from \$7.4 million in distributions from Novogyne, largely offset by changes in working capital due to the timing of certain payments, including those related to insurance, compensation and related liabilities and purchases of inventory.

***Investing Activities***

Net cash used in investing activities for the three months ended March 31, 2006 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.

Net cash used in investing activities for the three months ended March 31, 2005 was primarily attributable to \$30.0 million in net purchases of short-term investments, as well as the purchase of \$1.8 million in fixed assets to expand production capacity for future products. Beginning in the first quarter of 2005, 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 Statement

**Table of Contents**

of Financial Accounting Standards No. 115 Accounting for Certain Investments in Debt and Equity Securities .

***Financing Activities***

Net cash provided by financing activities for the three months ended March 31, 2006 and March 31, 2005 was primarily attributable to \$0.4 million and \$0.8 million, respectively, received in connection with the issuance of common stock from the exercise of stock options.

***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 three months ended March 31, 2006, substantially all of our income before income taxes was comprised of equity in earnings of Novogyne, a non-cash item. Accordingly, our net income may not be reflective of our cash from operations. 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 sales, royalties and license fees associated with transdermal HT 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 million milestone payment from Shire (the global licensee of the product) as a result of the approval of Daytrana, and Noven may also earn additional milestone payments of up to \$75 million depending on the level of Shire's commercial sales of the product. As of March 31, 2006 our inventories include \$5.6 million of Daytrana pre-launch inventories. If any Daytrana inventory is ultimately not commercially saleable (other than as a result of a failure by Noven to comply with its contractual obligations), our agreement with Shire provides that Shire would bear the full cost of any inventory write-off.

Capital expenditures were \$2.4 million for the three months ended March 31, 2006. We expect to continue to invest in capital expenditures during 2006 as we continue to expand our manufacturing and storage facilities for products under development, but we expect such expenditures to be significantly below 2005 levels. We expect to fund these 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.

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 possible direct sales of our own products. We expect that our cash requirements will generally continue to increase, primarily to fund plant and equipment purchases to expand production capacity for new products. If our products under development with Shire, Endo Pharmaceuticals Inc., Procter & Gamble Pharmaceuticals, Inc. and others are successful, these expenditures, which may include the cost of building an additional manufacturing plant, are expected to be significant.

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

## **Table of Contents**

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 well as in Part II Item 1A of this quarterly report on Form 10-Q.

Our cash and short-term investments are available for potential strategic acquisitions of technologies, products or businesses complementary to our business. 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 debt securities. If a material acquisition is completed, our results of operations and financial condition could change materially in future periods.

In addition, although we have not repurchased any of our common stock since 2003, it is possible that a portion of our cash and short-term investments could be used to repurchase Noven common stock under our previously-announced stock repurchase program. Stock repurchases, if any, may be made in the open market, including pursuant to a trading program under Rule 10b5-1 promulgated under the Securities and Exchange Act of 1934.

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, 2005 to our aggregate contractual obligations previously disclosed in our Form 10-K.

### **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:

#### *Stock-Based Compensation*

We currently use the Black-Scholes option pricing model to determine the fair value of stock options and SSARs. The determination of the fair value of stock-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include our expected stock price volatility over the term of the awards, actual and projected employee equity award exercise behaviors, risk-free interest rate, expected forfeiture rates and expected dividends.

We estimate the expected term of options granted by taking the average of the vesting term and the contractual term of the option, as described in SAB 107. We estimate the volatility of common stock by using a combination of both historical and implied volatility based on an equal

## **Table of Contents**

weighting of each as management believes it is the expected volatility that marketplace participants would likely use in determining an exchange price for an option. We base the risk-free interest rate that we use in the option pricing model on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term on the options. We do not anticipate paying any cash dividends in the foreseeable future and therefore use an expected dividend yield of zero in the option pricing model. We are required to estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. We use historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. All share based payment awards are amortized on a straight-line basis over the requisite service periods of the awards, which are generally the vesting periods. If factors change and we employ different assumptions for estimating stock-based compensation expense in future periods or if we decide to use a different valuation model, the future periods may differ significantly from what we have recorded in the current period and could materially affect our operating income, net income and net income per share. The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable, characteristics not present in our option grants. Existing valuation models, including the Black-Scholes and lattice binomial models, may not provide reliable measures of the fair values of our stock-based compensation. Consequently, there is a risk that our estimates of the fair values of our stock-based compensation awards on the grant dates may bear little resemblance to the actual values realized upon the exercise, expiration, early termination or forfeiture of those stock-based payments in the future. Stock options or SSARs may expire worthless or otherwise result in zero intrinsic value as compared to the fair values originally estimated on the grant date and reported in our financial statements. Alternatively, value may be realized from these instruments that is significantly higher than the fair values originally estimated on the grant date and reported in our financial statements. There currently is no market-based mechanism or other practical application to verify the reliability and accuracy of the estimates stemming from these valuation models, nor is there a means to compare and adjust the estimates to actual values.

The guidance in SFAS 123(R) and SAB 107 is relatively new. The application of these principles may be subject to further interpretation and refinement over time. There are significant differences among valuation models, and there is a possibility that we will adopt different valuation models in the future. This may result in a lack of consistency in future periods and materially affect the fair value estimate of stock-based payments. It may also result in a lack of comparability with other companies that use different models, methods and assumptions.

## **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 2006 there will not be any material:

changes in Noven's or Novogyne's accounting or accounting principles (except as indicated below with respect to Noven's method of accounting for equity compensation) or any of the estimates or judgments underlying our critical accounting policies;

regulatory, technological or clinical study developments;

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

changes in our business relationships/collaborations; or

changes in the economy or the health care sector generally.

Financial guidance is inherently uncertain. Accordingly, we cannot assure that we will achieve results consistent with this guidance, and our actual financial results could differ materially





## **Table of Contents**

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 and in Part II Item 1A of this quarterly report on Form 10-Q.

*Equity Compensation Expense.* Effective as of the first quarter of 2006, we adopted SFAS 123(R). As a result, our Statements of Operations in 2006 and subsequent periods will include significant expenses associated with equity compensation that were not included in 2005 and prior periods. Based on the expense associated with equity compensation previously awarded, and our estimate of the expense associated with equity compensation that may be awarded in the course of 2006, we estimate that our total equity compensation expense for full-year 2006 will be approximately \$3.5 million, including approximately \$0.5 million in equity compensation expense recorded in the 2006 first quarter. On our statements of operations, equity compensation expense is allocated among the various expense categories in which the compensation of the equity award recipients has historically been recorded. As a result, certain expense categories (including cost of products sold, research and development, and marketing general and administrative) in future periods may reflect increases associated with the expensing of equity compensation. The specific financial guidance provided below includes expected increases resulting from the expensing of stock-based compensation.

*Potential Daytrana Revenues.* On April 6, 2006, our amended NDA for Daytrana was approved for marketing by the FDA. On April 7, 2006, we received a \$50 million milestone payment from Shire (the global licensee of the product) as a result of the approval, and we may also earn additional milestone payments of up to \$75 million depending on the level of Shire's commercial sales of the product. We expect to defer and recognize approval and sales milestones as license revenues on a quarterly basis through the first quarter of 2013, which is our best estimate of the useful life of the product. We expect to begin recognizing the \$50 million milestone payment as well as the balance of the Shire deferred license revenues (\$4.8 million at March 31, 2006) starting in the second quarter of 2006. We also expect to earn revenues and gross profit on the finished product we manufacture and supply to Shire.

*HT Product Revenues.* Given customer orders and other factors, for full-year 2006 we forecast an aggregate increase in U.S. HT product revenues (led by sales of Vivelle-Dot) to approximately offset an expected aggregate decrease in international product revenues.

*Gross Margin.* Over the past two years, we prepared our facilities and increased staffing for the production of fentanyl, Daytrana and other developmental products. Our results of operations and gross margins for future periods are expected to continue to be adversely affected by these preparations and related continuing overhead expenses unless and until we are able to improve the utilization of these resources through the commercialization of additional products, and no assurance can be given that we will be able to improve the utilization of these resources. In addition, our gross margin in the 2006 first quarter was negatively affected by costs associated with the start-up of commercial production of Daytrana. We expect that our gross margin will begin to improve once Daytrana moves out of the start-up phase and into ongoing commercial production, which we expect will be in the second half of 2006.

*Research and Development.* We expect our research and development expense in 2006 to increase in the 10% range compared to full-year 2005 levels. We are working to formulate certain new transdermal products that, if successfully formulated, may enter human studies during 2006. These studies, if initiated, would be funded by Noven and would cause our research and development expense in 2006 to increase substantially over 2005 levels.

*Marketing, General and Administrative Expense.* We expect Noven's marketing, general and administrative expense in 2006 to increase in the 20% - 25% range over 2005 levels.

**Table of Contents**

*Novogyne.* Based on current prescription trends and other factors, we expect Novogyne's net revenues, net income and profit contribution to Noven will increase for full-year 2006 compared to 2005 levels.

*Effective Tax Rate.* We estimate that our effective tax rate for full-year 2006 will be in the 35%-37% range.

*Capital Expenditures.* We expect our capital expenditures for full-year 2006 to decrease significantly compared to 2005 levels, with 2006 spending weighted more heavily in the first half of the year.

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

Not Applicable.

**Item 4. Controls and Procedures**

Pursuant to Exchange Act Rule 13a-15, as of the end of the quarterly 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 our disclosure controls and procedures. In addition, we reviewed our internal controls, and there have been no significant changes in our internal controls or in other factors that could significantly affect those controls subsequent to the date of the last evaluation. Based upon that evaluation, the 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 us 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 the 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 all of Novogyne's financial, accounting, inventory, distribution, revenues and sales deductions functions are performed by Novartis, our disclosure controls and procedures with respect to Novogyne are necessarily more limited than those we maintain with respect to ourselves. No significant changes were made in our internal controls or in other factors that could significantly affect these controls subsequent to the date of the Chief Executive Officer's and Chief Financial Officer's evaluation.

**Table of Contents**

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 Securities and Exchange Commission'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.

**Table of Contents**

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

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. We do not expect any activity in this case in the near future, as the court has indicated that it intends 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 our CombiPatch® product. The plaintiffs claim compensatory and other damages in an unspecified amount.

Novartis has advised us that Novartis has been named as a defendant in at least 20 additional lawsuits that include approximately 27 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, Vivelle®, and CombiPatch® products. Novogyne has been named as a defendant in one lawsuit in addition to the ones 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. 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. These risk factors may cause our results to differ from the forward-looking statements made in this report or otherwise made by or on our behalf. The risks and uncertainties described in the Form 10-K 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.

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

The following table provides information with respect to our stock repurchases during the first quarter of 2006:

|                                       | Total<br>Number of<br>Shares<br>Purchased<br>as<br>Part of | Average<br>Price<br>Paid<br>Per Share | 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, 2006 to January 31, 2006   |  |                                       |                                  | \$ 23,711,040  |
| February 1, 2006 to February 28, 2006 |  |                                       |                                  | \$ 23,711,040  |
| March 1, 2006 to March 31, 2006       |  |                                       |                                  | \$ 23,711,040  |
| Totals                                |  |                                       |                                  | \$ 23,711,040  |

- (1) In March 2003, we announced a stock repurchase program authorizing the repurchase of up to \$25.0 million of our Common Stock. There is no expiration date specified for this program.

**Item 6. Exhibits**

- 10.1 Form of Stock Appreciation Rights Agreement (Employee)
- 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
- 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

**Table of Contents**

**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 8, 2006

By: /s/ Diane M. Barrett

Diane M. Barrett  
Vice President and  
Chief Financial Officer

38