

NOVEN PHARMACEUTICALS INC

Form 10-Q

May 14, 2003

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, 2003

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 Securities Exchange Act). Yes  No .

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

Class

Outstanding at April 30, 2003

Common stock \$.0001 par value

22,492,340

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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)

|   | <u>2003</u>   | <u>2002</u>     |
|---|---------------|-----------------|
| Revenues:   |               |                 |
| Product sales   | \$ 9,144      | \$ 11,991       |
| License revenue                                       | 881           | 744             |
|   | <u>10,025</u> | <u>12,735</u>   |
| Expenses:   |               |                 |
| Cost of products sold                                 | 4,285         | 5,900           |
| Research and development                              | 2,493         | 3,369           |
| Marketing, general and administrative                 | 4,181         | 2,933           |
|   | <u>10,959</u> | <u>12,202</u>   |
| Income (loss) from operations                         | (934)         | 533             |
| Equity in earnings of Novogyne                        | 1,525         | 1,515           |
| Interest income, net                                  | 148           | 207             |
|   | <u>739</u>    | <u>2,255</u>    |
| Income before income taxes                            | 739           | 2,255           |
| Provision for income taxes                            | 266           | 802             |
|   | <u>\$ 473</u> | <u>\$ 1,453</u> |
| Basic earnings per share                              | <u>\$ .02</u> | <u>\$ .06</u>   |
| Diluted earnings per share                            | <u>\$ .02</u> | <u>\$ .06</u>   |
| Weighted average number of common shares outstanding: |               |                 |
| Basic   | <u>22,581</u> | <u>22,491</u>   |
| Diluted   | <u>22,920</u> | <u>23,456</u>   |

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

## NOVEN PHARMACEUTICALS, INC.

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

|  | <u>March 31, 2003</u> | <u>December 31,<br/>2002</u> |
|--|-----------------------|------------------------------|
| <b>Assets</b>  |                       |                              |
| Current Assets:  |                       |                              |
| Cash and cash equivalents  | \$ 65,404             | \$ 58,684                    |
| Accounts receivable - trade (less allowance for doubtful accounts of \$64 in 2003 and \$79 in 2002)  | 3,559                 | 4,359                        |
| Accounts receivable - Novogyne   | 3,794                 | 2,581                        |
| Inventories  | 4,141                 | 5,613                        |
| Net deferred income tax asset  | 1,700                 | 2,600                        |
| Prepaid and other current assets   | 898                   | 541                          |
|  | <u>79,496</u>         | <u>74,378</u>                |
| Property, plant and equipment, net   | 17,130                | 16,232                       |
| Other Assets:  |                       |                              |
| Investment in Novogyne   | 25,561                | 34,684                       |
| Net deferred income tax asset  | 10,654                | 9,831                        |
| Patent development costs, net  | 2,023                 | 1,996                        |
| Deposits and other assets  | 481                   | 581                          |
|  | <u>38,719</u>         | <u>47,092</u>                |
|  | <u>\$ 135,345</u>     | <u>\$ 137,702</u>            |
| <b>Liabilities and Stockholders' Equity</b>  |                       |                              |
| Current Liabilities:   |                       |                              |
| Accounts payable   | \$ 6,774              | \$ 5,062                     |
| Notes payable, current portion   | 9                     | 8                            |
| Accrued compensation and related liabilities   | 2,200                 | 3,549                        |
| Other accrued liabilities  | 780                   | 2,063                        |
| Deferred contract revenue  | 968                   | 829                          |
| Deferred license revenue, current portion  | 3,526                 | 3,525                        |
|  | <u>14,257</u>         | <u>15,036</u>                |
| Long-Term Liabilities:   |                       |                              |
| Notes payable  | 2                     | 5                            |
| Deferred license revenue   | 25,038                | 25,920                       |
|  | <u>39,297</u>         | <u>40,961</u>                |
| Commitments and Contingencies (Note 10)  |                       |                              |
| 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 22,488,137 shares at March 31, 2003 and 22,579,112 at December 31, 2002 | 2                     | 2                            |
| Additional paid-in capital   | 77,192                | 78,358                       |
| Retained earnings  | 18,854                | 18,381                       |
|  | <u>18,854</u>         | <u>18,381</u>                |

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|  |                   |                   |
|--|-------------------|-------------------|
|  | 96,048            | 96,741            |
|  | <u>          </u> | <u>          </u> |
|  | \$ 135,345        | \$ 137,702        |
|  | <u>          </u> | <u>          </u> |

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

**NOVEN PHARMACEUTICALS, INC.**

## Condensed Statements of Cash Flows

Three Months Ended March 31,

(in thousands)

(unaudited)

|   | <u>2003</u>      | <u>2002</u>      |
|---|------------------|------------------|
| Cash flows from operating activities:   |                  |                  |
| Net income  | \$ 473           | \$ 1,453         |
| Adjustments to reconcile net income to net cash provided by (used in) operating activities: |                  |                  |
| Depreciation and amortization   | 577              | 530              |
| Amortization of patent costs  | 82               | 71               |
| Amortization of non-competition agreement   | 100              | 100              |
| Deferred income tax expense   | 77               | 374              |
| Recognition of deferred contract revenue  | (26)             | (574)            |
| Recognition of deferred license revenue   | (881)            | (744)            |
| Distributed (undistributed) earnings of Novogyne  | 9,123            | (1,515)          |
| Decrease (increase) in accounts receivable - trade, net                                     | 800              | (2,548)          |
| Increase in accounts receivable - Novogyne  | (1,213)          | (1,524)          |
| Decrease in inventories   | 1,472            | 414              |
| Increase in prepaid and other current assets  | (357)            | (174)            |
| Decrease in deposits and other assets   |                  | 2                |
| Increase in accounts payable  | 1,712            | 2,641            |
| (Decrease) increase in accrued compensation and related liabilities                         | (1,349)          | 769              |
| Decrease in other accrued liabilities   | (1,277)          | (1,195)          |
| Increase in deferred contract revenue   | 165              | 95               |
|   | <u>9,478</u>     | <u>(1,825)</u>   |
| Cash flows provided by (used in) operating activities                                       |                  |                  |
| Cash flows from investing activities:   |                  |                  |
| Purchase of property, plant and equipment, net  | (1,475)          | (182)            |
| Payments for patent development costs   | (109)            | (48)             |
|   | <u>(1,584)</u>   | <u>(230)</u>     |
| Cash flows used in investing activities   |                  |                  |
| Cash flows from financing activities:   |                  |                  |
| Issuance of common stock  | 117              | 183              |
| Purchase and retirement of common stock   | (1,289)          |                  |
| Repayments of notes payable   | (2)              | (247)            |
|   | <u>(1,174)</u>   | <u>(64)</u>      |
| Cash flows used in financing activities   |                  |                  |
| Net increase (decrease) in cash and cash equivalents  | 6,720            | (2,119)          |
| Cash and cash equivalents, beginning of period  | 58,684           | 49,389           |
|   | <u>\$ 65,404</u> | <u>\$ 47,270</u> |
| Cash and cash equivalents, end of period  |                  |                  |

The accompanying notes are an integral part of these statements.

**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® and Vivelle-Dot® and Noven's transdermal combination estrogen/progestin delivery system marketed under the brand name 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.

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, 2003, and the results of its operations for the three months ended March 31, 2003 and 2002. 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/A for the year ended December 31, 2002 ( Form 10-K ) as well as the risk that the results of recent and ongoing studies on the adverse health effects of certain forms of hormone replacement therapy ( HRT ) may result in lower sales by Noven or Novogyne in future periods, the risk that MethyPatch® may not be approved by the United States Food and Drug Administration ( FDA ), particularly in light of Noven's receipt of a not approvable letter from the FDA in April 2003, and the risk that Shire may elect to require Noven to repurchase the MethyPatch® rights for \$5 million. Accordingly, the results of operations and cash flows for the three months ended March 31, 2003 and 2002 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 2003.

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. RECLASSIFICATION:

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

4. INVENTORIES:

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

|                 | <b>March 31,<br/>2003</b>   | <b>December 31,<br/>2002</b> |
|-----------------|-----------------------------|------------------------------|
|                 | <u>                    </u> | <u>                    </u>  |
| Finished goods  | \$ 299                      | \$ 830                       |
| Work in process | 1,453                       | 1,390                        |
| Raw materials   | 2,389                       | 3,393                        |
|                 | <u>                    </u> | <u>                    </u>  |
| Total           | <b>\$4,141</b>              | <b>\$5,613</b>               |
|                 | <u>                    </u> | <u>                    </u>  |

5. EMPLOYEE STOCK PLANS:

In accordance with the provisions of Statement of Financial Accounting Standards No. 123 ( SFAS 123 ), Accounting for Stock-Based Compensation , as amended by Statement of Financial Accounting Standards No. 148 ( SFAS 148 ), Accounting for Stock-Based Compensation - Transition and Disclosure , Noven may elect to continue to apply the provisions of the Accounting Principles Board's Opinion No. 25 ( APB 25 ), Accounting for Stock Issued to Employees 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, 2003 and 2002 if the company had applied the fair value recognition provisions of SFAS 123, as amended by SFAS 148 (in thousands, except per share amounts):

|   | 2003      | 2002     |
|---|-----------|----------|
| <b>Net income:</b>  |           |          |
| As reported   | \$ 473    | \$ 1,453 |
| Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects | (1,176)   | (1,091)  |
| Pro forma   | \$ (703)  | \$ 362   |
| <b>Basic earnings per share:</b>  |           |          |
| As reported   | \$ 0.02   | \$ 0.06  |
| Pro forma   | \$ (0.03) | \$ 0.02  |
| <b>Diluted earnings per share:</b>  |           |          |
| As reported   | \$ 0.02   | \$ 0.06  |
| Pro forma   | \$ (0.03) | \$ 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 its 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 ending March 31, 2003 and 2002, respectively, may not be representative of the effects for future years because outstanding options vest over a period of several years and additional awards are generally made during each year.

### 6. CASH FLOW INFORMATION:

Cash payments for income taxes were \$1.3 million and \$1.7 million for the three months ended March 31, 2003 and 2002, respectively. Cash payments for interest were not material for the three months ended March 31, 2003 and 2002.

In connection with the CombiPatch® transaction consummated in March 2001, the final \$10.0 million quarterly installment of the purchase price was paid by Novogyne directly to Aventis in March 2002.

Noven recorded \$6,000 and \$51,000 in income tax benefits to additional paid-in capital for the three months ended March 31, 2003 and 2002, respectively, which were derived from the exercise of non-qualified stock options and disqualifying dispositions of incentive stock options.

7. LICENSE AGREEMENTS:

In the first quarter of 2003, Noven signed an agreement to license the exclusive global rights to market MethyPatch® to Shire Pharmaceuticals Group plc ( Shire ) for payments of up to \$150 million and ongoing manufacturing revenue. Consideration for the transaction is as follows: (a) \$25 million was paid upon closing of the transaction in April 2003; (b) \$50 million is payable upon receipt of final marketing approval for MethyPatch® by the FDA; and (c) 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 MethyPatch®, 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 (a) five years from the closing date or (b) payment of all of the sales milestones.

Under the terms of the transaction, Noven remains responsible for securing final regulatory approval for MethyPatch®. On April 25, 2003, Noven received a not approvable letter from the FDA relating to its MethyPatch® New Drug Application ( NDA ). A not approvable letter is issued if the FDA believes that the application contains insufficient information for an approval action at the time of issuance. The letter cited clinical and other issues as the basis for non-approval. Under the agreement, receipt of the not approvable letter gives Shire the right to require Noven to repurchase the product rights for \$5 million, but to date Shire has not exercised this right. For accounting purposes, \$20 million of the initial \$25 million payment is expected to be deferred and recognized as revenue over approximately 10 years beginning with the second quarter of 2003. The remaining \$5 million has been deferred and is expected to be recognized as revenue beginning at the time Shire's right to require us to repurchase the product rights expires. However, this accounting treatment would be expected to change if Shire were to exercise its right to require Noven to repurchase the product rights.

On the closing date, Noven entered into a long-term supply agreement under which it will manufacture and supply MethyPatch® 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.

8. INVESTMENT IN 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 2003 and 2002 to meet Novartis' annual preferred return for those years and for Noven to recognize earnings from Novogyne under the formula.

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During the three months ended March 31, 2003 and 2002, Noven had the following transactions with Novogyne (in thousands):

|                             | 2003    | 2002    |
|-----------------------------|---------|---------|
| <b>Revenue:</b>             |         |         |
| Trade product               | \$2,045 | \$5,117 |
| Sample product and other    | 885     | 1,260   |
| Royalty                     | 1,231   | 1,282   |
|                             | \$4,161 | \$7,659 |
| <b>Reimbursed Expenses:</b> |         |         |
| Services                    | \$4,782 | \$4,853 |
| Product specific marketing  | 1,401   | 2,829   |
|                             | \$6,183 | \$7,682 |

As of March 31, 2003 and December 31, 2002, Noven had amounts due from Novogyne of \$3.8 million and \$2.6 million, respectively, for products sold to, and marketing expenses reimbursable by, Novogyne.

The unaudited condensed Statements of Operations of Novogyne for the three months ended March 31, 2003 and 2002 are as follows (in thousands):

|  | 2003     | 2002     |
|--|----------|----------|
| Revenues                                     | \$24,464 | \$27,457 |
| Cost of sales                                | 5,765    | 6,476    |
| Selling, general and administrative expenses | 7,883    | 9,937    |
| Amortization of intangible assets            | 1,545    | 1,545    |
|  | 9,271    | 9,499    |
| Income from operations                       | 9,271    | 9,499    |
| Interest income                              | 85       | 70       |
|  | \$ 9,356 | \$ 9,569 |
| Net income                                   | \$ 9,356 | \$ 9,569 |
| Noven's equity in earnings of Novogyne       | \$ 1,525 | \$ 1,515 |

Royalties due to Noven on sales of Vivelle® and Vivelle-Dot® for 2002 have been reclassified from selling, general and administrative expenses to cost of sales to conform to the current year's presentation.

Subject to the approval of Novogyne's management committee, cash may be distributed to Novartis and Noven based upon a contractual formula. In March 2003, Noven received a distribution of \$10.6 million from Novogyne. This amount was recorded as a reduction in the investment in Novogyne in the first quarter of 2003.

9. 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 million of its common stock. As of March 31, 2003, Noven had repurchased 105,000 shares of its common stock at an aggregate price of approximately \$1.3 million. These shares were retired on March 31, 2003.

10. COMMITMENTS AND CONTINGENCIES:

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 condensed financial statements.

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

The following discussion and analysis should be read in conjunction with the financial statements, the related notes and management's discussion and analysis of financial condition and results of operations included in our Form 10-K for the year ended December 31, 2002 and the condensed financial statements and related notes included in Item 1 of this Quarterly Report on Form 10-Q. 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, expects, intends, may, plans, could, should, will, would and similar words. These statements are based on our 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 important factors described in our Form 10-K for the year ended December 31, 2002, the following important factors, among others, could cause our actual results to differ materially from those expressed in any forward-looking statements: uncertainties associated with the impact on the HRT market of published studies regarding the adverse health effects of certain forms of HRT and resulting label changes mandated by the FDA; uncertainties associated with future prescription trends for CombiPatch<sup>®</sup>, Vivelles<sup>®</sup> family products, Estalis<sup>®</sup> and Estradot<sup>®</sup>, including risks relating to declining physician or patient preference for HRT as a result of the published studies and label changes referred to above; risks associated with the commercialization of Noven's products; risks and uncertainties associated with the potential impact on our business of the effectiveness as of April 2003 of the privacy regulations issued by the Department of Health and Human Services under the Health Insurance Portability and Accountability Act of 1996 (HIPAA); risks and uncertainties associated with the impact of a Novogyne competitor's strategy of increasing market share by heavily discounting product sales to managed care organizations; risks associated with the expected launches in 2003 and 2004 of estrogen cream and gel products, which are new dosage forms in this category; risks associated with higher than desired Vivelles<sup>®</sup> returns to Novogyne and trade customer inventory levels of Vivelles<sup>®</sup>; risks and uncertainties relating to our dependence on Novartis to monitor trade inventory levels for Novogyne; uncertainties concerning the timing and extent of Estradot<sup>®</sup> regulatory approvals and launch orders and Estalis<sup>®</sup> orders and commercialization efforts by Novartis AG, particularly in light of the significant pricing and reimbursement issues faced by Novartis AG in Europe; our limited ability to accurately forecast international product orders from Novartis AG; the risk that MethyPatch<sup>®</sup> may not be approved by the FDA, particularly in light of the FDA's issuance of a not approvable letter; uncertainties associated with the timing, cost and outcomes of clinical trials and product development, including the regulatory review process for MethyPatch<sup>®</sup> and any future generations of our combination estrogen/progestin patch; risks and uncertainties associated with product liability claims that may be brought against us as a result of published studies regarding the adverse health effects of HRT; our dependence on strategic alliances and our relationships with our licensees, and our vulnerability to the risks and uncertainties of our licensees' businesses, inventory requirements and marketing strategies; the risk that our licensees may favor their own competitive products over the products licensed from us; the risk that Shire may seek to exercise its right to require us to repurchase the rights to MethyPatch<sup>®</sup> for \$5 million, and the risk that such an exercise would change our method of accounting for the initial amount received from Shire; risks associated with the availability of a non-stimulant therapy to treat children with Attention Deficit Hyperactivity

Disorder ( ADHD ); risks associated with our ability to meet Shire's manufacturing requirements for MethyPat<sup>®</sup> and expected fluctuations in quarterly revenue and research and development expenses, including fluctuations in revenues resulting from factors not within our control and the timing of royalty reconciliations and payments under our license agreements; risks and uncertainties relating to the fact that a majority of our cash flow is dependent upon Novogyne's ability to pay distributions to us; the effect of a recent change in New Jersey State tax law, which may increase Noven's tax liability in future years; our reliance on Shire's marketing efforts and success to achieve the MethyPat<sup>®</sup> sales levels necessary to trigger our milestone payments; the effect of changes in taxation or accounting principles generally accepted in the United States (including changes in accounting principles relating to the accounting treatment for employee stock options); and economic, competitive, governmental and technological factors affecting our operations, markets, products, prices and prospects.

Based on information that we have received from Novartis, we believe that trade inventory levels of Vivelle<sup>®</sup> are modestly higher than desired in light of current and expected demand. We believe that Novogyne's inventories are at acceptable levels, primarily due to recent inventory management initiatives. We expect that sales of Vivelle<sup>®</sup> in future periods may be impacted as trade customers are expected to reduce their Vivelle<sup>®</sup> inventories.

Our supply agreement with Novogyne for Vivelle<sup>®</sup> and Vivelle-Dot<sup>®</sup> expired in January 2003. The parties are negotiating an extension to the agreement. Since the expiration of the Vivelle<sup>®</sup> and Vivelle-Dot<sup>®</sup> supply agreement, the parties have continued to operate in accordance with the supply agreement's commercial terms, and we expect that the supply agreement will be extended on satisfactory terms. However, we cannot assure that the agreement will be extended on satisfactory terms or at all. Failure to extend the supply agreement could have a material adverse effect on our business, results of operations, financial conditions and prospects. Designation of a new supplier and approval of a new supply agreement would require the affirmative vote of 4 of the 5 members of Novogyne's Management Committee. Accordingly, both Novartis and Noven must agree on Novogyne's supplier.

In November 2000, we entered into an exclusive license agreement with Novartis AG pursuant to which we granted Novartis AG the right to market Vivelle-Dot<sup>®</sup> under the name Estradot<sup>®</sup> in all countries other than the United States, Canada and Japan. Under the terms of the agreement, Novartis AG is responsible for seeking approval to market Estradot<sup>®</sup> in its territories. The product has been approved for marketing in over 30 foreign countries and the regulatory authorities of other countries are reviewing Novartis' registration applications. Novartis AG has launched the product in Germany and a number of smaller countries. However, Novartis AG has informed us that pricing and reimbursement issues are adversely impacting its launch plans in many countries, including the United Kingdom, France, Spain and Italy. Accordingly, we cannot assure that Novartis AG will be successful in effecting additional registrations of Estradot<sup>®</sup> or that Novartis AG will launch Estradot<sup>®</sup> in any particular country. Novartis AG markets several other transdermal HRT products in addition to our products, which may limit the efforts Novartis AG devotes to our products. In some countries, including the United Kingdom and France, Novartis AG is seeking a marketing partner to launch the product but to date has been unsuccessful. We cannot assure that Novartis AG will be successful in securing a marketing partner or in launching Estradot<sup>®</sup> in those countries.

***HRT Studies***

In July 2002, the National Institute of Health ( NIH ) released data from its Women ' s Health Initiative ( WHI ) study on the risks and benefits associated with long-term use of oral HRT by healthy women. The NIH announced that it was discontinuing the arm of the study investigating the use of oral estrogen/progestin combination HRT products after an average follow-up period of 5.2 years because the oral HRT product used in the study was shown to cause an increase in the risk of invasive breast cancer. The study also found an increased risk of stroke, heart attacks and blood clots and concluded that overall health risks exceeded benefits from use of the orally delivered combined estrogen plus progestin product among healthy postmenopausal women. Also in July 2002, results of an observational study sponsored by the National Cancer Institute ( NCI ) on the effects of estrogen replacement therapy ( ERT ) were announced. The main finding of the study was that postmenopausal women who used ERT for 10 or more years had a higher risk of developing ovarian cancer than women who never used HRT. In October 2002, a significant HRT study being conducted in the United Kingdom was also halted. Our transdermal HRT products differ from the products used in the WHI study and the primary products observed in the NCI and United Kingdom studies. There are, however, no studies comparing the safety of our products against other HRT therapies.

Although the range of consequences of these studies cannot be predicted, it is possible that they could result in a significant permanent decrease in the market for our HRT products, either as physicians withdraw their patients from HRT or as women elect to discontinue HRT on their own. In addition, the market growth that would have been expected if HRT had been found safe and effective for additional indications, such as heart disease, is now unlikely to materialize. In January 2003, the FDA announced that marketers of HRT products, including Novogyne, are required to modify their HRT product labels to include additional safety information and warnings. Among other things, the labels must indicate that HRT should be used for short-term therapy only and that, in the absence of clinical studies demonstrating that HRT products other than the oral product studied in the WHI are safe, physicians should assume that all HRT products carry the same risks. Novartis has informed us that it has submitted proposed revised labeling to the FDA and will begin using the revised label at the time it reaches agreement with the FDA on the language. Healthcare regulators also could delay the approval of new HRT products, such as those presently under development by Novartis AG and us, or require that any new HRT products be subject to more extensive or more rigorous study and testing prior to being approved. Further, because these studies show that certain uses of certain HRT products may result in a higher likelihood of certain adverse health effects, it is possible that we could be named as a defendant in product liability lawsuits relating to our HRT products.

Other studies evaluating HRT are currently underway or in the planning stages. In particular, the estrogen-only arm of the WHI study is ongoing. We are unable to predict the effect of new study results, once available, on the short and long-term prospects for the HRT market or on the market for our transdermal HRT products. Since publication of the WHI and NCI study data, United States prescriptions have declined for substantially all HRT products, including our products, and prescriptions in Europe have also declined. In the first quarter of 2003, total prescriptions for Novogyne ' s HRT products (in the aggregate) were lower than in the fourth quarter of 2002. The WHI safety board re-evaluates the risk/benefit profile of the estrogen-only arm as frequently as twice per year. If the estrogen-only study or any other currently ongoing HRT study is halted, the market for HRT products, including ours, both in the United States and abroad, could be further adversely impacted. The HRT label changes mandated by the FDA may also negatively impact our products, particularly with physicians and patients who now believe that transdermal HRT products are safer than orally delivered HRT products. Currently, our results of operations and business prospects are dependent on sales, license royalties and fees associated with transdermal HRT products. Accordingly, any further adverse change in the market for HRT products (including any adverse changes resulting from the foregoing studies) could have a material adverse impact on our liquidity, results of operations and business prospects.

**MethyPatch®**

We have developed a once-daily transdermal methylphenidate delivery system for the treatment of ADHD, which is intended to be marketed under the trade name MethyPatch®. We filed an NDA with the FDA in June 2002.

In the first quarter of 2003, we signed an agreement to license the exclusive global rights to market MethyPatch® to Shire for payments of up to \$150 million and ongoing manufacturing revenue. Consideration for the transaction is as follows: (a) \$25 million was paid upon closing of the transaction in April 2003; (b) \$50 million is payable upon receipt of final marketing approval for MethyPatch® by the FDA; and (c) 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 MethyPatch®, 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 (a) five years from the closing date or (b) payment of all of the sales milestones.

On the closing date, we entered into a long-term supply agreement under which we will manufacture and supply MethyPatch® 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.

Under the terms of the transaction, we remain responsible for securing final regulatory approval for MethyPatch®. On April 25, 2003, we received a not approvable letter from the FDA relating to our MethyPatch® NDA. A not approvable letter is issued if the FDA believes that the application contains insufficient information for an approval action at the time of issuance. Under the agreement, receipt of the not approvable letter gives Shire the right to require us to repurchase the product rights for \$5 million, but to date Shire has not exercised this right. For accounting purposes, \$20 million of the initial \$25 million payment is expected to be deferred and recognized as revenue over approximately 10 years beginning with the second quarter of 2003. The remaining \$5 million has been deferred and is expected to be recognized as revenue beginning at the time Shire's right to require us to repurchase the product rights expires. However, this accounting treatment would be expected to change if Shire were to exercise its right to require Noven to repurchase the product rights.

The FDA cited clinical and other issues as the basis for non-approval. We are developing a strategy for approval, and plan to meet with the FDA to clarify its concerns and to determine what additional studies, analysis or other actions would resolve the issues raised in the letter. We cannot assure that we will develop a strategy for approval that will be acceptable to the FDA, that we will successfully execute any strategy we develop or that successfully executing any strategy will result in approval. We also cannot assure that any additional requirements imposed by the FDA will not be cost-prohibitive, impair the commercial value of MethyPatch®, or otherwise cause us and/or Shire to elect not to pursue commercialization of the product. Therefore, we cannot assure that MethyPatch® will ever be approved by the FDA or ultimately commercialized.

**Results of Operations***Three months ended March 31, 2003 compared to three months ended March 31, 2002***Revenues:**

Total revenues for the three months ended March 31, 2003 and 2002 are summarized as follows (dollar amounts in thousands):

|   | <b>2003</b> | <b>2002</b> | <b>Percentage<br/>Change</b> |
|---|-------------|-------------|------------------------------|
| Product revenue   | \$ 7,890    | \$ 10,135   | (22%)                        |
| Contract revenue  | 26          | 574         | (95%)                        |
| Royalties   | 1,228       | 1,282       | (4%)                         |
|   | <hr/>       | <hr/>       |                              |
| Product sales   | 9,144       | 11,991      | (24%)                        |
| License revenue   | 881         | 744         | 18%                          |
|   | <hr/>       | <hr/>       |                              |
| Total revenue   | \$ 10,025   | \$ 12,735   | (21%)                        |
|   | <hr/>       | <hr/>       |                              |
| Gross profit (product sales less cost of products sold) | \$ 4,859    | \$ 6,091    | (20%)                        |
|   | <hr/>       | <hr/>       |                              |
| Gross margin (as a percentage of product sales)         | 53%         | 51%         |                              |
|   | <hr/>       | <hr/>       |                              |

The decrease in total revenues for the three months ended March 31, 2003 as compared to the same period in 2002 was primarily attributable to lower sales of Vivelle-Dot® and CombiPatch® to Novogyne and, to a lesser extent, lower sales of Menorest® and Estradot®, partially offset by higher sales of Estalis® to Novartis AG. This decline in revenues reflects the impact of inventory reduction initiatives intended to align inventories for our products with current demand and to a lesser extent, a production issue relating to material supplied by one vendor that caused us to suspend shipments of CombiPatch® to Novogyne. We believe we have resolved this production issue, and have re-commenced shipments of CombiPatch® in the second quarter of 2003.

A further decline in prescriptions of Novogyne's HRT products, whether as a result of the HRT studies, related product label changes, or otherwise, would adversely impact Novogen's future revenues. We are unable to predict the timing or impact of any further decline on future sales and results of operations.

**Gross Margin:**

Our gross margin was 53% (or gross profit of \$4.9 million) for the three months ended March 31, 2003 versus 51% (or gross profit of \$6.1 million) for the three months ended March 31, 2002. The increase in gross margin was primarily due to a decrease in the deferred profit related to sales of product to Novogyne. The decrease in deferred profit on sales to Novogyne resulted from lower inventories at Novogyne as a result of our inventory reduction initiatives and the CombiPatch® production issue. The increase in gross margin was partially offset by lower overhead absorption due to lower production volumes.

**Operating Expenses:**

Operating expenses for the three months ended March 31, 2003 and 2002 are summarized as follows (dollar amounts in thousands):

|                                       | <u>2003</u> | <u>2002</u> | <u>Percentage<br/>Change</u> |
|---------------------------------------|-------------|-------------|------------------------------|
| Research and development              | \$2,493     | \$3,369     | (26%)                        |
| Marketing, general and administrative | 4,181       | 2,933       | 43%                          |

**Research and Development**

The \$0.9 million, or 26%, decrease in research and development expenses for the three months ended March 31, 2003 as compared to the same period in 2002 was primarily attributable to a decrease in clinical study expenses for MethyPatch<sup>®</sup> due to the completion of Phase III clinical trials, partially offset by increases in research and development expenditures for our fentanyl transdermal delivery system.

**Marketing, General and Administrative**

The \$1.2 million, or 43%, increase in marketing, general and administrative expenses for the three months ended March 31, 2003 as compared to the same period in 2002 was primarily attributable to an increase in pre-launch marketing expenses for MethyPatch<sup>®</sup>, increased insurance costs, and legal fees incurred in connection with the Shire transaction.

**Interest Income:**

Interest income, net, decreased approximately \$0.1 million, or 29%, for the three months ended March 31, 2003 as compared to the same period in 2002, primarily due to lower interest rates.

**Income Taxes:**

Our effective tax rate increased to 36.0% for the three months ended March 31, 2003 from 35.6% for the three months ended March 31, 2002. The provision for income taxes is based on the Federal statutory and state income tax rates. Net deferred income tax assets are measured using the average graduated tax rate for the estimated amount of annual taxable income in the years that the liability is expected to be settled or the asset recovered. The effect of adjusting the expected tax rate related to the net deferred income tax assets is included in the provision for income taxes. As of March 31, 2003, we had a net deferred tax asset of \$12.4 million. Realization of this deferred tax asset depends upon the generation of sufficient future taxable income. Although realization is not assured, we believe it is more likely than not that the deferred income tax asset will be realized based upon estimated future taxable income.

**Equity in Earnings of Novogyne:**

We share in the earnings of Novogyne, after satisfaction of an annual preferred return of \$6.1 million to Novartis, according to an established formula. Novogyne produced sufficient income in the first quarters of 2003 and 2002 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 Statements of Operations.

The financial results of Novogyne for the three months ended March 31, 2003 and 2002 are summarized as follows (dollar amounts in thousands):

|  | <u>2003</u> | <u>2002</u> | <u>Percentage<br/>Change</u> |
|--|-------------|-------------|------------------------------|
| <b>Novogyne's Summary Results:</b>           |             |             |                              |
| Revenues                                     | \$ 24,464   | \$ 27,457   | (11%)                        |
| Cost of sales                                | 5,765       | 6,476       | (11%)                        |
| Gross profit                                 | 18,699      | 20,981      | (11%)                        |
| Gross margin percentage                      | 76%         | 76%         |                              |
| Selling, general and administrative expenses | 7,883       | 9,937       | (21%)                        |
| Amortization of intangible assets            | 1,545       | 1,545       |                              |
| Income from operations                       | 9,271       | 9,499       | (2%)                         |
| Interest income                              | 85          | 70          | 21%                          |
| Net income                                   | \$ 9,356    | \$ 9,569    | (2%)                         |
| Noven's equity in earnings of Novogyne       | \$ 1,525    | \$ 1,515    | 1%                           |

Royalties due to us on sales of Vivelle® and Vivelle-Dot® for 2002 have been reclassified from selling, general and administrative expenses to cost of sales to conform to the current year's presentation.

The decrease in Novogyne's revenues of \$3.0 million, or 11%, for the three months ended March 31, 2003 as compared to the same period in 2002 is primarily attributable to decreased sales of Vivelle®. Revenues for the first quarter of 2003 reflect the impact of inventory reduction initiatives intended to align inventories for Novogyne's products with current demand. CombiPatch® sales also decreased due to the continuing effect of the HRT studies described above and, to a lesser extent, the CombiPatch® production issue that we believe has been resolved. The decrease in revenues was partially offset by higher sales of Vivelle-Dot®. Revenues for March 31, 2003 and 2002 are net of sales allowances and returns of \$6.1 million and \$5.2 million, respectively.

Novogyne's gross margin was 76% (or gross profit of \$18.7 million) for the three months ended March 31, 2003 versus 76% (or gross profit of \$21.0 million) for the three months ended March 31, 2002.

Novogyne's selling, general and administrative expenses decreased to \$7.9 million for the three months ended March 31, 2003 from \$9.9 million in 2002, primarily due to lower expenses relating to the promotion of CombiPatch® and lower sample expense in 2003.

Novogyne amortized \$1.5 million related to the CombiPatch® acquisition cost during the three months ended March 31, 2003 and 2002.

**Liquidity and Capital Resources**

As of March 31, 2003 and December 31, 2002, we had \$65.4 million and \$58.7 million in cash and cash equivalents, and working capital of \$65.2 million and \$59.3 million, respectively.

Cash provided by (used in) operating, investing and financing activities for the three months ended March 31, 2003 and 2002 is summarized as follows (amounts in thousands):

|                      | <u>2003</u> | <u>2002</u> |
|----------------------|-------------|-------------|
| Cash flows:          |             |             |
| Operating activities | \$ 9,478    | \$(1,825)   |
| Investing activities | (1,584)     | (230)       |
| Financing activities | (1,174)     | (64)        |

***Operating Activities:***

Net cash provided by operating activities for the three months ended March 31, 2003 primarily resulted from a \$10.6 million distribution from Novogyne, partially offset by changes in working capital due to the timing of product shipments and payments for inventory and income taxes.

Net cash provided by operating activities for the three months ended March 31, 2002 primarily resulted from changes in working capital due to the timing of product shipments and payments for inventory and income taxes.

***Investing Activities:***

Net cash used in investing activities for the three months ended March 31, 2003 and 2002 was primarily attributable to the purchase of fixed assets to expand production capacity and payment of patent development costs.

***Financing Activities:***

Net cash used in financing activities for the three months ended March 31, 2003 was primarily attributable to the repurchase of 105,000 shares of our common stock, partially offset by cash received in connection with the issuance of common stock from the exercise of stock options.

Net cash used in financing activities for the three months ended March 31, 2002 was primarily attributable to the payoff of all borrowings under a master lease facility in March 2002, partially offset by cash 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 license agreements and distributions from Novogyne. In April 2003, Shire paid us \$25 million upon closing of the MethyPatch<sup>®</sup> transaction. For the three months ended March 31, 2003, all of our income before income taxes was comprised of equity in earnings of Novogyne, a non-cash item. Our short-term cash flow is dependent on sales, royalties and license fees associated with transdermal HRT 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 results of the recent or ongoing HRT studies or the pending product label changes), the failure of the transdermal HRT market to resume its prior growth trends, or the inability or failure of Novogyne to pay distributions would have a material adverse effect on our short-term cash flow and require us to rely more heavily on our existing cash reserves or on borrowings to support our operations and business. 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. We cannot assure that MethyPatch<sup>®</sup> will be approved by the FDA, particularly in light of the not approvable letter we received from the FDA in April 2003, or that Shire will generate MethyPatch<sup>®</sup> sales at levels that would trigger our milestone payments; therefore, we cannot assure that we will receive any further payments from Shire. Under the agreement, the not approvable letter gives Shire the right to require us to repurchase the rights to MethyPatch<sup>®</sup> for \$5 million but to date Shire has not exercised that right.

In the first quarter of 2003, our Board of Directors authorized a share repurchase program under which we may acquire up to \$25 million of our common stock. As of March 31, 2003, we had repurchased 105,000 shares of our common stock at an aggregate price of approximately \$1.3 million. Any repurchases of common stock under our share repurchase program could adversely affect our short-term liquidity.

We believe that we will have sufficient cash available to meet our operating needs and anticipated short-term capital requirements. For our long-term operating needs, we intend to utilize funds derived from the above sources, as well as funds generated through sales of products under development or products that we may license or acquire from others. We expect that such funds will be comprised of payments received pursuant to future development and licensing arrangements, as well as direct sales of our own products. We expect that our cash requirements will continue to increase, primarily to fund clinical studies for products under development and for plant and equipment to expand production capacity. 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 is incurred prior to product launch, 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.

We are unable to predict the effect of the results of the discontinued and ongoing HRT studies discussed above on the short and long-term prospects for the HRT market or for the market for our transdermal HRT products. Accordingly, we are not able to predict the effect that those studies may have on our short-term or long-term liquidity, results of operations and business prospects.

To the extent that capital requirements exceed available capital, we will seek alternative sources of financing to fund our operations. We did not extend our credit facility, which expired in April 2003. 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.

**Critical Accounting Policies**

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 Noven's Form 10-K for the year ended December 31, 2002.

**Outlook**

A discussion of the factors that could impact our 2003 financial results is provided below, elsewhere in this Form 10-Q, and under the caption Cautionary Factors that May Have an Impact on Future Results included in Item 7 of our Form 10-K. Other factors, trends, risks and uncertainties unknown to us could also influence our financial results.

**U.S. HRT**

We have inventory management initiatives underway intended to align U.S. HRT inventory with the reduced demand that followed the early termination of the WHI study. We now believe that inventories at Novogyne have been reduced to acceptable levels, and that Vivelle inventories at the trade level remain modestly higher than desired. We expect to conclude our inventory reduction initiatives in the 2003 second quarter.

International HRT

We do not expect international sales to contribute to our growth in 2003 unless Novartis AG launches Estradot® in additional major markets. Estradot® has been launched in Germany and in several other countries, but, according to Novartis AG, significant pricing and reimbursement issues in the remaining major markets, including the United Kingdom, France, Spain and Italy, have to date prevented Novartis AG from launching in those countries. Because of these significant reimbursement and pricing issues and Novartis' lack of success to date in securing a marketing partner in the United Kingdom and France for Estradot®, we do not expect any additional major market launches of Estradot® in the remainder of 2003.

MethyPatch®

In light of our receipt of the FDA not approvable letter for MethyPatch®, we are unable to assure or predict the timing of either product approval or launch, nor can we predict when, if ever, we will receive additional milestone payments or manufacturing revenues from Shire. In addition, we may be required or elect to undertake additional clinical studies or other initiatives, the cost of which could have a material adverse impact on our results of operations.

Summary

For the second quarter of 2003, we expect to report revenues in the \$12.0 million range and earnings per share of \$0.13 to \$0.16, subject to any material changes to our results associated with receipt of the FDA not approvable letter and our response to it.

For the full year, we expect Novogyne's revenues, selling, general and administrative expense and net income to approximate 2002 levels.

We expect Noven's overall HRT business to decline significantly compared to 2002, reflecting (i) the impact of WHI; (ii) our inventory reduction initiatives, which did not affect Noven until 2003; (iii) strong U.S. HRT sales in the first half of 2002, and (iv) lower international sales in 2003 due to launch delays for Estradot® and declines in volume of our other products. We believe Noven's revenues in the second half of 2003 may be lower than the 2003 first half, principally due to expected lower sales of our international products and CombiPatch®.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Noven had no variable rate debt outstanding during the three months ended March 31, 2003. Therefore, changes in interest rates did not affect interest expense, earnings or cash flows in 2003. We cannot predict market fluctuations in interest rates and their impact on any variable rate debt that we may have outstanding from time to time, nor can there be any assurance that fixed rate long-term debt will be available at favorable rates, if at all.

Item 4. Controls and Procedures

Within ninety days prior to the date of this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective in timely alerting them to material information relating to 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 Novogyne's financial, accounting, inventory 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.

PART II. OTHER INFORMATION

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

- 10.1 License Agreement, dated as of April 7, 2003, by and between Noven Pharmaceuticals, Inc. and Shire Pharmaceuticals Ireland Limited (with certain provisions omitted pursuant to Rule 24b-2) (incorporated by reference to Exhibit 10.25 of Noven's Form 10-K for the year ended December 31, 2002) (File No. 0-17254).
- 10.2 Toll Conversion and Supply Agreement, dated as of April 7, 2003, by and between Noven Pharmaceuticals, Inc. and Shire Pharmaceuticals Ireland Limited (with certain provisions omitted pursuant to Rule 24b-2) (incorporated by reference to Exhibit 10.25 of Noven's Form 10-K for the year ended December 31, 2002) (File No. 0-17254).
- 99.1 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
- 99.2 Certification of James B. Messiry, 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

(b) Reports on Form 8-K

On February 28, 2003, Noven filed a current report on Form 8-K relating to the MethyPatch<sup>®</sup> transaction with Shire Pharmaceuticals Group plc.

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.

Date: May 14, 2003

NOVEN PHARMACEUTICALS, INC.

By: /s/ James B. Messiry

James B. Messiry  
Vice President and  
Chief Financial Officer

**Certifications**

Certification of Principal Executive Officer

I, Robert C. Strauss, President, Chief Executive Officer and Chairman of the Board of Noven Pharmaceuticals, Inc., certify that:

- 1) I have reviewed this quarterly report on Form 10-Q of Noven Pharmaceuticals, Inc.;
- 2) Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
- 3) Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
- 4) The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and
  - c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
- 5) The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
- 6) The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ Robert C. Strauss

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Name: Robert C. Strauss  
Title: President, Chief Executive Officer and Chairman of the Board  
Date: May 14, 2003

**Certifications**

Certification of Principal Financial Officer

I, James B. Messiry, Vice President and Chief Financial Officer of Noven Pharmaceuticals, Inc., certify that:

- 1) I have reviewed this quarterly report on Form 10-Q of Noven Pharmaceuticals, Inc.;
- 2) Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
- 3) Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
- 4) The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and
  - c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
- 5) The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
- 6) The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ James B. Messiry

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Name: James B. Messiry  
Title: Vice President and Chief Financial Officer  
Date: May 14, 2003