

NOVEN PHARMACEUTICALS INC

Form 10-Q

May 04, 2005

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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**

**FORM 10-Q**

**Quarterly Report Pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934**

For the quarterly period ended March 31, 2005

Commission file number 0-17254

**NOVEN PHARMACEUTICALS, INC.**

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(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 an accelerated filer (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.

| <u>Class</u>                   | <u>Outstanding at April 29, 2005</u> |
|--------------------------------|--------------------------------------|
| Common stock \$.0001 par value | 29,558,750                           |

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Cautionary Factors: This report contains forward-looking statements. 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 listed, by category, starting on page 31 of this report. For additional information regarding these and other risks and uncertainties, readers should refer to our Annual Report on Form 10-K for the year ended December 31, 2004, as well as other reports filed from time to time with the Securities and Exchange Commission.

Trademark Information: Vivelle, Vivelle-Dot, Estalis, Estradot, Famvir and Menorest are trademarks of Novartis AG or its affiliated companies; CombiPatch is a registered trademark of Vivelle Ventures LLC; Duragesic is a registered trademark of Johnson & Johnson; Intrinsa is a trademark of Procter & Gamble Pharmaceuticals, Inc.

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## PART I. FINANCIAL INFORMATION

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

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

|                                       | Three Months |          |
|---------------------------------------|--------------|----------|
|                                       | 2005         | 2004     |
| Revenues:                             |              |          |
| Product revenues Novogyne:            |              |          |
| Product sales                         | \$ 4,978     | \$ 5,808 |
| Royalties                             | 1,114        | 890      |
| Total product revenues Novogyne       | 6,092        | 6,698    |
| Product revenues third parties        | 4,038        | 2,977    |
| Total product revenues                | 10,130       | 9,675    |
| Contract and license revenues:        |              |          |
| Contract                              | 595          | 519      |
| License                               | 1,011        | 936      |
| Contract and license revenues         | 1,606        | 1,455    |
| Net revenues                          | 11,736       | 11,130   |
| Expenses:                             |              |          |
| Cost of products sold                 | 5,757        | 5,518    |
| Research and development              | 3,010        | 2,255    |
| Marketing, general and administrative | 4,055        | 3,904    |
| Total expenses                        | 12,822       | 11,677   |
| Loss from operations                  | (1,086)      | (547)    |
| Equity in earnings of Novogyne        | 912          | 637      |
| Interest income, net                  | 503          | 156      |

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|   |         |         |
|---|---------|---------|
| Income before income taxes                            | 329     | 246     |
| Provision for income taxes                            | 118     | 88      |
| Net income  | \$ 211  | \$ 158  |
| Basic earnings per share                              | \$ 0.01 | \$ 0.01 |
| Diluted earnings per share                            | \$ 0.01 | \$ 0.01 |
| Weighted average number of common shares outstanding: |         |         |
| Basic   | 23,509  | 23,066  |
| Diluted   | 23,966  | 24,281  |

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

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

|   | March 31,<br>2005 | December 31,<br>2004 |
|---|-------------------|----------------------|
| Assets  |                   |                      |
| Current Assets:   |                   |                      |
| Cash and cash equivalents   | \$ 64,315         | \$ 93,958            |
| Short-term investments  | 29,950            |                      |
| Accounts receivable trade (less allowance for doubtful accounts of \$54 in 2005 and \$64 in 2004) | 2,655             | 5,395                |
| Accounts receivable Novogyne, net   | 6,803             | 10,098               |
| Inventories   | 18,349            | 15,988               |
| Net deferred income tax asset, current portion  | 5,900             | 6,700                |
| Prepaid income taxes  | 9,369             | 9,344                |
| Prepaid and other current assets  | 1,930             | 1,238                |
|   | 139,271           | 142,721              |
| Property, plant and equipment, net  | 24,364            | 22,587               |
| Other Assets:   |                   |                      |
| Investment in Novogyne  | 19,701            | 26,233               |
| Net deferred income tax asset   | 9,051             | 8,239                |
| Patent development costs, net   | 2,222             | 2,174                |
| Deposits and other assets   | 21                | 21                   |
|   | 30,995            | 36,667               |
|   | \$ 194,630        | \$ 201,975           |
| Liabilities and Stockholders Equity   |                   |                      |
| Current Liabilities:  |                   |                      |
| Accounts payable and accrued expenses   | \$ 7,278          | \$ 12,176            |
| Capital lease obligations current portion   | 116               | 114                  |
| Accrued liability Shire   | 14,949            | 10,587               |
| Accrued compensation and related liabilities  | 3,248             | 5,762                |
| Other accrued liabilities   | 2,865             | 3,015                |
| Deferred rent credit  | 52                |                      |
| Deferred contract revenues  | 2,031             | 2,076                |
| Deferred license revenues current portion   | 10,160            | 11,642               |
|   | 40,699            | 45,372               |
| Long-Term Liabilities:  |                   |                      |
| Capital lease obligations   | 81                | 121                  |
| Deferred rent credit  | 473               |                      |
| Deferred license revenues   | 23,234            | 27,443               |

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|   |            |            |
|---|------------|------------|
|   | 64,487     | 72,936     |
| 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 23,549,785 at March 31, 2005 and 23,481,264 at December 31, 2004 | 2          | 2          |
| Additional paid-in capital  | 89,129     | 88,236     |
| Retained earnings   | 41,012     | 40,801     |
|   | 130,143    | 129,039    |
|   | \$ 194,630 | \$ 201,975 |

*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)

|   | 2005     | 2004    |
|---|----------|---------|
| Cash flows from operating activities:   |          |         |
| Net income  | \$ 211   | \$ 158  |
| Adjustments to reconcile net income to net cash flows provided by operating activities: |          |         |
| Depreciation and amortization   | 581      | 588     |
| Amortization of patent costs  | 108      | 91      |
| Amortization of non-competition agreement   |          | 100     |
| Amortization of deferred rent credit  | (8)      |         |
| Income tax benefits on exercise of stock options  | 77       | 2,761   |
| Deferred income tax benefit   | (12)     | (2,110) |
| Recognition of deferred license revenues  | (1,011)  | (936)   |
| Equity in earnings of Novogyne  | (912)    | (637)   |
| Distributions from Novogyne   | 7,444    | 6,044   |
| Changes in operating assets and liabilities:  |          |         |
| Decrease in accounts receivable trade, net  | 2,740    | 1,417   |
| Decrease in accounts receivable Novogyne, net   | 3,295    | 1,265   |
| Increase in inventories   | (2,361)  | (89)    |
| Increase in prepaid income taxes  | (25)     | (197)   |
| Increase in prepaid and other current assets  | (692)    | (504)   |
| Increase in deposits and other assets   |          | (4)     |
| (Decrease) increase in accounts payable   | (4,898)  | 1,170   |
| Increase in accrued liability - Shire   | 4,362    |         |
| Decrease in accrued compensation and related liabilities                                | (2,514)  | (1,233) |
| Decrease in other accrued liabilities   | (150)    | (1,590) |
| (Decrease) increase in deferred contract revenue  | (45)     | 1,381   |
| Increase in deferred license revenue  |          | 6,500   |
| Direct expenses incurred in pursuit of methylphenidate patch regulatory approval        | (4,680)  | (147)   |
| Cash flows provided by operating activities   | 1,510    | 14,028  |
| Cash flows from investing activities:   |          |         |
| Purchases of property, plant and equipment, net   | (1,825)  | (579)   |
| Payments for patent development costs, net  | (156)    | (133)   |
| Purchases of short-term investments   | (95,100) |         |
| Proceeds from sale of short-term investments  | 65,150   |         |
| Cash flows used in investing activities   | (31,931) | (712)   |
| Cash flows from financing activities:   |          |         |
| Issuance of common stock from exercise of stock options                                 | 816      | 5,245   |
| Repayments of capital leases and notes payable  | (38)     |         |



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|  |           |            |
|--|-----------|------------|
| Cash flows provided by financing activities          | 778       | 5,245      |
| Net (decrease) increase in cash and cash equivalents | (29,643)  | 18,561     |
| Cash and cash equivalents, beginning of period       | 93,958    | 83,381     |
| Cash and cash equivalents, end of period             | \$ 64,315 | \$ 101,942 |

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

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**NOVEN PHARMACEUTICALS, INC.**

Notes to Unaudited Condensed Financial Statements

1. DESCRIPTION OF BUSINESS:

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

Noven and Novartis Pharmaceuticals Corporation ( Novartis ) entered into a joint venture, Vivelle Ventures LLC (d/b/a Novogyne Pharmaceuticals) ( Novogyne ), effective May 1, 1998, to market and sell women's prescription healthcare products in the United States and Canada. These products include Noven's transdermal estrogen delivery systems marketed under the brand names Vivelle®, Vivelle-Dot™ and CombiPatch®. Noven accounts for its 49% investment in Novogyne under the equity method and reports its share of Novogyne's earnings as Equity in earnings of Novogyne on its 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, 2005, and the results of its operations and its cash flows for the three months ended March 31, 2005 and 2004. Noven's business is subject to numerous risks and uncertainties including, but not limited to, those set forth in Noven's Annual Report on Form 10-K for the year ended December 31, 2004 ( Form 10-K ), and in Part I Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations of this quarterly report on Form 10-Q. Accordingly, the results of operations and cash flows for the three months ended March 31, 2005 and 2004 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 2005 or for periods thereafter.

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

3. 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, 2005, and December 31, 2004, 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. Beginning in the first quarter of 2005, Noven invested a portion of its cash

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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, 2005, the cost of all short-term investments approximated fair value. Therefore, no unrealized gains and losses have been recognized for the quarter ended March 31, 2005. Realized gains and losses and interest and dividends are included in interest income or interest expense, as appropriate.

**4. RECENT ACCOUNTING PRONOUNCEMENTS:**

In November 2004, the Financial Accounting Standards Board ( FASB ) issued Statement of Financial Accounting Standard No. 151 Inventory Costs an amendment of ARB No. 43, Chapter 4 ( SFAS 151 ), to clarify the accounting for abnormal amounts of idle facility expense, freight or wasted material (spoilage). SFAS 151 requires that those items be recognized as current-period charges regardless of whether they meet the so abnormal criterion outlined in Accounting Research Bulletin 43, Chapter 4, Inventory Pricing . SFAS 151 also introduces the concept of normal capacity and requires the allocation of fixed production overheads to inventory based on the normal capacity of the production facilities. Unallocated overheads must be recognized as an expense in the period in which they are incurred. This statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Noven is currently assessing SFAS 151 and Noven is unable to estimate the impact it will have on its results of operations and financial condition.

In December 2004, the FASB issued SFAS No. 123(R) Share-Based Payment (Revised 2004) that will require compensation costs related to share-based payment transactions to be recognized in the financial statements. With limited exceptions, the amount of compensation cost will be measured based on the grant-date fair value of the equity or liability instruments issued. Compensation cost will be recognized over the period that an employee provides service in exchange for the award, which is generally over the vesting period. SFAS 123(R) replaces SFAS 123, Accounting for Stock-Based Compensation , and supersedes APB 25, Accounting for Stock Issued to Employees . For public companies such as Noven, the statement is effective as of the beginning of the first annual reporting period that begins after June 15, 2005 and accordingly, Noven anticipates adopting this statement in the first quarter of 2006.

**5. RECLASSIFICATIONS:**

Certain reclassifications have been made to prior period financial statements to conform to the current year s presentation.

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## 6. INVENTORIES:

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

|                 | March 31,<br>2005 | December<br>31,<br>2004 |
|-----------------|-------------------|-------------------------|
| Finished goods  | \$ 859            | \$ 610                  |
| Work in process | 8,082             | 6,522                   |
| Raw materials   | 9,408             | 8,856                   |
| <br>            |                   |                         |
| Total           | \$ 18,349         | \$ 15,988               |

Included in the amounts identified above as of March 31, 2005 and December 31, 2004, were \$12.5 million and \$10.8 million, respectively, in inventories to manufacture launch supplies of Noven's generic fentanyl patch for which an Abbreviated New Drug Application has been filed and is pending before the U.S. Food and Drug Administration ( FDA ). See Note 9 Contract and License Agreements Endo Collaboration and Note 12 Fentanyl Inventories. The remaining inventories as of March 31, 2005 and December 31, 2004 relate to Noven's marketed products.

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 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:

In accordance with the provisions of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation ( SFAS 123 ), as amended by Statement of Financial Accounting Standards No. 148, Accounting for Stock-Based Compensation -Transition and Disclosure ( SFAS 148 ), Noven may elect 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, or adopt the fair value method of accounting prescribed by SFAS 123. Noven has elected to continue to account for its stock plans using APB 25, and therefore no stock-based employee compensation cost is reflected in net income, 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.

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The following table illustrates the effect on net income and earnings per share for the three months ended March 31, 2005 and 2004 if Noven had applied the fair value recognition provisions of SFAS 123, as amended by SFAS 148 (in thousands, except per share amounts):

|   | Three Months |           |
|---|--------------|-----------|
|   | 2005         | 2004      |
| Net income:   |              |           |
| As reported   | \$ 211       | \$ 158    |
| Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects | (1,747)      | (740)     |
| Pro forma   | \$ (1,536)   | \$ (582)  |
| Basic earnings per share:   |              |           |
| As reported   | \$ 0.01      | \$ 0.01   |
| Pro forma   | \$ (0.07)    | \$ (0.03) |
| Diluted earnings per share:   |              |           |
| As reported   | \$ 0.01      | \$ 0.01   |
| Pro forma   | \$ (0.06)    | \$ (0.02) |

SFAS 123 requires the use of option valuation models that require the input of highly subjective assumptions, including expected stock price volatility. Because Noven's stock options have characteristics significantly different from traded options and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable measure of the fair value of Noven's employee stock options.

The effect of applying the fair value method of accounting for stock options on reported net income and earnings per share for the three months ended March 31, 2005 and 2004, respectively, may not be representative of the effects for future periods.

As noted in Note 4 Recent Accounting Pronouncements, above, in December 2004, the FASB issued SFAS 123(R) that will require compensation costs related to share-based payment transactions to be recognized in the financial statements. Noven will be required to adopt the standards of stock option expensing under SFAS 123(R) beginning with its first fiscal quarter of 2006. On April 5, 2005, the Compensation and Stock Option Committee of the Board of Directors of Noven approved the acceleration of vesting of unvested out-of-the-money stock options under the Noven 1999 Long-Term Incentive Plan. The affected options are those with exercise prices greater than \$17.28 per share, which was the closing price of Noven's common stock on April 7, 2005 (the effective date of the modification to accelerate vesting of the out-of-the-money stock options). As a result of this action, options to purchase approximately 932,000 shares of Noven's common stock became immediately exercisable, including options held by Noven's executive officers to purchase approximately 401,000 shares. The purpose of the accelerated vesting is to eliminate the future compensation expense that Noven would otherwise recognize in its Statement of Operations with respect to these accelerated options upon the adoption of SFAS 123(R). As a result of acceleration of vesting of unvested out-of-the-money stock options in April 2005, Noven expects a substantial decrease in pro forma net income and pro forma earnings per share as presented in this footnote for the three months ended June 30, 2005.



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**8. CASH FLOW INFORMATION:**

Cash payments for income taxes were not material for the three months ended March 31, 2005 and were \$2.9 million for the three months ended March 31, 2004. Cash payments for interest were not material for the three months ended March 31, 2005 and 2004.

*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 leasehold improvements. See Note 12 Commitments and Contingencies Facility Lease.

During the three months ended March 31, 2004, Noven entered into a capital lease obligation of \$0.3 million for new equipment.

**9. CONTRACT AND LICENSE AGREEMENTS:**

*Endo Collaboration*

In July 2003, Noven submitted an Abbreviated New Drug Application ( ANDA ) to the FDA seeking approval to market a generic version of Duragesic® (fentanyl transdermal system). Duragesic® is a transdermal patch containing fentanyl, an opioid analgesic and a Schedule II controlled substance, indicated for the management of chronic pain. Noven's ANDA for this product was accepted for filing as of October 1, 2003 and is under review at the FDA. Johnson & Johnson's patent and exclusivity status for Duragesic® expired in January 2005, after which the FDA approved the fentanyl transdermal system ANDA filed by Mylan Laboratories. Also in January 2005, the FDA denied several citizen petitions intended to prevent or delay the approval of certain generic versions of Duragesic®.

In the first quarter of 2004, Noven entered into an exclusive license agreement with Endo Pharmaceuticals Inc. ( Endo ) pursuant to which Noven granted Endo the right to market Noven's fentanyl patch in the United States and Canada. Noven retained all rights to the fentanyl patch outside of the United States and Canada, and Noven is exploring strategies to commercialize the product in other territories. In April 2005, Endo returned the Canadian marketing rights to Noven. Noven received an up-front payment of \$8.0 million from Endo upon signing the agreement. The agreement provides that, upon Endo's first commercial sale of the fentanyl patch, Noven is entitled to receive an additional milestone payment ranging from \$5.0 million to \$10.0 million, depending on the timing of launch and the number of generic competitors in the market. Under a long-term supply agreement entered into between the parties, Noven will manufacture and supply the product at its cost and will share in Endo's profit generated from U.S. product sales.

Under the terms of the transaction, Noven remains responsible for securing final regulatory approval for its fentanyl patch. The agreement provides that Endo may terminate the agreement, and its obligation to launch the product, if launch is delayed either (i) because of a delayed FDA approval or (ii) Noven fails to supply Endo with its launch requirements after approval, and in either case if as a result of the delay there is additional generic competition beyond that expected by the parties at the time of execution of the agreement. The earliest that this right could be triggered under the agreement is 120 days after the launch of the next generic fentanyl transdermal product. In the event of such a termination, rights to the fentanyl patch would return to Noven.

In addition to the fentanyl license, Noven has established collaboration with Endo to seek to identify and develop new transdermal therapies. Of the \$8.0 million received at signing, \$1.5 million has been allocated to



fund feasibility studies that seek to determine whether certain

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compounds identified by the parties can be delivered through Noven's transdermal patch technology. Endo is expected to fund and manage clinical development of those compounds proceeding into clinical trials.

Of the \$8.0 million received at signing, \$6.5 million will be recognized as license revenues as earned over a 10-year period, which is the estimated product life cycle of the fentanyl patch. The remaining \$1.5 million is being recognized as contract revenues over the course of feasibility development of any additional patches developed under the Noven/Endo collaboration.

*Shire*

In the first quarter of 2003, Noven signed an agreement to license the exclusive global rights to market its methylphenidate patch for Attention Deficit Hyperactivity Disorder (ADHD) to Shire Pharmaceuticals Group plc (Shire) for payments of up to \$150 million and ongoing manufacturing revenues. Consideration for the transaction is as follows: (i) \$25 million was paid upon closing of the transaction in April 2003; (ii) \$50 million is payable upon receipt of final marketing approval for the methylphenidate patch by the FDA; and (iii) three installments of \$25 million each are payable upon Shire's achievement of \$25 million, \$50 million and \$75 million in annual net sales of the methylphenidate patch, respectively. Shire's annual net sales will be measured quarterly on a trailing 12-month basis, with each milestone payment due 45 days after the end of the first quarter during which trailing 12-month sales exceed the applicable threshold. Shire has agreed that it will not sell any other product containing methylphenidate as an active ingredient until the earlier of (i) five years from the closing date or (ii) payment of all of the sales milestones. On the closing date, Noven entered into a long-term supply agreement under which it expects to manufacture and supply its methylphenidate patch to Shire. The agreement gives Shire the right to qualify a second manufacturing source and purchase a portion of its requirements from the second source. If Shire were to exercise this right, Noven's manufacturing revenues from sales of its methylphenidate patch would be adversely affected. Pursuant to the agreement, under certain circumstances Shire has the right to require Noven to repurchase the product rights for \$5 million.

In April 2003, Noven received a not approvable letter from the FDA relating to its methylphenidate patch New Drug Application (NDA). In April 2005, Noven and Shire announced preliminary results from additional clinical trials conducted in 2004 and 2005 that were intended to address clinical issues raised in the not approvable letter. Noven and Shire plan to include these trial results in an amendment to the NDA that the parties expect to file during 2005. The amendment is expected to receive a six-month review by the FDA. No assurance can be given that the data obtained from the additional studies will in fact address the FDA's issues or that the FDA may not raise additional issues following any submission of an amendment to the NDA for Noven's methylphenidate patch.

Noven's direct costs incurred in pursuit of approval are being deferred and offset against a portion of the \$25.0 million deferred revenue previously received from Shire. Such expenses did not impact Noven's research and development expenses in 2004 or the quarter ended March 31, 2005, although the direct expenses incurred in pursuit of FDA approval reduce Noven's cash position and will have the effect of reducing the amount of deferred revenues that Noven may recognize in future periods. As of March 31, 2005, the amount of available deferred revenues was \$1.0 million (which excludes the \$5.0 million of deferred revenues related to Shire's repurchase right) and Noven does not expect its prospective cost in pursuit of approval to exceed this amount.

Under Noven's agreements with Shire, Shire has certain rights to terminate the license of Noven's methylphenidate patch, including if Shire determines that submission of the results of the additional clinical studies to the FDA would not result in approval of a commercially-viable

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product. If Shire were to terminate on this basis, all product rights would revert to Noven, and Noven would retain the \$25.0 million previously paid by Shire. Shire also has the right to require Noven to repurchase the product rights to the methylphenidate patch for \$5.0 million under certain circumstances.

In June 2004, Noven entered into an agreement with Shire for the development of a transdermal amphetamine patch for ADHD. The agreement provides for the payment to Noven of up to \$5.0 million if certain development milestones are achieved. The product is in pre-clinical development and Noven is recognizing payments received as contract revenue as the work is performed.

*P&G Pharmaceuticals Collaboration*

In April 2003, Noven established a collaboration with Procter & Gamble Pharmaceuticals, Inc. ( P&G Pharmaceuticals ) for the development of new prescription patches. The products under development explore follow-on product opportunities for Intrinsa<sup>®</sup>, P&G Pharmaceuticals in-licensed investigational transdermal testosterone patch designed to help restore desire in menopausal women who have Hypoactive Sexual Desire Disorder. P&G Pharmaceuticals withdrew its NDA for Intrinsa<sup>®</sup> in December 2004 based on feedback from an FDA Advisory Committee and has stated its intention to file a new NDA with additional clinical data. During 2004, Noven earned \$4.4 million under the P&G Pharmaceuticals collaboration. No development milestones under this collaboration were earned for the three months ended March 31, 2005.

## 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 2005 and 2004 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, 2005 and 2004, Noven had the following transactions with Novogyne (in thousands):

|                     | Three Months |          |
|---------------------|--------------|----------|
|                     | 2005         | 2004     |
| Revenues:           |              |          |
| Product sales       | \$ 4,978     | \$ 5,808 |
| Royalties           | 1,114        | 890      |
|                     | \$ 6,092     | \$ 6,698 |
| Reimbursed expenses | \$ 7,242     | \$ 6,289 |

As of March 31, 2005 and December 31, 2004, Noven had amounts due from Novogyne of \$6.8 million and \$10.1 million, respectively, for products sold to, and marketing expenses reimbursable by, Novogyne.

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The unaudited condensed Statements of Operations of Novogyne for the three months ended March 31, 2005 and 2004 are as follows (in thousands):

|  | Three Months |           |
|--|--------------|-----------|
|  | 2005         | 2004      |
| Gross revenues                               | \$ 27,334    | \$ 25,134 |
| Sales allowances                             | 3,395        | 2,772     |
| Sales return allowances                      | 1,266        | 1,009     |
| Sales allowances and returns                 | 4,661        | 3,781     |
| Net revenues                                 | 22,673       | 21,353    |
| Cost of sales                                | 4,555        | 4,835     |
| Selling, general and administrative expenses | 8,670        | 7,625     |
| Amortization of intangible assets            | 1,545        | 1,545     |
| Income from operations                       | 7,903        | 7,348     |
| Interest income                              | 93           | 40        |
| Net income                                   | \$ 7,996     | \$ 7,388  |
| Noven's equity in earnings of Novogyne       | \$ 912       | \$ 637    |

The activity in the Investment in Novogyne account for the three months ended March 31, 2005 is as follows (in thousands):

|   |           |
|---|-----------|
| Investment in Novogyne, beginning of period | \$ 26,233 |
| Equity in earnings of Novogyne              | 912       |
| Cash distributions from Novogyne            | (7,444)   |
| Investment in Novogyne, end of period       | \$ 19,701 |

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, 2005 and 2004, Noven received cash distributions of \$7.4 million and \$6.0 million from Novogyne, respectively. These amounts were recorded as reductions in the investment in Novogyne when deemed 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, 2005 and 2004.

12. COMMITMENTS AND CONTINGENCIES:

*HT Studies*

In July 2002, the National Institutes of Health ( NIH ) released data from its Women ' s Health Initiative ( WHI ) study on the risks and benefits associated with the use of oral combination hormone therapy ( HT ). The study revealed an increase in the risk of developing breast cancer and increased risks of stroke, heart attack and blood clots. The WHI study was

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followed by the publication during 2002 – 2004 of the results of a number of other studies that found that the overall health risks from the use of certain HT products exceed the benefits from the use of those products. In the first quarter of 2004, the NIH discontinued the estrogen-only arm of the WHI study because results were showing an increased risk of stroke and because, after nearly seven years of follow-up, the NIH determined that it had sufficient data to assess the risks and benefits of estrogen use in the trial. Researchers continue to analyze data from both arms of the WHI study and other studies, and other publications may be forthcoming.

These studies and others have caused the HT market, and the market for Noven's products, to significantly decline. 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 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.

As a result of the 2003 recall of Vivelle-Dot patches, Noven initiated a series of special stability protocols to monitor commercial lots in distribution as well as future production of Vivelle-Dot. As previously disclosed, 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 specifications or were associated with lots that did not meet specifications. Because these lots were manufactured in 2003, Noven estimates that an immaterial number of patches from these lots currently remain in distribution. The effect of these recalled lots on Noven's and Novogyne's results of operations was immaterial.

Based on testing and analysis to date, Noven believes that the probable cause of the Vivelle-Dot stability failures remains related to certain patch backing material that Noven obtained from a raw material supplier. Noven and Novartis have established a joint task force to identify the definitive root cause of the Vivelle-Dot stability failures. If the root cause determination or additional testing (including Noven's routine stability testing) indicates that the production issue affects more product than Noven's current testing and analysis suggests, additional recalls may be required. The final field alert for the recall of the additional lots of Vivelle-Dot was submitted to the FDA in March 2005. Noven cannot predict what action, if any, the FDA may take with respect to the recalls of Vivelle-Dot. Although Noven and Novartis are working together in assessing the Vivelle-Dot production issues, the decision to recall product resides with Novartis as the holder of the Vivelle-Dot NDA and is not within Noven's control. Among others risks, the recent, or any additional, recalls of Vivelle-Dot could result in a decision to: recall all or a significant portion of the product in distribution until a definitive root cause has been identified and any required corrective action has been completed; cease production or shipment of new product until a definitive root cause has been identified and any required corrective action has been completed; or reduce the shelf-life of Vivelle-Dot. Vivelle-Dot represented over 80% of Novogyne's total prescriptions in the first quarter of 2005

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and Noven's and Novogyne's results of operations and prospects would be materially and adversely affected in the event these or similar actions were to occur.

As previously disclosed by Noven, in late 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. Novartis has recalled the affected lot. The 2004 recall of this lot did not have a material impact on Noven's and Novogyne's financial statements. Noven continues to manufacture and ship CombiPatch® to Novogyne. Noven continues to maintain stability testing for CombiPatch®, and is undertaking additional testing related to the October 2004 stability failure. If Noven's testing indicates that additional CombiPatch® lots do not meet specifications or are affected by the issue impacting the lot recalled, Novartis could initiate additional recalls. Although Noven and Novartis are working together to assess production issues, the decision to recall product resides with Novartis as the holder of the CombiPatch® NDA and is not within Noven's control. If Noven's estimates concerning product returns associated with the recall are incorrect, or if Noven's continued testing indicates that more than one lot is 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.

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 Noven's 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'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*

On March 15, 2005, the United States District Court for the Southern District of Florida issued an order dismissing without prejudice the lawsuit filed against Noven and certain individual defendants styled In re: Noven Pharmaceuticals, Inc. Securities Litigation. The notice of voluntary dismissal (attached to the order of dismissal) indicated that the lead plaintiffs and their counsel, after further investigation, concluded that the complaint should be voluntarily dismissed. Noven agreed to the dismissal, with each party bearing its own costs.

In July 2004, an individual plaintiff and her husband filed a complaint in Superior Court of New Jersey Law Division, Atlantic County, against Noven, Novartis, Wyeth Pharmaceuticals, Inc. and others alleging liability in connection with personal injury claims allegedly arising from the use of HT products, including CombiPatch®, which is manufactured by Noven and distributed by Novogyne. The plaintiffs claim compensatory, punitive and other damages in an unspecified amount. In April 2005, the plaintiff agreed to substitute Aventis Pharmaceuticals, Inc. for Noven and Novartis in this case and to dismiss Noven and Novartis without prejudice for





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a period of six months and with prejudice thereafter. In addition, Novartis has advised Noven that Novartis has been named as a defendant in at least 13 additional lawsuits that include approximately 23 plaintiffs that allege liability in connection with personal injury claims allegedly arising from the use of HT patches distributed and sold by Novartis and Novogyne, including Noven's Vivelle®, Vivelle-Dot and CombiPatch® products. To date, Noven has been named in one lawsuit and, to Noven's knowledge, Novogyne has not been named in any. Novartis has indicated that it will seek indemnification from Noven and Novogyne to the extent permitted by the agreements between and among Novartis, Novogyne and Noven. Novogyne's accrual for expected legal fees and settlements of these lawsuits was \$2.4 million as of March 31, 2005, for which there was a related insurance receivable of \$1.4 million. Novogyne recognized a \$0.1 million expense for the three months ended March 31, 2005, based on the net increase during such three month period in this accrual less the insurance receivable. This accrual represents Novartis management's best estimate as of March 31, 2005. The ultimate outcome of these product liability lawsuits cannot be predicted.

Noven is involved in certain litigation and claims incidental to its business. Noven does not believe, based on currently available information, that these matters will have a material adverse effect on the accompanying financial statements.

### *Contract and License Agreements*

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

### *Internal Revenue Service Audit*

Noven, from time to time, is subject to audits by taxing authorities, covering a wide range of matters and the Internal Revenue Service is currently auditing Noven's federal income tax returns for certain open years. Such matters are subject to various uncertainties, and it is possible that some of these matters may be resolved unfavorably to Noven. Since 2001, Noven has established \$1.1 million in accruals for pending matters that it believes are probable and reasonably estimable. There was no change in the amount for the periods ended March 31, 2005 and 2004. The outcome of the pending matters cannot ultimately be predicted.

### *Fentanyl Inventories*

As of March 31, 2005, Noven had incurred \$12.5 million for the cost of producing pre-launch inventories for its fentanyl patch. If approval of the fentanyl patch is not ultimately received or is delayed, Noven's agreement with Endo provides that the parties will share the cost of manufacturing product that cannot be sold by Endo in accordance with an agreed-upon formula. In such a case, Noven may be unable to recover its share of such costs, which could be up to approximately \$7.2 million.

### *Facility Lease*

In February 2005, Noven entered into an Industrial Long-Term Lease (the "Lease") for approximately 73,000 square feet of newly constructed space located in close proximity to its manufacturing facility in Miami, Florida. Noven intends to use the leased space for the storage and, as needed, the manufacture of new product. The lease term is 10 years, which may be extended for up to an additional 21 years pursuant to four renewal options of five years each and a one-time option to renew for one year. The annual base rent is \$6.40 per square foot. Noven will also pay a monthly management fee equal to 1.5% of the base rent. The rent for the first year is discounted to \$3.20 per square foot. The base rent is subject to annual increases of 3%



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during the initial 10-year term. After the initial term, the rent will be 95 percent of the fair market rate of the leased space as determined under the Lease. Noven is in the process of improving the leased space in order to prepare it for its intended use. The landlord will be responsible for leasehold improvements paid to the general contractor improving the leased space, up to approximately \$0.9 million. Any amounts paid to the general contractor in excess of this amount and any other leasehold improvements will be the responsibility of Noven. For accounting purposes, Noven is amortizing the expected rental payments on a straight-line basis over the initial 10-year term of the Lease. The renewal terms have not been included for amortization purposes because Noven cannot reasonably estimate the rental payments after the initial term and Noven cannot assure that it will renew the Lease after the initial term. Any leasehold improvements will be recorded at cost and will be amortized on a straight-line basis over the shorter of the estimated useful life of the improvements or the remaining initial 10-year lease term. Leasehold improvements to the leased space paid by the landlord will be recorded by Noven as a deferred rent credit and will be amortized on a straight-line basis when incurred over the remaining initial 10-year lease term as a reduction of rent expense. Rent expense related to this lease was \$0.1 million for the three months ended March 31, 2005. Leasehold improvements paid by the landlord and recorded as a deferred rent credit were approximately \$0.5 million for the three months ended March 31, 2005.

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**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

The following section addresses material aspects of Noven's financial condition at March 31, 2005, and the results of operations for the three months ended March 31, 2005 and 2004. The contents of this section include:

An overview of Noven and our Novogyne joint venture;

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

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

A discussion of recently issued accounting standards and the application of our critical accounting policies;

An outlook that includes our current financial guidance for 2005; and

A review of cautionary factors that could have a material adverse effect on our business, financial condition and results of operations.

This discussion should be read in conjunction with Noven's financial statements for the three months ended March 31, 2005 and 2004 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 Annual Report on Form 10-K for the year ended December 31, 2004.

**Overview**

We develop and manufacture advanced transdermal patches and presently derive substantially all of our revenues from sales of transdermal patches for use in menopausal hormone therapy. 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 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 AG (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 \$0.9 million and \$0.6 million for the three months ended March 31, 2005 and 2004, respectively. The income we recognize from Novogyne is a non-cash item. Any cash we receive from Novogyne is in the form of cash



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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, 2005 and 2004, we received \$7.4 million and \$6.0 million, respectively, in distributions from Novogyne, which accounted for a substantial portion of our net cash flows provided 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 could 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 2005, total prescriptions dispensed in the HT market in the United States decreased by 51%. For the same period, aggregate prescriptions for Noven's United States HT products decreased 14%. The estrogen segment of the HT market in the United States declined 47%, while our Vivelle® line of products decreased 4%. Vivelle-Dot, which represented 83% of our total United States prescriptions in the first quarter of 2005, increased 19% from the second quarter of 2002 to the first quarter of 2005. 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 12% of our total United States prescriptions in the first quarter of 2005) declined 51% from the second quarter of 2002 to the first quarter of 2005, while prescriptions for the total United States market for fixed combination hormone therapy products decreased 70%. 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 these marketing rights, which would adversely affect the results of operations of both Noven and Novogyne.

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

### *Stock Options*

In April 2005, the Compensation and Stock Option Committee of the Board of Directors of Noven approved the acceleration of vesting of unvested out-of-the-money stock options under the Noven 1999 Long-Term Incentive Plan. The affected options are those with exercise prices greater than \$17.28 per share, which was the closing price of Noven's common stock on April 7, 2005 (the effective date of the modification to accelerate vesting of the out-of-the-money stock options). As a result of this action, options to purchase approximately 932,000 shares of Noven's common stock became immediately exercisable, including options held by Noven's executive officers to purchase approximately 401,000 shares. The accelerated options represent approximately 26% of Noven's total outstanding options on the date of the transaction. The exercise prices of the accelerated options range from \$17.88 to \$41.81 per share.

The purpose of the accelerated vesting is to eliminate the future compensation expense that Noven would otherwise recognize in its Statement of Operations with respect to these accelerated options upon the adoption of Financial Accounting Standards Board Statement of Financial Accounting Standards No. 123 (Revised 2004), Share-Based Payment (SFAS 123R). SFAS 123R is effective from the first annual reporting period that begins after June 15, 2005, and will require that



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the compensation expense associated with stock options be recognized in Noven's Statement of Operations, rather than as historically presented as a footnote disclosure in Noven's financial statements. We anticipate adopting this statement in the first quarter of 2006.

*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 a result of the 2003 recall of Vivelle-Dot patches, Noven initiated a series of special stability protocols to monitor commercial lots in distribution as well as future production of Vivelle-Dot. As previously disclosed, in the first quarter of 2005, a total of ten lots of Vivelle-Dot manufactured in 2003 were identified for recall when one of our stability protocols revealed that these lots did not meet required specifications or were associated with lots that did not meet specifications. Because these lots were manufactured in 2003, we estimate that an immaterial number of patches from these lots currently remain in distribution. The effect of these recalled lots on Noven's and Novogyne's results of operations was immaterial.

Based on testing and analysis to date, Noven believes that the probable cause of the Vivelle-Dot stability failures remains related to certain patch backing material that Noven obtained from a raw material supplier. Noven and Novartis have established a joint task force to identify the definitive root cause of the Vivelle-Dot stability failures. If the root cause determination or additional testing (including Noven's routine stability testing) indicates that the production issue affects more product than Noven's current testing and analysis suggests, additional recalls may be required. The final field alert for the recall of the additional lots of Vivelle-Dot was submitted to the FDA in March 2005. We cannot predict what action, if any, the FDA may take with respect to the recalls of Vivelle-Dot. Although Noven and Novartis are working together in assessing the Vivelle-Dot production issues, the decision to recall product resides with Novartis as the holder of the Vivelle-Dot NDA and is not within our control. Among others risks, the recent, or any additional, recalls of Vivelle-Dot could result in a decision to: recall all or a significant portion of the product in distribution until a definitive root cause has been identified and any required corrective action has been completed; cease production or shipment of new product until a definitive root cause has been identified and any required corrective action has been completed; or reduce the shelf-life of Vivelle-Dot. Vivelle-Dot represented over 80% of Novogyne's total prescriptions in the first quarter of 2005 and Noven's and Novogyne's results of operations and prospects would be materially and adversely affected in the event these or similar actions were to occur.

As previously disclosed by Noven, in late October 2004, our 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. Novartis has recalled the affected lot. The 2004 recall of this lot did not have a material impact on Noven's and Novogyne's financial statements. We continue to manufacture and ship CombiPatch® to Novogyne. We continue to maintain our stability testing for CombiPatch®, and are undertaking additional testing related to the October 2004 stability failure. If our testing indicates that additional CombiPatch® lots do not meet specifications or are affected by the issue impacting the lot recalled, Novartis could initiate additional recalls. Although Noven and Novartis are working together to assess production issues, the decision to recall product resides with Novartis as the holder of the CombiPatch® NDA and is not within our control. If our estimates concerning product returns associated with the recall are incorrect, or if our continued testing indicates that more than one lot is 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.



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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.

*Shire*

We are developing a transdermal methylphenidate patch for ADHD. Global rights to the developmental product were licensed to Shire in the first quarter of 2003 for payments up to \$150.0 million, including \$25.0 million paid at closing of the license transaction.

In April 2005, Noven and Shire announced preliminary results from additional clinical trials conducted in 2004 and 2005 that were intended to address clinical issues raised in the not approvable letter that we received from the FDA in April 2003. Noven and Shire plan to include these trial results in an amendment to the NDA that the parties expect to file during 2005. The amendment is expected to receive a six-month review by the FDA. No assurance can be given that the data obtained from the additional studies will in fact address the FDA's issues or that the FDA may not raise additional issues following any submission of an amendment to the NDA for our methylphenidate patch, including issues raised by a 2005 study by researchers at the M.D. Anderson Cancer Center that found adverse chromosomal effects on 12 children treated with oral methylphenidate.

Noven's direct costs incurred in pursuit of approval are being deferred and offset against a portion of the \$25.0 million deferred revenue previously received from Shire. Such expenses did not impact Noven's research and development expenses in 2004 or the quarter ended March 31, 2005, although the direct expenses incurred in pursuit of FDA approval reduce our cash position and will have the effect of reducing the amount of deferred revenues that Noven may recognize in future periods. As of March 31, 2005, the amount of available deferred revenues was \$1.0 million (which excludes the \$5.0 million of deferred revenues related to Shire's repurchase right) and Noven does not expect its prospective cost in pursuit of approval to exceed this amount.

**Table of Contents****Results of Operations****Three months ended March 31, 2005 compared to the three months ended March 31, 2004*****Revenues***

Total revenues for the three months ended March 31, 2005 and 2004 are summarized as follows (dollar amounts in thousands):

|                                 | Three Months |           | %      |
|---------------------------------|--------------|-----------|--------|
|                                 | 2005         | 2004      | Change |
| Product revenues Novogyne:      |              |           |        |
| Product sales                   | \$ 4,978     | \$ 5,808  | (14%)  |
| Royalties                       | 1,114        | 890       | 25%    |
|                                 | 6,092        | 6,698     | (9%)   |
| Product revenues third parties: |              |           |        |
| Product sales                   | 3,965        | 2,838     | 40%    |
| Royalties                       | 73           | 139       | (47%)  |
|                                 | 4,038        | 2,977     | 36%    |
| Total product revenues          | 10,130       | 9,675     | 5%     |
| Contract and license revenues:  |              |           |        |
| Contract                        | 595          | 519       | 15%    |
| License                         | 1,011        | 936       | 8%     |
|                                 | 1,606        | 1,455     | 10%    |
| Net revenues                    | \$ 11,736    | \$ 11,130 | 5%     |

**Net Revenues**

As described in more detail below, the increase in net revenues for the three months ended March 31, 2005 as compared to the same period in 2004 was primarily attributable to receipt of a \$1.2 million price adjustment payment related to international product sales, partially offset by an aggregate decline in sales to Novogyne. In addition, royalties increased for the three months ended March 31, 2005 as compared to the same period in 2004 as a result of Novogyne's higher sales of Vivelle® and Vivelle-Dot.

Product Revenues - Novogyne

Product revenues - Novogyne consists of our sales of Vivelle®, Vivelle-Dot™/Estradot and CombiPatch® 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® and Vivelle-Dot™.

The \$0.6 million decrease in product revenues from Novogyne for the three months ended March 31, 2005 as compared to the same period in the prior year primarily related to a \$0.3 million and \$0.5 million reduction in unit sales of Vivelle-Dot™ and Estradot, respectively, partially offset by a \$0.2 million increase in royalties. The decline in sales of Vivelle-Dot™ to Novogyne was primarily due to the timing of Vivelle-Dot™ sample orders. In addition, sales to Novogyne in the

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first quarter of 2004 benefited from stocking orders of Estradot related to a planned transition from Vivelle® to Estradot in Canada.

**Product Revenues – Third Parties**

Product revenues – third parties consists primarily of sales of Menorest, Estradot and Estalf® 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 \$1.1 million increase in product revenues from third parties for the three months ended March 31, 2005 as compared to the same period in the prior year primarily related to \$1.5 million in increased revenue related to pricing, partially offset by \$0.5 million of lower unit sales. The \$1.5 million price increase is primarily related to a \$1.2 million price adjustment payment from Novartis Pharma, which was recorded 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. No such price adjustment was recorded for the three months ended March 31, 2004. The decline in unit sales reflected continuing lower prescription trends following the publication of the WHI and other study results.

**Contract and License Revenues**

The increase in license revenues for the three months ended March 31, 2005 as compared to the same period in the prior year was due to the recognition in the current period of license revenue in connection with our collaboration with Endo. The increase in contract revenues for the three months ended March 31, 2005 related to work performed on certain development contracts. We entered into our collaboration with Endo on February 25, 2004 and did not recognize meaningful revenue from it during the first quarter of 2004.

***Gross Margin***

Gross margin for the three months ended March 31, 2005 and 2004 are summarized as follows (dollar amounts in thousands):

|   | 2005      | 2004     | %<br>Change |
|---|-----------|----------|-------------|
| Total product revenues  | \$ 10,130 | \$ 9,675 | 5%          |
| Cost of products sold   | 5,757     | 5,518    | 4%          |
| Gross profit (product revenues less cost of products sold)      | 4,373     | 4,157    | 5%          |
| Gross margin (gross profit as a percentage of product revenues) | 43%       | 43%      |             |
| Changes in deferred profit on sales of product to Novogyne      | 142       | 218      | (35%)       |
| Gross margin excluding impact of deferred profit                | 45%       | 45%      |             |

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



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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.

Gross margin (both including and excluding the impact of deferred profit) was consistent for the three months ended March 31, 2005 as compared to the same period in 2004.

***Operating Expenses***

Operating expenses for the three months ended March 31, 2005 and 2004 are summarized as follows (dollar amounts in thousands):

|                                       | Three Months |          | %      |
|---------------------------------------|--------------|----------|--------|
|                                       | 2005         | 2004     | Change |
| Research and development              | \$ 3,010     | \$ 2,255 | 33%    |
| Marketing, general and administrative | 4,055        | 3,904    | 4%     |

**Research and Development**

The \$0.8 million increase in research and development expenses for the three months ended March 31, 2005 as compared to the same period in 2004 was primarily attributable to an increase in non-clinical development expenses related to our fentanyl transdermal system.

**Marketing, General and Administrative**

There were no material fluctuations in the components of marketing, general and administrative expenses for the three months ended March 31, 2005 compared to the same period in 2004.

**Other Income and Expenses*****Income Taxes***

Our effective tax rate was approximately 36% for each of the three months ended March 31, 2005 and 2004. The provision for income taxes is based on the Federal statutory and state income tax rates. From time to time, we are subject to audits by taxing authorities covering a wide range of matters, and the Internal Revenue Service is currently auditing our federal income tax returns for certain open years. Such matters are subject to various uncertainties, and it is possible that some of these matters may be resolved unfavorably to us. Since 2001, we have established accruals for pending matters that we believe are probable and reasonably estimable. As of March 31, 2005, we had \$1.1 million in accruals related to these matters. Management believes that any liability that may ultimately result from the resolution of pending matters in excess of the amount accrued should not have a material adverse effect on our financial position, results of operations or cash flows.

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, 2005, we had a net deferred tax asset of \$15.0 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

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than not that the deferred income tax asset will be realized based upon estimated future taxable income.

*Equity in Earnings of Novogyne*

We share in the earnings of Novogyne according to an established formula after satisfaction of an annual preferred return of \$6.1 million to Novartis. Our share of Novogyne's earnings increases as Novogyne's product sales increase, subject to a cap of 49%. Novogyne produced sufficient income in the first quarters of 2005 and 2004 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 on our unaudited Condensed Statements of Operations.

The financial results of Novogyne for the three months ended March 31, 2005 and 2004 are summarized as follows (dollar amounts in thousands):

|  | Three Months |           | %<br>Change |
|--|--------------|-----------|-------------|
|  | 2005         | 2004      |             |
| Gross revenues <sup>(1)</sup>                | \$ 27,334    | \$ 25,134 | 9%          |
| Sales allowances                             | 3,395        | 2,772     | 22%         |
| Sales returns allowances                     | 1,266        | 1,009     | 25%         |
| Sales and returns allowances                 | 4,661        | 3,781     | 23%         |
| Net revenues                                 | 22,673       | 21,353    | 6%          |
| Cost of sales                                | 4,555        | 4,835     | (6%)        |
| Gross profit                                 | 18,118       | 16,518    | 10%         |
| Gross margin percentage                      | 80%          | 77%       |             |
| Selling, general and administrative expenses | 8,670        | 7,625     | 14%         |
| Amortization of intangible asset             | 1,545        | 1,545     |             |
| Income from operations                       | 7,903        | 7,348     | 8%          |
| Interest income                              | 93           | 40        | 133%        |
| Net income                                   | \$ 7,996     | \$ 7,388  | 8%          |
| Noven's equity in earnings of Novogyne       | \$ 912       | \$ 637    | 43%         |

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



Novogyne Net Revenues

Novogyne's gross revenues increased \$2.2 million for the three months ended March 31, 2005 compared to the same period in the prior year, primarily due to a \$4.6 million increase in sales of Vivelle-Dot™ partially offset by a \$1.2 million decrease in sales of Estradot to Canada and a \$0.8 million decrease in sales of CombiPatch®. In addition, Vivelle®, our first generation estrogen patch, decreased \$0.4 million in unit sales. Approximately \$3.5 million of the Vivelle-Dot™ increase was due to increased unit sales based on increased trade demand, while the remaining \$1.1 million increase related to price increases. We believe Vivelle-Dot™ sales in the first quarter of 2004 were adversely affected by the timing of orders by trade customers. Sales to Canada by Novogyne in the first quarter of 2004 benefited from stocking orders of Estradot related to a planned transition from Vivelle® to

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Estradot Canada. The lower sales of CombiPatch® were due to a continuing decline in the market for combination therapies after the publication of the combination arm of the WHI study. The decline in unit sales of Vivelle® is primarily attributable to product maturity.

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 12% and 11% of gross revenues for the three months ended March 31, 2005 and 2004, respectively.

Sales returns allowances consist of: (i) allowances for returns of expiring product, and (ii) allowances for returns for product recalls. The activity for sales returns allowances for the three months ended March 31, 2005 and 2004 was as follows:

|   | Three Months |            |
|---|--------------|------------|
|   | 2005         | 2004       |
| Changes in allowances for returns of expiring product | \$ 1,266     | \$ 1,709   |
| Changes in allowances for returns for product recalls |              | (700)      |
| Net change in sales returns allowances                | \$ 1,266     | \$ 1,009   |
| Actual returns for expiring product                   | (928)        | (2,273)    |
| Actual returns for product recalls                    |              | (2,007)    |
| Actual returns for the period                         | \$ (928)     | \$ (4,280) |
| Balance of sales returns allowances at March 31,      | \$ 9,507     | \$ 10,969  |

The decline in allowances for returns of expiring product for the three months ended March 31, 2005 as compared to the same period in 2004 is primarily related to lower expected returns as a result of a decline in actual returns of Vivelle® in the current period as compared to the same period in the prior year. The reduction in allowances for returns for product recalls for the three months ended March 31, 2004 was based on a review at the time of available relevant information, including actual product returns and future expected returns for the 2003 recalls.

**Novogyne Gross Margin**

Gross margin increased for the three months ended March 31, 2005 as compared to the same period in 2004 due 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 have a lower gross margin.

**Novogyne Selling, General and Administrative Expenses**

Selling, general and administrative expenses for the three months ended March 31, 2005 increased \$1.0 million compared to the same period in 2004, due primarily to increased advertising and promotional costs, increased sales force expenses and the elimination of the reduction in expenses associated with the co-promotion of Novartis Famv® product, partially offset by a \$0.5 million decrease in samples expense.

Novogyne Amortization of Intangible Asset

Novogyne amortized \$1.5 million related to the acquisition cost for the CombiPatch® product for each of the three month periods ended March 31, 2005 and 2004. Our CombiPatch® product was licensed by Novogyne in March 2001.

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As of March 31, 2005 and December 31, 2004, we had the following (amounts in thousands):

|                           | March 31,<br>2005 | December 31,<br>2004 |
|---------------------------|-------------------|----------------------|
| Cash and cash equivalents | \$ 64,315         | \$ 93,958            |
| Short-term investments    | 29,950            |                      |
| Working capital           | 98,572            | 97,349               |

Cash provided by (used in) operating, investing and financing activities for the three months ended March 31, 2005 and 2004 is summarized as follows (amounts in thousands):

|                      | Three Months |           |
|----------------------|--------------|-----------|
|                      | 2005         | 2004      |
| Cash flows:          |              |           |
| Operating activities | \$ 1,510     | \$ 14,028 |
| Investing activities | (31,931)     | (712)     |
| Financing activities | 778          | 5,245     |

***Operating Activities***

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.

Net cash provided by operating activities for the three months ended March 31, 2004 primarily resulted from the receipt of an \$8.0 million license payment upon the closing of the Endo transaction in February 2004 and \$6.0 million in distributions from Novogyne.

***Investing Activities***

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

Net cash used in investing activities for the three months ended March 31, 2004 was primarily attributable to the purchase of fixed assets to expand production capacity for future products and payment of patent development costs.

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***Financing Activities***

Net cash provided by financing activities for the three months ended March 31, 2005 and March 31, 2004 was primarily attributable to \$0.8 million and \$5.2 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, 2005, 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 liquidity and require us to rely on our existing cash balances or on borrowings to support our operations and business.

For the three months ended March 31, 2005, \$4.7 million in deferred license revenues were used to offset development expenses related to our methylphenidate patch. As of March 31, 2005, \$14.9 million remained payable to Shire, of which \$10.0 million was paid in April 2005. The remaining \$4.9 million is expected to be paid in the second quarter of 2005. We cannot assure that our methylphenidate patch will be approved by the FDA, particularly in light of the not approvable letter we received from the FDA in April 2003, and there is no assurance that the recently completed additional studies will address the FDA's issues or that the FDA may not raise additional issues following any submission of an amendment to our methylphenidate patch NDA. Additionally, even if the FDA approves our methylphenidate patch, we cannot assure that Shire will generate sales at levels that would trigger our milestone payments; therefore, we cannot assure that we will receive any further payments from Shire with respect to our methylphenidate patch or that we will be able to recover our development expenses through sales of the product.

As of March 31, 2005, we had incurred \$12.5 million for the cost of producing pre-launch inventories for our fentanyl patch. If approval is not ultimately received or is delayed, our agreement with Endo provides that the parties will share the cost of manufacturing product that cannot be sold by Endo in accordance with an agreed-upon formula. In such a case, we may be unable to recover our share of such costs, which could be up to approximately \$7.2 million. If the product has not been approved within 120 days after the launch of the next generic fentanyl transdermal product, Endo may have the right to terminate the license.

Capital expenditures were \$2.3 million in the first quarter of 2005, of which \$0.5 million represented leasehold improvements paid by the landlord of a leased facility. We expect that our capital expenditures will increase significantly in 2005 as we continue to expand our manufacturing and storage facilities for products under development, including those under development with Endo, Shire, P&G Pharmaceuticals and others. 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.

In February 2005, we entered into an Industrial Long-Term Lease (the Lease) for approximately 73,000 square feet of newly constructed space located in close proximity to our



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manufacturing facility in Miami, Florida. We intend to use the leased space for the storage and, as needed, the manufacture of new product. The lease term is 10 years, which may be extended for up to an additional 21 years pursuant to four renewal options of five years each and a one-time option to renew for one year. The annual base rent is \$6.40 per square foot. We also pay a monthly management fee equal to 1.5% of the base rent. The rent for the first year is discounted to \$3.20 per square foot. The base rent is subject to annual increases of 3% during the initial 10-year term. After the initial term, the rent will be 95 percent of the fair market rate of the leased space as determined under the Lease. We are in the process of improving the leased space in order to prepare it for its intended use. The landlord will be responsible for leasehold improvements paid to the general contractor improving the leased space, up to approximately \$0.9 million. Any amounts paid to the general contractor in excess of this amount and any other leasehold improvements will be our responsibility. For accounting purposes, we are amortizing the expected rental payments on a straight-line basis over the initial 10-year term of the Lease. The renewal terms have not been included for amortization purposes because we cannot reasonably estimate the rental payments after the initial term and we cannot assure that we will renew the Lease after the initial term. Any leasehold improvements will be recorded at cost and will be amortized on a straight-line basis over the shorter of the estimated useful life of the improvements or the remaining initial 10-year lease term. Leasehold improvements to the leased space paid by the landlord will be recorded by us as a deferred rent credit and will be amortized on a straight-line basis when incurred over the remaining initial 10-year lease term as a reduction of rent expense. Leasehold improvements paid by the landlord and recorded as a deferred rent credit were approximately \$0.5 million for the three months ended March 31, 2005.

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 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, P&G Pharmaceuticals 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 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 under **Cautionary Factors that May Impact Future Results** as well as in our Annual Report on Form 10-K for the year ended December 31, 2004.

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.

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### **New Accounting Standards**

In November 2004, the FASB issued Statement of Financial Accounting Standard No. 151 *Inventory Costs* an amendment of ARB No. 43, Chapter 4 ( *SFAS 151* ), to clarify the accounting for abnormal amounts of idle facility expense, freight, or wasted material (spoilage). SFAS 151 requires that those items be recognized as current-period charges regardless of whether they meet the *so abnormal* criterion outlined in Accounting Research Bulletin 43, Chapter 4, *Inventory Pricing* . SFAS 151 also introduces the concept of *normal capacity* and requires the allocation of fixed production overheads to inventory based on the normal capacity of the production facilities. Unallocated overheads must be recognized as an expense in the period in which they are incurred. This statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. We are currently assessing SFAS 151 and we are unable to estimate the impact it will have on our results of operations and financial condition.

In December 2004, the FASB issued SFAS No. 123(R) *Share-Based Payment (Revised 2004)* that will require compensation costs related to share-based payment transactions to be recognized in the financial statements. With limited exceptions, the amount of compensation cost will be measured based on the grant-date fair value of the equity or liability instruments issued. Compensation cost will be recognized over the period that an employee provides service in exchange for the award, which is generally over the vesting period. SFAS 123(R) replaces SFAS 123, *Accounting for Stock-Based Compensation* , and supersedes APB 25, *Accounting for Stock Issued to Employees* . For public companies such as Noven, the statement is effective as of the beginning of the first annual reporting period that begins after June 15, 2005 and accordingly, we anticipate adopting this statement in the first quarter of 2006.

### **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 Policies* , which is included in our Form 10-K for the year ended December 31, 2004.

### **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 that during the remainder of 2005 (except as otherwise indicated below) there will not be any material:

transactions;

changes in Noven's or Novogyne's accounting or accounting principles;

regulatory, technological or clinical study developments;

changes in the supply of, demand for, or distribution of our HT products (including any changes resulting from product recalls, competitive HT products, 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. If our assumptions or expectations concerning any of these matters prove to be incorrect, our actual financial results could differ materially from the expected results discussed below. For a discussion of certain



factors that may impact our actual financial results for the periods referenced, readers should carefully consider the risks, uncertainties

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and cautionary factors discussed below under the caption "Factors Affecting Our Business and Prospects" and in our Annual Report on Form 10-K for the year ended December 31, 2004.

*Novogyne.* Based on current prescription forecasts and our estimates of trade inventory levels, we believe that Novogyne's revenues and net income for full-year 2005 should increase modestly over 2004 levels.

*Potential Fentanyl Revenues.* Our ANDA for our generic fentanyl patch is currently pending at the FDA, and we are unable to predict when or if it will be approved. If our ANDA is approved and the product is launched by Endo (the licensee of the product in the U.S.), we expect to receive a launch-related milestone payment ranging from \$5.0 million to \$10.0 million, which payment will be deferred and recognized as Noven license and contract revenues over the remainder of the 10-year period that began on the closing of the Endo license transaction in the first quarter of 2004. Under the terms of our agreement with Endo, we will manufacture and supply Endo with finished product at our cost and will share in Endo's profit generated from U.S. product sales. At this time, we do not have sufficient information regarding timing of approval, number of competitors, market share, product pricing and other factors necessary to forecast an expected contribution of our fentanyl patch to our 2005 financial results.

*Research and Development.* In support of our strategy to expand our product pipeline, we expect to continue to invest in research and development in 2005 at levels comparable to 2004. In addition, we are working to formulate certain new transdermal products that, if successfully formulated, may enter human studies during 2005. These studies, if initiated, would be funded by Noven and may cause our research and development expense in 2005 to increase substantially over 2004 levels.

*Marketing, General and Administrative Expense.* We expect Noven's marketing, general and administrative expense in 2005 to increase over 2004 levels, with anticipated increases in costs associated with facility expansion, product liability insurance, professional services fees and other areas.

*Capital Expenditures.* We expect that our capital expenditures will increase significantly in 2005 as we continue to expand our manufacturing and storage facilities for products under development with Endo, Shire, P&G Pharmaceuticals and others.

**Cautionary Factors that May Impact Future Results**

Except for historical information contained herein, the matters discussed in this report are forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements about our and our licensees' respective plans, objectives, expectations, estimates, strategies, prospects, product approvals and development plans, and anticipated financial results. These statements are typically identified by the use of terms such as "anticipates," "believes," "estimates," "hopes," "expects," "intends," "may," "plans," "could," "should," "will," "would" and similar words. These statements are current expectations and beliefs concerning future events and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed herein. 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. In addition to the factors described elsewhere in this report and in our Form 10-K for the year ended December 31, 2004 the risks and uncertainties in the following categories, among others, as well as our success at managing those risks, could cause our actual results to differ materially from those expressed in any forward-looking statements:

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*HT Market*, risks associated with increased competition in the HT market, including as a result of the 2004 launches of estrogen cream and gel products, each of which is a new dosage form in this category; any further impact on our HT business due to the announcement of additional negative clinical results or otherwise, which could reduce or eliminate any profit contribution by Novogyne to us and/or sales of HT products from us to Novartis Pharma; uncertainties regarding any future regulatory developments resulting from those studies; the risk that Novogyne may not be able to realize the full value of the marketing rights for our CombiPatch product; the European HT market may be limited due to pricing pressures and delayed Estradot launches in certain countries due to labeling issues; and the risk of product liability claims resulting from the use of HT products such as the lawsuits presently pending against Noven and Novartis with respect to our products, as well as any indemnification or contribution obligations that we may have to Novartis or Novogyne related to product liability claims.

*Regulatory Matters*, uncertainties relating to actions that may be taken against us by the FDA or other regulators, whether relating to manufacturing processes, suppliers, commercialized products, products in development or otherwise, and any related costs; uncertainties related to the FDA's discretion to approve or not approve a product; the timing of any FDA approval for any of our products in development, which is outside our control and which may impact the success of product launch and market penetration; and uncertainties related to our ability to comply with Drug Enforcement Administration regulations related to our purchase, storage and usage of controlled substances in products we may manufacture, including our developmental methylphenidate and fentanyl patch.

*Production Matters*, risks related to our reliance on suppliers for the availability and quality of raw materials used in our products; risks related to our reliance on a single supplier for certain raw materials and compounds used in our products; uncertainties regarding the timing and magnitude of any product recalls; the impact of the recalls or related issues on Novartis or other partners' strategy for the commercialization of our products; the possibility that our estimates of the impact of future returns and charges may prove inaccurate, incomplete or otherwise incorrect; the impact of detected or undetected product stability failures or other product defects on our ability to estimate our reserves for sales returns and other associated accounting consequences.

*Our Partners*, the risk that our development partners may have different or conflicting priorities than ours which may adversely impact their ability or willingness to assist in the development and commercialization of our products or to continue the development programs in which they and we have partnered; uncertainties regarding our ability to attract additional development partners; the possibility that our technologies may not be approvable or suitable for use in additional therapeutic categories, including those categories addressed through products developed with our development partners; the possibility that we may be unsuccessful in achieving milestone objectives under our development programs and may not receive any further payments; the possibility that our development programs may not proceed on schedule or as expected, which could, among other things, prevent us from achieving milestone objectives under our development programs and/or cause delays or cancellations of programs; the possibility that our current development priorities could render us unable to advance our other development projects or increase the cost of advancing those projects; risks related to our dependence on Novartis to perform Novogyne's financial, accounting, inventory, distribution, revenues and sales deductions functions (including any asset impairment decisions for Novogyne), including the risk that Novartis may perform these functions differently than we would have, inadequately or incorrectly; risks and uncertainties related to the fact that Vivelle-Dot comprises a substantial majority of Novogyne's aggregate total prescriptions; and the possibility that our financial results could fluctuate from period to period or otherwise be affected by Novartis' monitoring of trade inventory levels for Novogyne and its decisions related thereto.

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*Methylphenidate Patch*, the risk that the FDA may determine that our protocols and/or clinical strategies do not address the FDA's concerns regarding the approval of our methylphenidate patch NDA; the risk that our filing of an amendment to our methylphenidate patch NDA could be delayed past 2005; the possibility that the additional studies of our methylphenidate patch will not produce results that the FDA believes support approval or that our methylphenidate patch may not ultimately be approved or commercialized; the timing of the FDA's review of any amended NDA for our methylphenidate patch as well as any product approval, which are outside Noven's control and which may impact the success of product launch and market penetration; risks and uncertainties related to the 2005 study by researchers at the M.D. Anderson Cancer Center that found adverse chromosomal effects on 12 children treated with oral methylphenidate, including risks related to the timing of any FDA approval of our methylphenidate patch, the impact on the market for methylphenidate products (including our patch, if approved) and any follow-on or related study finding adverse effects from methylphenidate use; any exercise of Shire's right to terminate the agreement, including the risk that, in such event, our right to receive a \$50.0 million approval milestone would terminate, and that we may be unable or unwilling to proceed with the project or may be unable to license our methylphenidate patch to a third party or to a party with the resources of Shire on commercially reasonable terms; the possibility that our method of accounting for the \$25.0 million received from Shire could change under certain circumstances, including if the parties' product strategy changes or if our methylphenidate patch development is discontinued; and the likelihood that our development strategy would change if Shire were to terminate the agreement under certain circumstances, or if our methylphenidate patch were not ultimately approved or were abandoned.

*Fentanyl Patch*, the risks and uncertainties associated with the FDA's review of Noven's fentanyl ANDA; the risks and uncertainties associated with the recent label change to the product, including risks related to the delay in the approval of Noven's fentanyl ANDA or the launch of our fentanyl patch; the possibility that milestone payments may be reduced and/or that Endo may exercise its contractual right to terminate the license agreement if the product launch is delayed for any reason, including delay in obtaining FDA approval; patent or other strategies by third parties could delay or prevent the launch of our fentanyl patch or other products; the possibility that we may be unable to recover significant costs to manufacture launch supplies of fentanyl patches prior to product launch if FDA approval is not obtained on a timely basis or at all; the possibility that, even if approved, our fentanyl patch or other products may not be successfully commercialized due to competitive market conditions or other factors, including physician/patient preferences for other therapies; and in recent periods, companies offering generic drug products have experienced significant product pricing pressure, often earlier than expected in the product's life cycle, which has negatively affected the profitability of certain of their generic products.

*Other Matters*, expected fluctuations in quarterly revenues and research and development expenses; and uncertainties associated with our beliefs regarding the timing of trade customer orders. We caution that the foregoing list of factors is not exhaustive.

## **Item 3. Quantitative and Qualitative Disclosure 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,

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Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective in timely alerting them to material information relating to Noven required to be included in our periodic Securities and Exchange Commission filings. However, that conclusion should be considered in light of the various limitations described below on the effectiveness of those controls and procedures, some of which pertain to most if not all business enterprises, and some of which arise as a result of the nature of our business. Our management, including 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.

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.

We do not control Novogyne and Novartis performs all of Novogyne's financial, accounting, inventory, sales and sales deductions functions. As previously disclosed, in the course of its audit of Novogyne's financial statements for the year ended December 31, 2004, Novogyne's independent registered public accounting firm identified what it believes is a significant deficiency in Novogyne's internal controls which related to oversights by Novartis in connection with Novogyne's accounting for certain rebate accruals. These oversights resulted in an immaterial adjustment at Novogyne in the fourth quarter of 2004. We have been advised that the Audit and Compliance Committee of Novartis AG has engaged outside counsel and is conducting an ongoing internal investigation of this matter. It is not possible for us to predict what impact, if any, Novartis' internal investigation may have. To our knowledge, none of the issues that are the subject of the investigation involves Noven, Noven's accounting policies or practices, or any of Noven's officers, directors or employees.

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**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

On March 15, 2005, the United States District Court for the Southern District of Florida issued an order dismissing without prejudice the lawsuit filed against Noven and certain individual defendants styled In re: Noven Pharmaceuticals, Inc. Securities Litigation. The notice of voluntary dismissal (attached to the order of dismissal) indicated that the lead plaintiffs and their counsel, after further investigation, concluded that the complaint should be voluntarily dismissed. Noven agreed to the dismissal, with each party bearing its own costs.

In July 2004, an individual plaintiff and her husband filed a complaint in Superior Court of New Jersey Law Division, Atlantic County, against Noven, Novartis, Wyeth Pharmaceuticals, Inc. and others alleging liability in connection with personal injury claims allegedly arising from the use of HT products, including CombiPatch<sup>®</sup>, which is manufactured by Noven and distributed by Novogyne. The plaintiffs claim compensatory, punitive and other damages in an unspecified amount. In April 2005, the plaintiff agreed to substitute Aventis Pharmaceuticals, Inc. for Noven and Novartis in this case and to dismiss Noven and Novartis without prejudice for a period of six months and with prejudice thereafter. In addition, Novartis has advised Noven that Novartis has been named as a defendant in at least 13 additional lawsuits that include approximately 23 plaintiffs that allege liability in connection with personal injury claims allegedly arising from the use of HT patches distributed and sold by Novartis and Novogyne, including Noven's Vivelle<sup>®</sup>, Vivelle-Dot and CombiPatch<sup>®</sup> products. To date, Noven has been named in one lawsuit and, to Noven's knowledge, Novogyne has not been named in any. Novartis has indicated that it will seek indemnification from Noven and Novogyne to the extent permitted by the agreements between and among Novartis, Novogyne and Noven. Novogyne's accrual for expected legal fees and settlements of these lawsuits was \$2.4 million as of March 31, 2005, for which there was a related insurance receivable of \$1.4 million. This accrual represents Novartis management's best estimate as of March 31, 2005. The ultimate outcome of these product liability lawsuits cannot be predicted.

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The following table provides information with respect to our stock repurchases during the first quarter of 2005:

|                                       | Total<br>Number of<br>Shares<br>Purchased | Average<br>Price<br>Paid<br>Per Share | Total<br>Number of<br>Shares<br>Purchased<br>as<br>Part of<br>Publicly<br>Announced<br>Program | Approximate<br>Dollar Value<br>That May Yet<br>be Purchased<br>under the<br>Program <sup>(1)</sup> |
|---------------------------------------|---|---------------------------------------|--|--|
| January 1, 2005 to January 31, 2005   |   |                                       |  | \$ 23,711,040  |
| February 1, 2005 to February 28, 2005 |   |                                       |  | \$ 23,711,040  |
| March 1, 2005 to March 31, 2005       |   |                                       |  | \$ 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**

- 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



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Signatures

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

NOVEN PHARMACEUTICALS, INC.

Date: May 4, 2005

By: /s/ Diane M. Barrett

Diane M. Barrett  
Vice President and  
Chief Financial Officer