NOVEN PHARMACEUTICALS INC
Form 10-Q
May 03, 2004

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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, 2004

Commission file number 0-17254

NOVEN PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

| STATE OF DELAWARE | 59-2767632 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification Number) |

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

(Address of principal executive offices) (Zip Code)

(305) 253-5099

(Registrant s telephone number, including area code)

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes [X] 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, 2004 |
|---|---|
| Common stock $.0001 par value | 23,383,112 |

**NOVEN PHARMACEUTICALS, INC.**

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Trademark information: Vivelle, Vivelle Dot, Estalis, Estradot and Menorest are trademarks of Novartis AG or its affiliated companies; CombiPatch is a registered trademark of Vivelle Ventures, LLC; MethyPatch is a registered trademark of Noven Pharmaceuticals, Inc.; 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)

| | 2004 | 2003 |
|---|---|---|
| Revenues: | | |
| Product revenues Novogyne: | | |
| Product sales | $ 5,808 | $ 2,930 |
| Royalties | 890 | 1,231 |
| Total product revenues Novogyne | 6,698 | 4,161 |
| Product revenues third parties | 2,977 | 4,957 |
| Total product revenues | 9,675 | 9,118 |
| License and contract revenues | 1,455 | 907 |
| Net revenues | 11,130 | 10,025 |
| Expenses: | | |
| Cost of products sold | 5,518 | 4,285 |
| Research and development | 2,255 | 2,493 |
| Marketing, general and administrative | 3,904 | 4,181 |
| Total expenses | 11,677 | 10,959 |
| Loss from operations | (547) | (934) |
| Equity in earnings of Novogyne | 637 | 1,525 |
| Interest income, net | 156 | 148 |
| Income before income taxes | 246 | 739 |
| Provision for income taxes | 88 | 266 |
| Net income | $ 158 | $ 473 |

| | | |
|---|---|---|
| Basic earnings per share | $ 0.01 | $ 0.02 |
| Diluted earnings per share | $ 0.01 | $ 0.02 |
| Weighted average number of common shares outstanding: | | |
| Basic | 23,066 | 22,581 |
| Diluted | 24,281 | 22,920 |

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

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**NOVEN PHARMACEUTICALS, INC.**

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

| | March 31, 2004 | December 31, 2003 |
|---|---|---|
| Assets | | |
| Current Assets: | | |
| Cash and cash equivalents | $ 101,942 | $ 83,381 |
| Accounts receivable trade (less allowance for doubtful accounts of $69 in 2004 and $84 in 2003) | 2,392 | 3,809 |
| Accounts receivable Novogyne, net | 5,055 | 6,320 |
| Inventories | 5,289 | 5,200 |
| Net deferred income tax asset, current portion | 6,700 | 6,500 |
| Prepaid income taxes and other current assets | 3,920 | 3,219 |
| | 125,298 | 108,429 |
| Property, plant and equipment, net | 18,651 | 18,354 |
| Other Assets: | | |
| Investment in Novogyne | 22,961 | 28,368 |
| Net deferred income tax asset | 15,585 | 12,175 |
| Patent development costs, net | 2,019 | 1,977 |
| Deposits and other assets | 85 | 181 |
| | 40,650 | 42,701 |
| | $ 184,599 | $ 169,484 |
| Liabilities and Stockholders Equity | | |
| Current Liabilities: | | |
| Accounts payable | $ 5,230 | $ 4,060 |
| Capital lease obligations current portion | 92 | |
| Accrued compensation and related liabilities | 2,501 | 3,734 |
| Other accrued liabilities | 2,000 | 2,090 |
| Deferred contract revenues | 2,153 | 772 |
| Deferred license revenues current portion | 21,614 | 21,112 |
| | 33,590 | 31,768 |
| Long-Term Liabilities: | | |

| | | |
|---|---|---|
| Capital lease obligations | 214 | |
| Deferred license revenues | 33,808 | 28,893 |
| | 67,612 | 60,661 |
| Commitments and Contingencies (Note 11) | | |
| 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 23,382,382 in 2004 and 22,722,060 in 2003 | 2 | 2 |
| Additional paid-in capital | 87,250 | 79,244 |
| Retained earnings | 29,735 | 29,577 |
| | 116,987 | 108,823 |
| | $ 184,599 | $ 169,484 |

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

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**NOVEN PHARMACEUTICALS, INC.**

Condensed Statements of Cash Flows
Three Months Ended March 31,
(in thousands)
(unaudited)

| | 2004 | 2003 |
|---|---|---|
| Cash flows from operating activities: | | |
| Net income | $ 158 | $ 473 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Depreciation and amortization | 588 | 577 |
| Amortization of patent costs | 91 | 82 |
| Amortization of non-competition agreement | 100 | 100 |
| Income tax benefits on exercise of stock options | 2,761 | 6 |
| Deferred income tax (benefit) expense | (3,610) | 77 |
| Recognition of deferred contract revenues | (519) | (26) |
| Recognition of deferred license revenues | (936) | (881) |
| Equity in earnings of Novogyne | (637) | (1,525) |
| Distributions from Novogyne | 6,044 | 10,648 |
| Changes in operating assets and liabilities: | | |
| Decrease in accounts receivable trade, net | 1,417 | 800 |
| Decrease (increase) in accounts receivable Novogyne, net | 1,265 | (1,213) |
| (Increase) decrease in inventories | (89) | 1,472 |
| Increase in prepaid income taxes and other current assets | (701) | (357) |
| Increase in deposits and other assets | (4) | |
| Increase in accounts payable | 1,170 | 1,712 |
| Decrease in accrued compensation and related liabilities | (1,233) | (1,349) |
| Decrease in other accrued liabilities | (90) | (1,283) |
| Increase in deferred contract revenue | 1,900 | 165 |
| Increase in deferred license revenue | 6,500 | |
| Direct expenses incurred in pursuit of MethyPatch® product regulatory approval | (147) | |
| Cash flows provided by operating activities | 14,028 | 9,478 |
| Cash flows from investing activities: | | |
| Purchases of property, plant and equipment, net | (579) | (1,475) |
| Payments for patent development costs | (133) | (109) |
| Cash flows used in investing activities | (712) | (1,584) |
| Cash flows from financing activities: | | |
| Issuance of common stock | 5,245 | 117 |
| Purchase and retirement of common stock | | (1,289) |
| Repayments of notes payable | | (2) |

| | | |
|---|---|---|
| Cash flows provided by (used in) financing activities | 5,245 | (1,174) |
| Net increase in cash and cash equivalents | 18,561 | 6,720 |
| Cash and cash equivalents, beginning of period | 83,381 | 58,684 |
| Cash and cash equivalents, end of period | $101,942 | $65,404 |

*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® and Vivelle Dot® and, effective March 30, 2001, 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 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, 2004, and the results of its operations for the three months ended March 31, 2004 and 2003. 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, 2003 ( Form 10-K ), and in 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, 2004 and 2003 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 2004.

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. RECENT ACCOUNTING PRONOUNCEMENTS:

In December 2003, the Financial Accounting Standards Board ( FASB ) issued Interpretation No. 46R, Consolidation of Variable Interest Entities ( FIN 46 ). This Interpretation of Accounting Research Bulletin 51, Consolidated Financial Statements, addresses consolidation by business enterprises of variable interest entities which have one or both of the following characteristics: (i) the equity investment at risk is not sufficient to permit

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the entity to finance its activities without additional subordinated financial support from other parties, which is provided through other interests that will absorb some or all of the expected losses of the entity, and (ii) the equity investors lack one or more of the characteristics of a controlling financial interest. This interpretation applies immediately to variable interest entities created after January 31, 2003, and to variable interest entities in which an enterprise obtains an interest after that date. It applies no later than the first reporting period ending after March 15, 2004 to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. Noven s investment in Novogyne is not considered a variable interest in a Variable Interest Entity ( VIE ) under the provisions of FIN 46. Therefore, the consolidation and disclosure rules of FIN 46 are not applicable to Noven and Noven does not expect any impact on its financial statements from adopting this interpretation. These conclusions are based on currently available information and require Noven to assess its investment interest and ownership rights in Novogyne. If Noven s conclusions or underlying assumptions of factual information concerning its investment in Novogyne were to change, Novogyne may be considered a VIE and Noven s investment in Novogyne could become subject to the consolidation and disclosure rules of FIN 46. In that case, a determination would have to be made as to the primary beneficiary of Novogyne s interest. The primary beneficiary would then consolidate Novogyne. Noven believes that, even if a determination were made that Novogyne was a VIE at March 31, 2004, Novartis is the primary beneficiary due to its preferred return and 51% equity interest in Novogyne and would continue to consolidate Novogyne.

4. RECLASSIFICATIONS:

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

5. INVENTORIES:

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

| | March 31, 2004 | December 31, 2003 |
|---|---|---|
| Finished goods | $1,178 | $ 806 |
| Work in process | 1,696 | 1,722 |
| Raw materials | 2,415 | 2,672 |
| Total | $5,289 | $5,200 |

6. 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, 2004 and 2003 if Noven had applied the fair value recognition provisions of SFAS 123, as amended by SFAS 148 (in thousands, except per share amounts):

| | 2004 | 2003 |
|---|---|---|
| Net income (loss): | | |
| As reported | $ 158 | $ 473 |
| Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects | (740) | (1,176) |
| Pro forma | $ (582) | $ (703) |
| Basic earnings (loss) per share: | | |
| As reported | $ 0.01 | $ 0.02 |
| Pro forma | $(0.03) | $ (0.03) |
| Diluted earnings (loss) per share: | | |
| As reported | $ 0.01 | $ 0.02 |
| Pro forma | $(0.02) | $ (0.03) |

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 ended March 31, 2004 and 2003, 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.

7. CASH FLOW INFORMATION:

Cash payments for income taxes were $2.9 million and $1.3 million for the three months ended March 31, 2004 and 2003, respectively. Cash payments for interest were not material for the three months ended March 31, 2004 and 2003.

*Non-cash Investing Activities*

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

8. LICENSE AND CONTRACT AGREEMENTS:

*Endo License of Fentanyl Patch*

On February 25, 2004, Noven licensed its developmental generic fentanyl patch to Endo Pharmaceuticals Inc. ( Endo ). Noven s fentanyl patch is intended to be the generic equivalent of Johnson & Johnson s Duragesic® fentanyl patch.

Noven received an $8.0 million non-refundable up-front payment from Endo on signing. Upon Endo s first commercial sale of the fentanyl patch, Noven is entitled to receive an

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additional payment ranging from $5.0 million to $10.0 million, depending on the timing of launch and the number of generic fentanyl competitors in the market. Noven will manufacture and supply the product at its cost and will share in Endo s profit from net product sales.

Based on the current patent and exclusivity status of Johnson & Johnson s Duragesic patch, Noven believes that the earliest its generic fentanyl patch could be launched is January 2005, assuming Food and Drug Administration ( FDA ) approval is received by that time, but Noven cannot assure that it will receive FDA approval by that time or at all. Noven and Endo may elect to manufacture launch supplies prior to receipt of tentative FDA approval. If launch supplies are manufactured and approval is not ultimately received or is delayed, the agreement provides that Noven and Endo will share the cost of manufacturing product that cannot be sold by Endo in accordance with an agreed-upon formula. However, in that case, Noven would not be able to offset all of its up-front production costs with sales of the product. If the product has not been approved or Noven has not supplied Endo s launch requirements by May 2005, Endo may have the right to terminate the license, depending on the number of generic competitors in the market.

In addition to the fentanyl license, Noven has established a collaboration with Endo to identify and develop new transdermal therapies. Of the $8.0 million up-front payment, $1.5 million has been allocated to fund feasibility studies to determine whether certain compounds identified by the parties can be delivered using Noven s transdermal technology. Noven believes the $1.5 million represents the fair value of such services. 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 revenues over a 10-year period, which is the estimated product life cycle. The remaining $1.5 million is expected to be recognized as revenues over the course of feasibility development of any additional patches developed under the Noven/Endo collaboration.

*P&G Pharmaceuticals Contract*

In April 2003, Noven established a collaboration with P&G Pharmaceuticals, Inc. ( P&GP ), a subsidiary of The Procter & Gamble Company, for the development of new prescription patches. The products under development explore follow-on product opportunities for Intrinsa™, P&GP s in-licensed investigational transdermal testosterone patch designed to help restore desire in menopausal women who have Hypoactive Sexual Desire Disorder. P&GP has initiated studies of the first product in humans. In the first quarter of 2004, Noven received and recognized as contract revenues a $0.4 million development milestone under this collaboration. Potential development milestones totaling $4.4 million remain to be received under the P&GP collaboration, a portion of which is expected to be received in the remainder of 2004.

9. 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 2004 and 2003 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, 2004 and 2003, Noven had the following transactions with Novogyne (in thousands):

| | 2004 | 2003 |
|---|---|---|
| Revenues: | | |
| Product sales | $5,808 | $2,930 |
| Royalties | 890 | 1,231 |
| | $6,698 | $4,161 |
| Reimbursed expenses | $6,289 | $6,183 |

As of March 31, 2004 and December 31, 2003, Noven had amounts due from Novogyne of $5.1 million and $6.3 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, 2004 and 2003 are as follows (in thousands):

| | 2004 | 2003 |
|---|---|---|
| Gross revenues | $25,134 | $30,592 |
| Sales allowances | 2,772 | 3,464 |
| Sales return allowances | 1,009 | 2,664 |
| Sales allowances and returns | 3,781 | 6,128 |
| Net revenues | 21,353 | 24,464 |
| Cost of sales | 4,835 | 5,765 |
| Selling, general and administrative expenses | 7,625 | 7,883 |
| Amortization of intangible assets | 1,545 | 1,545 |
| Income from operations | 7,348 | 9,271 |
| Interest income | 40 | 85 |
| Net income | $ 7,388 | $ 9,356 |

| | | |
|---|---|---|
| Noven s equity in earnings of Novogyne | $ 637 | $ 1,525 |

The activity in the Investment in Novogyne account for the three months ended March 31, 2004 is as follows (in thousands):

| | |
|---|---|
| Investment in Novogyne, beginning of period | $28,368 |
| Equity in earnings of Novogyne | 637 |
| Cash distributions from Novogyne | (6,044) |
| Investment in Novogyne, end of period | $22,961 |

Subject to the approval of Novogyne s management committee, cash may be distributed to Novartis and Noven based upon a contractual formula. For the three months ended March 31, 2004 and 2003, Noven received distributions of $6.0 million and $10.6 million from Novogyne,

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respectively. These amounts were recorded as reductions in the investment in Novogyne when deemed received.

10. 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 a result, Noven had repurchased 105,000 shares of its common stock at an aggregate price of approximately $1.3 million during the three months ended March 31, 2003. These shares were retired on March 31, 2003. No shares were repurchased during the three months ended March 31, 2004.

11. 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 followed by publication in 2002 and 2003 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 of 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. This arm of the WHI study also found that the use of an estrogen-only oral formulation appeared to decrease the risk of hip fracture, and did not appear to affect heart disease or to increase the risk of breast cancer. 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®, our 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*

In 2003, Noven s product stability testing program revealed that certain lots of CombiPatch and Vivelle Dot patches did not maintain required specifications throughout the products shelf lives, resulting in product recalls.

The CombiPatch stability failures resulted from a production issue related to a problematic raw material supplied by one vendor. After addressing the issues with the specific raw material, Noven continues to manufacture and ship CombiPatch to Novogyne and there was no interruption of trade supplies.

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Based on results of Noven s testing and analysis to date, Noven believes the probable cause of the Vivelle Dot production issue related to the use of certain rolls of patch backing material provided by a raw material supplier. Based on this testing and analysis, Noven further believes that the Vivelle Dot product that is currently in distribution and in its inventory will maintain required stability. If the root cause determination or additional testing indicates that the production issue affects more product than Noven s current testing and analysis suggests, additional recalls may be required. If Noven s estimate concerning the scope of, or amount of, the product returns is incorrect or if Novartis should initiate further unexpected recalls, then Noven s results of operations could be materially different.

*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. Failure to extend the agreement or to continue to operate under the agreement s commercial terms could have a material adverse effect on Noven s financial position and results of operations.

*Litigation, Claims and Assessments*

On August 7, 2003, an individual filed a lawsuit on behalf of a purported class of purchasers of Noven s common stock during the period from October 29, 2001 through April 28, 2003. The complaint alleges that, during the subject period, Noven and its officers named as defendants violated the Securities Exchange Act of 1934 by making false and misleading statements in its public disclosures regarding Noven s MethyPatch product. Following the filing of Plaintiff s complaint, five other substantially similar complaints were filed against Noven and its officers named as defendants in the above referenced action. In response to a joint motion, on or about January 6, 2004, the Court entered an order consolidating the six related actions. Pursuant to this order, plaintiffs must file a consolidated class action complaint not later than 60 days after the entry of an order appointing lead plaintiff and lead counsel. An order appointing lead plaintiff and lead counsel has not yet been entered. This development did not have a material effect on the action or on Noven s financial position or results of operations.

Noven believes the lawsuit is without merit, and intends to vigorously defend the lawsuit, but its outcome cannot be predicted. The lawsuit, if determined adversely to Noven, could have a material adverse effect on Noven s financial position and results of operations. Noven s ultimate liability, if any, with respect to the lawsuit is presently not determinable.

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.

*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.

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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, 2004, and the results of operations for the three months then ended. The contents of this section include:

An overview of Noven and:

- the license of our fentanyl patch to Endo during the first quarter of 2004,
- our collaboration with P&G Pharmaceuticals, and
- MethyPatch®, our methylphenidate patch for the treatment of ADHD;

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

A review of recent accounting pronouncements;

An outlook that includes our current financial guidance and certain factors that we believe may influence our financial results for the remainder of 2004; and

A discussion of forward-looking statements used in this report and a summary 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, 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, 2003.

**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 ( HT ). In the United States, our HT products are marketed and sold by Novogyne, the joint venture that we formed with Novartis in 1998. In all countries other than the United States, Canada and Japan, our HT products are marketed and sold by Novartis Pharma AG ( Novartis Pharma ), an affiliate of Novartis. 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.

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 discontinuation of the combined arm of the WHI study) to the first quarter of 2004, total prescriptions dispensed in the HT market in the United States declined by 45%. For the same period, aggregate prescriptions for Noven s United States products decreased 15%. The estrogen segment of the HT market in the United States declined 39%, while our Vivelle product family decreased 8%. Vivelle Dot, which represented 75% of our total United States prescriptions in the first quarter of 2004, increased 8% from the second quarter of 2002 to the first quarter of 2004. We believe Vivelle Dot patch prescriptions have benefited from patient conversions from original Vivelle. At the end of the first quarter of 2004, the Vivelle family held a 41% share of total estrogen patch prescriptions, compared to a 35% share at the end of the second quarter of 2002. Our Vivelle Dot estrogen patch is currently the most frequently dispensed estrogen patch in the United States. We believe this is due in

part to the beneficial wear characteristics made possible by our technology.

United States prescriptions for our CombiPatch product (which represented approximately 15% of our total United States prescriptions in the first quarter of 2004) declined 40% from the second quarter of 2002 to the first quarter of 2004, while prescriptions for the total United States market for fixed combination hormone therapy declined 60%. The combination therapy arm of WHI involved an

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oral combination estrogen/progestin product and, accordingly, that segment of the HT market has experienced the most significant decline. As noted above, prescriptions for our CombiPatch combination estrogen/progestin patch, like most combination HT therapies, have declined significantly since WHI. Further declines for our CombiPatch product could require Novogyne (which holds the CombiPatch marketing rights) to record an impairment loss related to the these marketing rights, which would harm both our and Novogyne s results of operations.

*Endo*

An important part of our business strategy is to seek to diversify our product offerings beyond the HT market through strategic collaborations and new product developments. On February 25, 2004, we licensed our developmental generic fentanyl patch to Endo. Our fentanyl patch is intended to be the generic equivalent of Johnson & Johnson s Duragesic® fentanyl patch.

We received an $8.0 million non-refundable up-front payment from Endo on signing. Upon Endo s first commercial sale of the fentanyl patch, we are entitled to receive an additional payment ranging from $5.0 million to $10.0 million, depending on the timing of launch and the number of generic fentanyl competitors in the market. We will manufacture and supply the product at our cost and will share in Endo s profit from product sales.

Based on the current patent and exclusivity status of Johnson & Johnson s Duragesic® patch, we believe that the earliest our generic fentanyl patch could be launched is January 2005, assuming FDA approval is received by that time, but we cannot assure that we will receive FDA approval by that time or at all. Noven and Endo may elect to manufacture launch supplies prior to receipt of tentative FDA approval. If launch supplies are manufactured and approval is not ultimately received or is delayed, the agreement provides that Noven and Endo will share the cost of manufacturing product that cannot be sold by Endo in accordance with an agreed-upon formula, but we would be unable to offset all of our up-front production costs with sales of the product. If the product has not been approved or we have not supplied Endo s launch requirements by May 2005, Endo may have the right to terminate the license, depending on the number of generic competitors in the market.

In addition to the fentanyl license, we have established a collaboration with Endo to seek to identify and develop new transdermal therapies. Of the $8.0 million up-front payment, $1.5 million will be allocated to fund feasibility studies to determine whether certain compounds identified by the parties can be delivered using our transdermal 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 revenues over a 10-year period, which is the estimated product life cycle. The remaining $1.5 million is expected to be recognized as revenues over the course of feasibility development of any additional patches developed under the Noven/Endo collaboration.

*P&G Pharmaceuticals*

In April 2003, we established a collaboration with P&G Pharmaceuticals, Inc. ( P&GP ), a subsidiary of The Procter & Gamble Company, for the development of new prescription patches. The products under development explore follow-on product opportunities for Intrinsa™, P&GP s in-licensed investigational transdermal testosterone patch designed to help restore desire in menopausal women who have Hypoactive Sexual Desire Disorder. P&GP has initiated studies of the first product in humans. In the first quarter of 2004, Noven received and recognized as contract revenues a $0.4 million development milestone under this collaboration. Potential development milestones totaling $4.4 million remain to be received under the P&GP collaboration, a portion of which is expected to be received in the remainder of 2004.

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*Shire*

In April 2003, we received a not approvable letter from the FDA relating to our MethyPatch New Drug Application ( NDA ). Together with Shire, we have been in dialogue with the FDA regarding our strategy to address the clinical risk-benefit and other issues raised in the not approvable letter, and we expect to meet with the FDA in the second quarter of 2004 in this regard. Assuming we can reach agreement with the FDA on an appropriate strategy, Noven and Shire expect to undertake additional MethyPatch clinical studies during 2004. Noven has committed to fund the additional studies. Noven s direct costs incurred in pursuit of approval are expected to be deferred and offset against a portion of the $25 million deferred revenue previously received from Shire, and therefore such expenses are not expected to impact our research and development expenses in 2004. It is possible that we will not reach agreement with the FDA on an appropriate strategy, development will not be completed and/or that our MethyPatch product will not be approved or launched, and we may not receive additional milestone payments or manufacturing revenues from Shire.

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**Results of Operations**

**Three months ended March 31, 2004 compared to the three months ended March 31, 2003**

***Revenues***

Total revenues for the three months ended March 31, 2004 and 2003 are summarized as follows (dollar amounts in thousands):

| | 2004 | 2003 | % Change |
|---|---|---|---|
| Product revenues Novogyne: | | | |
| Product sales | $ 5,808 | $ 2,930 | 98% |
| Royalties | 890 | 1,231 | (28%) |
| | 6,698 | 4,161 | 61% |
| Product revenues third parties: | | | |
| Product sales | 2,838 | 4,960 | (43%) |
| Royalties | 139 | (3) | |
| | 2,977 | 4,957 | (40%) |
| Total product revenues | 9,675 | 9,118 | 6% |
| License and contract revenues: | | | |
| Contract | 519 | 26 | |
| License | 936 | 881 | 6% |
| | 1,455 | 907 | 60% |
| Net revenues | $11,130 | $10,025 | 11% |

Net Revenues

As described in more detail below, the increase in total revenues for the three months ended March 31, 2004 as compared to the same period in 2003 was primarily attributable to higher unit sales for our U.S. products and an increase in our contract revenue due to the attainment of certain product development milestones in the current period. These increases were partially offset by a decline in unit sales for our international products.

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 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 $2.5 million increase in product revenues from Novogyne for the three months ended March 31, 2004 as compared to the same period in the prior year primarily relates to $1.7 million in higher unit sales for Vivelle Dot. This increase is primarily due to lower sales in the prior period as a result of the impact of inventory reduction initiatives intended to align inventories with post-WHI demand.

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Product Revenues Third Parties

Product revenues third parties substantially consists of sales of Menorest, Estradot and Estalis to Novartis Pharma at a price based on a percentage of the licensee 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 $2.0 million decline in product revenues from third parties for the three months ended March 31, 2004 as compared to the same period in the prior year primarily relates to $1.6 million in lower unit sales of Estalis. The decline in Estalis reflects lower prescription trends following the publication of the WHI study.

License and Contract Revenues

The increase in contract revenues for the three months ended March 31, 2004 as compared to the same period in the prior year is primarily attributable to the attainment of certain product development milestones and the completion of certain product development contracts in the current period. The increase in license revenues for the three months ended March 31, 2004 as compared to the same period in the prior year is due to the recognition of license revenue in connection with the Endo transaction.

***Gross Margin***

Gross margin for the three months ended March 31, 2004 and 2003 are summarized as follows (dollar amounts in thousands):

| | **2004** | **2003** |
|---|---|---|
| Total product revenues | $9,675 | $9,118 |
| Gross profit (product revenues less cost of products sold) | 4,157 | 4,833 |
| Gross margin (gross profit as a percentage of product revenues) | 43% | 53% |

The decline in gross margin for the three months ended March 31, 2004 as compared to the same period in the prior year is primarily due to an increase of $1.1 million in the deferred profit related to sales of product to Novogyne. We defer 49% of the profit on product we sell to Novogyne until that product is sold by Novogyne to trade customers. As a result, if Novogyne sells more product than we provide it in a given period (i.e. if Novogyne s inventories decline), we will defer less profit from Novogyne, which increases our gross margins. The increase in deferred profit on sales to Novogyne for the current period compared to the prior period reflects Novogyne s inventory reduction initiatives in the prior period. That initiative reduced Novogyne s inventories at the end of the prior period and, consequently, caused a reduction in our costs of products sold and thus increased the gross margin in the prior period.

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***Operating Expenses***

Operating expenses for the three months ended March 31, 2004 and 2003 are summarized as follows (dollar amounts in thousands):

| | 2004 | 2003 | % Change |
|---|---|---|---|
| Research and development | $2,255 | $2,493 | (10%) |
| Marketing, general and administrative | 3,904 | 4,181 | (7%) |

Research and Development

The $0.2 million decline in research and development expenses for the three months ended March 31, 2004, as compared to the same period in 2003 was primarily attributable to a decrease in development expenses for our MethyPatch product. We licensed MethyPatch to Shire in April 2003 at which time Shire assumed certain development expenses for this product.

Marketing, General and Administrative

The $0.3 million decrease in marketing, general and administrative expenses for the three months ended March 31, 2004 as compared to the same period in 2003 was primarily attributable to a $0.9 million reduction in costs due to the elimination of pre-launch marketing expenses for MethyPatch, which ceased the second quarter of 2003 as a result of license of MethyPatch to Shire Pharmaceuticals Group plc, partially offset by $0.4 million of increased compensation costs, $0.2 million of increased consulting and professional fees primarily related to new requirements resulting from Sarbanes-Oxley, and $0.2 million of increased insurance costs.

***Income Taxes***

Our effective tax rate was approximately 36% for each of the three months ended March 31, 2004 and 2003. 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, 2004, we had a net deferred tax asset of $22.3 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, up to 49%, 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 2004 and 2003 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.

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The financial results of Novogyne for the three months ended March 31, 2004 and 2003 are summarized as follows (dollar amounts in thousands):

| | 2004 | 2003 | % Change |
|---|---|---|---|
| Gross revenues[1] | $25,134 | $30,592 | (18%) |
| Sales allowances | 2,772 | 3,464 | (20%) |
| Sales returns allowances | 1,009 | 2,664 | (62%) |
| Sales allowances and returns | 3,781 | 6,128 | (38%) |
| Net revenues | 21,353 | 24,464 | (13%) |
| Cost of sales | 4,835 | 5,765 | (16%) |
| Gross profit | 16,518 | 18,699 | (12%) |
| Gross margin percentage | 77% | 76% | |
| Selling, general and administrative expenses | 7,625 | 7,883 | (3%) |
| Amortization of intangible asset | 1,545 | 1,545 | |
| Income from operations | 7,348 | 9,271 | (21%) |
| Interest income | 40 | 85 | (53%) |
| Net income | $ 7,388 | $ 9,356 | (21%) |
| Noven s equity in earnings of Novogyne | $ 637 | $ 1,525 | (58%) |

[1]Novogyne s gross revenues, which are calculated by adding sales allowances and sales returns allowances to net revenues, is 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

Gross revenues decreased for the three months ended March 31, 2004 compared to the prior year, primarily due to $2.2 million in decreased sales of Vivelle and $5.4 million in decreased sales of Vivelle Dot. Vivelle is in a declining trend due to product maturity. Since underlying prescriptions were relatively consistent from period to period, we

believe the decline in Vivelle Dot is related to the timing of orders from trade customers. The decrease was partially offset by a $2.0 million increase in sales of Estradot to Canada primarily due to the timing of orders. Price changes were not a significant factor from quarter to quarter.

Sales allowances consist of chargebacks, Medicaid rebates, managed healthcare rebates, cash discounts and other allowances, which tend to fluctuate based on changes in gross revenues. These sales allowances were 11% of gross revenues for each of the three months ended March 31, 2004 and 2003. The declines in sales returns allowances for the three months ended March 31, 2004 compared to the prior year were attributable to higher returns of Vivelle Dot in the prior period.

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Novogyne Gross Margin

The increase in gross margin for the three months ended March 31, 2004 as compared to the prior period was primarily due to lower sales allowances and returns, which increased net revenues without affecting cost of goods sold.

Novogyne Selling, General and Administrative Expenses

There were no material fluctuations in selling, general and administrative expenses for the three months ended March 31, 2004.

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, 2004 and 2003. Our CombiPatch product was licensed by Novogyne in March 2001.

**Liquidity and Capital Resources**

As of March 31, 2004 and December 31, 2003, we had $101.9 million and $83.4 million in cash and cash equivalents, and working capital of $91.7 million and $76.7 million, respectively.

Cash provided by (used in) operating, investing and financing activities for the three months ended March 31, 2004 and 2003 is summarized as follows (amounts in thousands):

| | 2004 | 2003 |
|---|---|---|
| Cash flows: | | |
| Operating activities | $14,028 | $ 9,478 |
| Investing activities | (712) | (1,584) |
| Financing activities | 5,245 | (1,174) |

***Operating Activities***

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

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 and amount 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, 2004 and 2003 was primarily attributable to the purchase of fixed assets to expand production capacity for future products and payment of patent development costs.

***Financing Activities***

Net cash provided by financing activities for the three months ended March 31, 2004 was primarily attributable to $5.2 million received in connection with the issuance of common stock from the exercise of stock options.

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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.

***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, 2004, all of our income before income taxes was comprised of equity in earnings of Novogyne, a non-cash item. 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. In February 2004, Endo paid us $8.0 million upon closing of the fentanyl patch licensing transaction.

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 recent or ongoing 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.

We also expect our funding of any additional studies for our MethyPatch product will have a negative impact on our short-term liquidity. We cannot assure that MethyPatch will be approved by the FDA, particularly in light of the not approvable letter we received from the FDA in April 2003, or that, even if approved, Shire will generate MethyPatch product sales at levels that would trigger our milestone payments; therefore, we cannot assure that we will receive any further payments from Shire. Our short-term liquidity may also be adversely affected in 2004 prior to the launch of our transdermal fentanyl system as we expect to incur new and additional expenses and capital expenditures during 2004 related to the manufacture of the new product as well as the cost for pre-launch inventories. However, we cannot assure that we will recover all or any portion of these expenditures in our expected time-frame or at all.

We believe that we will have sufficient liquidity available to meet our operating needs and anticipated short-term capital requirements. For our long-term operating needs, we intend to utilize funds derived from the above sources, as well as funds generated through sales of products under development or products that we may license or acquire from others. We expect that such funds will be comprised of payments received pursuant to future development and licensing arrangements, as well as 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 for new products. We cannot assure that we will successfully complete the development of such products, that we will obtain regulatory approval for any such products, that any approved product may be produced in commercial quantities, at reasonable costs, and be successfully marketed, or that we will successfully negotiate future licensing or product acquisition arrangements. Because much of the cost associated with product development 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.

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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.

**Recent Accounting Pronouncements**

In December 2003, the FASB issued Interpretation No. 46R, Consolidation of Variable Interest Entities ( FIN 46 ). This Interpretation of Accounting Research Bulletin 51, Consolidated Financial Statements, addresses consolidation by business enterprises of variable interest entities which have one or both of the following characteristics: (i) the equity investment at risk is not sufficient to permit the entity to finance its activities without additional subordinated financial support from other parties, which is provided through other interests that will absorb some or all of the expected losses of the entity, and (ii) the equity investors lack one or more of the characteristics of a controlling financial interest. This interpretation applies immediately to variable interest entities created after January 31, 2003, and to variable interest entities in which an enterprise obtains an interest after that date. It applies no later than the first reporting period ending after March 15, 2004 to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. Our investment in Novogyne is not considered a variable interest in a Variable Interest Entity ( VIE ) under the provisions of FIN 46. Therefore, the consolidation and disclosure rules of FIN 46 are not applicable to us and we do not expect any impact on our financial statements from adopting this interpretation. These conclusions are based on currently available information and require us to assess our investment interest and ownership rights in Novogyne. If our conclusions or our underlying assumptions of factual information concerning our investment in Novogyne were to change, Novogyne may be considered a VIE and our investment in Novogyne could become subject to the consolidation and disclosure rules of FIN 46. In that case, a determination would have to be made as to the primary beneficiary of Novogyne s interest. The primary beneficiary would then consolidate Novogyne. We believe that, even if a determination were made that Novogyne was a VIE at March 31, 2004, Novartis is the primary beneficiary due to its preferred return and 51% equity interest in Novogyne and would continue to consolidate Novogyne.

**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 our Form 10-K for the year ended December 31, 2003.

**Outlook**

A summary of our current financial guidance and outlook for 2004 is provided below. This information is based on our current assumptions and expectations, many of which are beyond our control to achieve. This information is also premised on our current assumption that during 2004 there will not be any unforeseen material:

transactions;

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

regulatory or clinical study developments;

changes in the supply of, demand for, or distribution of our HT products (including any changes resulting from the impact of competitive HT products that we expect others to launch in 2004);

changes in our business relationships/collaborations; or

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changes in the economy or the health care sector generally.

If our assumptions or expectations concerning these matters prove to be incorrect, our actual financial results could differ materially from the expected results discussed below. Accordingly, we cannot assure that we will achieve results consistent with this guidance. For a discussion of these and other factors that may impact our actual financial results for 2004, we refer you to the risks, uncertainties and cautionary factors discussed below under the caption Cautionary Factors that May Impact Future Results as well as those discussed in our Form 10-K for the year ended December 31, 2003.

For full-year 2004, we currently expect:

Noven s net revenues to approximate 2003 results;

Noven s research and development spending in 2004 to increase compared to 2003;

Noven s fully diluted earnings per share to be in the $0.40 to $0.45 range; and

Novogyne s 2004 net revenues and net income to approximate 2003 results.

Novogyne s operating results are expected to fluctuate by quarter during 2004 in part due to the timing of orders placed by trade customers. We expect that Novogyne s 2004 second quarter contribution to Noven s profit will be higher than in the 2004 first quarter, due in part to the satisfaction in the first quarter of a $6.1 million preferred return to Novartis under the joint venture agreements, and to the timing of orders placed by trade customers, which we believe had a negative impact on Novogyne s 2004 first quarter sales.

In the first quarter of 2004, we received and recognized as contract revenues a $0.4 million development milestone under our collaboration with P&GP. Potential development milestones totaling $4.4 million remain to be received under the P&GP collaboration, a portion of which is expected to be received in the remainder of 2004.

We expect that Noven and Shire will meet with the FDA during the second quarter of 2004 to address the clinical risk-benefit and other issues raised in the FDA s not approvable letter relating to our MethyPatch New Drug Application. If we can reach agreement with the FDA on an appropriate strategy, we expect to undertake additional MethyPatch clinical studies during 2004. Under our agreement with Shire, we have committed to fund any additional studies, and we expect to defer and offset our direct costs incurred in any additional studies against a portion of the $25 million deferred revenue that we previously received from Shire. As a result, we do not expect any MethyPatch clinical study expenses to impact our research and development expenses in 2004. If we do not reach an agreement with the FDA on an appropriate strategy, or if development is not successfully completed, or if MethyPatch is not approved or launched, we will not receive additional milestone payments or manufacturing revenues from Shire.

Based on the current patent and exclusivity status of Johnson & Johnson s Duragesic fentanyl patch, we believe that the earliest our generic fentanyl patch (licensed to Endo) could be launched in the United States is January 2005, assuming FDA approval is received by that time, but we cannot assure that we will receive FDA approval by that time or at all. In addition to the fentanyl license, we have established a collaboration with Endo to seek to identify and develop new transdermal therapies and we expect to undertake feasibility studies for selected compounds in 2004. Of the $8.0 million received from Endo at closing of the fentanyl license, $6.5 million will be recognized as revenues over a 10-year period, which is the estimated product life cycle. The remaining $1.5 million will be recognized as revenues over the course of feasibility development of any additional patches developed under the Noven/Endo collaboration.

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**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 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, 2003, 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:

*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; and the European HT market may be limited due to pricing pressures and delayed Estradot launches in certain countries due to labeling issues.

*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; and 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.

*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; 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

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increase the cost of advancing those projects; risks related to our dependence on Novartis to perform Novogyne s financial, accounting, inventory, distribution 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; 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.

*MethyPatch,* the risk that the FDA may determine that our proposed protocols and/or proposed clinical strategies are not acceptable or do not address the FDA s concerns regarding the approval of the MethyPatch product NDA; the possibility that additional MethyPatch product studies may not be commenced in a timely manner or at all due to FDA concerns or otherwise; Shire s control over the management of any additional MethyPatch product clinical trials, including the risk that Shire may elect to manage any such studies differently than we might have, incorrectly or inadequately; the possibility that any additional studies of MethyPatch will not produce results that support approval or that, even if the additional studies are completed and are successful, MethyPatch may not ultimately be approved or commercialized; the availability of non-stimulant or other once-daily ADHD therapies could negatively impact market penetration of MethyPatch; the possibility that the cost of any additional MethyPatch product study and related expenses may be higher than anticipated and may exceed the total amount of license revenues available to offset such costs and expenses; the possibility that our method of accounting for the $25 million received from Shire could change under certain circumstances, including if the parties MethyPatch product strategy changes or if our MethyPatch product 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 MethyPatch product were not ultimately approved or were abandoned.

*Fentanyl Patch,* the risks and uncertainties associated with the FDA s review of Noven s fentanyl Abbreviated New Drug Application; 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 fentanyl patches prior to product launch if FDA approval is not obtained on a timely basis or at all; and 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.

*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.

## 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, 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

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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.

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.

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PART II. OTHER INFORMATION

Item 2. Changes in Securities and Use of Proceeds

The following table provides information with respect to our stock repurchases during the first quarter of 2004:

| | Total Number of Shares Purchased | Average Price Paid Per Share | Total Number of Shares Purchased as Part of Publicly Announced Program | Approximate Dollar Value That May Yet be Purchased under the Program(1) |
|---|---|---|---|---|
| January 1, 2004 to January 31, 2004 | | | | $23,711,040 |
| February 1, 2004 to February 29, 2004 | | | | $23,711,040 |
| March 1, 2004 to March 31, 2004 | | | | $23,711,040 |
| Totals | | | | $23,711,040 |

(1) In March 2003, we announced a stock repurchase program authorizing the buy back of up to $25 million of our Common Stock. There is no expiration date specified for this program.

Item 6. Exhibits and Reports on Form 8-K

(a) 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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(b) Reports on Form 8-K

During the three months ended March 31, 2004, we filed one report on Form 8-K on February 26, 2004, Item 5. Other Events with respect to a license agreement that we entered into with Endo Pharmaceuticals Inc.

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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 3, 2004

By: /s/ Diane M. Barrett

Diane M. Barrett
Vice President and
Chief Financial Officer