NOVEN PHARMACEUTICALS INC
Form 10-Q
August 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 June 30, 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 o.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes x No o.

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 July 28, 2004
Common stock $.0001 par value	23,404,157

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 and Six Months Ended June 30,
(in thousands, except per share amounts)
(unaudited)

	Three Months		Six Months	
	2004	**2003**	**2004**	**2003**
Revenues:				
Product revenues Novogyne:				
Product sales	$ 4,886	$ 6,086	$10,694	$ 9,016
Royalties	1,608	968	2,498	2,199
Total product revenues Novogyne	6,494	7,054	13,192	11,215
Product revenues third parties	3,564	3,786	6,541	8,743
Total product revenues	10,058	10,840	19,733	19,958
License and contract revenues	1,897	1,421	3,352	2,328
Net revenues	11,955	12,261	23,085	22,286
Expenses:				
Cost of products sold	4,975	6,040	10,493	10,325
Research and development	2,734	2,154	4,989	4,647
Marketing, general and administrative	3,762	3,293	7,666	7,474
Total expenses	11,471	11,487	23,148	22,446
Income (loss) from operations	484	774	(63)	(160)
Equity in earnings of Novogyne	8,228	3,795	8,865	5,320
Interest income, net	184	198	340	346

Income before income taxes	8,896	4,767	9,142	5,506
Provision for income taxes	3,218	1,717	3,306	1,983
Net income	$ 5,678	$ 3,050	$ 5,836	$ 3,523
Basic earnings per share	$ 0.24	$ 0.14	$ 0.25	$ 0.16
Diluted earnings per share	$ 0.23	$ 0.13	$ 0.24	$ 0.15
Weighted average number of common shares outstanding:				
Basic	23,386	22,493	23,226	22,536
Diluted	24,387	22,937	24,334	22,928

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)

	June 30, 2004	December 31, 2003
Assets		
Current Assets:		
Cash and cash equivalents	$ 106,810	$ 83,381
Accounts receivable trade (less allowance for doubtful accounts of $66 in 2004 and $84 in 2003)	2,620	3,809
Accounts receivable Novogyne, net	3,538	6,320
Inventories	5,452	5,200
Net deferred income tax asset, current portion	7,800	6,500
Prepaid income taxes and other current assets	4,082	3,219
	130,302	108,429
Property, plant and equipment, net	19,783	18,354
Other Assets:		
Investment in Novogyne	23,278	28,368
Net deferred income tax asset	13,954	12,175
Patent development costs, net	2,076	1,977
Deposits and other assets	20	181
	39,328	42,701
	$ 189,413	$ 169,484
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable	$ 6,549	$ 4,060
Capital lease obligations current portion	101	
Accrued compensation and related liabilities	2,891	3,734
Other accrued liabilities	1,218	2,090
Deferred contract revenues	2,575	772
Deferred license revenues current portion	22,415	21,112

	35,749	31,768
Long-Term Liabilities:		
Capital lease obligations	162	
Deferred license revenues	30,764	28,893
	66,675	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 23,393,697 at June 30, 2004 and 22,722,060 at December 31, 2003	2	2
Additional paid-in capital	87,323	79,244
Retained earnings	35,413	29,577
	122,738	108,823
	$ 189,413	$ 169,484

The accompanying notes are an integral part of these statements.

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NOVEN PHARMACEUTICALS, INC.

Condensed Statements of Cash Flows
Six Months Ended June 30,
(in thousands)
(unaudited)

	2004	2003
Cash flows from operating activities:		
Net income	$ 5,836	$ 3,523
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,173	1,146
Amortization of patent costs	186	166
Amortization of non-competition agreement	167	200
Income tax benefits on exercise of stock options	2,728	17
Deferred income tax benefit	(3,079)	(8,782)
Non-cash expense related to issuance of stock to outside directors	30	31
Recognition of deferred contract revenues	(1,372)	(65)
Amortization of deferred license revenues	(1,980)	(2,263)
Equity in earnings of Novogyne	(8,865)	(5,320)
Distributions from Novogyne	12,263	11,980
Changes in operating assets and liabilities:		
Decrease in accounts receivable trade, net	1,189	187
Decrease (increase) in accounts receivable Novogyne, net	2,782	(3,392)
(Increase) decrease in inventories	(252)	1,362
Decrease (increase) in prepaid income taxes and other current assets	829	(1,410)
Increase in deposits and other assets	(6)	
Increase in accounts payable	2,489	189
Decrease in accrued compensation and related liabilities	(843)	(1,298)
(Decrease) increase in other accrued liabilities	(872)	55
Increase in current tax payable		7,537
Increase in deferred contract revenue	3,175	665
Increase in deferred license revenue	6,500	25,000
Direct expenses incurred in pursuit of MethyPatch® product regulatory approval	(1,346)	
Cash flows provided by operating activities	20,732	29,528
Cash flows from investing activities:		
Purchases of property, plant and equipment, net	(2,290)	(3,109)
Payments for patent development costs	(285)	(168)
Cash flows used in investing activities	(2,575)	(3,277)

Cash flows from financing activities:		
Issuance of common stock	5,321	147
Purchase and retirement of common stock		(1,289)
Repayments of capital leases and notes payable	(49)	(4)
Cash flows provided by (used in) financing activities	5,272	(1,146)
Net increase in cash and cash equivalents	23,429	25,105
Cash and cash equivalents, beginning of period	83,381	58,684
Cash and cash equivalents, end of period	$106,810	$83,789

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 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 June 30, 2004, and the results of its operations for the three and six months ended June 30, 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, as amended, 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 and six months ended June 30, 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 the entity to finance its activities without additional subordinated financial support from other

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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 the adoption of this interpretation has had no impact on Noven s financial statements. These conclusions are based on currently available information and require Noven to periodically assess its investment interest and ownership rights in Novogyne. If Noven s conclusions or underlying assumptions of factual information concerning its investment in Novogyne prove incorrect or 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 June 30, 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):

	June 30, 2004	December 31, 2003
Finished goods	$1,546	$ 806
Work in process	875	1,722
Raw materials	3,031	2,672
Total	$5,452	$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 and six months ended June 30, 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):

	Three Months		Six Months	
	2004	2003	2004	2003
Net income:				
As reported	$ 5,678	$ 3,050	$ 5,836	$ 3,523
Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(984)	(933)	(1,724)	(2,109)
Pro forma	$ 4,694	$ 2,117	$ 4,112	$ 1,414
Basic earnings per share:				
As reported	$ 0.24	$ 0.14	$ 0.25	$ 0.16
Pro forma	$ 0.20	$ 0.09	$ 0.18	$ 0.06
Diluted earnings per share:				
As reported	$ 0.23	$ 0.13	$ 0.24	$ 0.15
Pro forma	$ 0.19	$ 0.09	$ 0.17	$ 0.06

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 and six months ended June 30, 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 $3.2 million for each of the six months ended June 30, 2004 and 2003, respectively. Cash payments for interest were not material for the six months ended June 30, 2004 and 2003.

Non-cash Operating Activities

In 2002, the State of New Jersey enacted legislation that requires Novogyne to remit estimated state income tax payments on behalf of its owners, Noven and Novartis. In April 2004 and 2003, Novogyne paid $1.7 million to the

New Jersey Department of Revenue, representing Noven s portion of Novogyne s estimated state income tax payment. These payments were deemed a distribution to Noven.

Non-cash Investing Activities

During the six months ended June 30, 2004, Noven entered into a capital lease obligation of $0.3 million for new equipment.

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8. LICENSE AND CONTRACT AGREEMENTS:

Endo Collaboration

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 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 give any assurance 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 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. 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 as earned 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 Collaboration

In April 2003, Noven established a collaboration with Procter & Gamble Pharmaceuticals, Inc. (P&G Pharmaceuticals) for the development of new prescription patches. The products under development explore follow-on product opportunities for Intrinsa™, P&G Pharmaceuticals in-licensed investigational transdermal testosterone patch designed to help restore desire in menopausal women who have Hypoactive Sexual Desire Disorder. P&G Pharmaceuticals has initiated studies of the first product in humans. For the three and six months ended June 30, 2004, Noven recognized as contract revenues $0.8 million and $1.2 million, respectively, in development milestones under this collaboration based on P&G Pharmaceuticals determination that Noven had met the applicable performance criteria. No development milestones under this collaboration were recognized for the same periods in 2003. Potential development milestones totaling $3.6 million remain to be earned under the collaboration.

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Shire

Noven is developing a transdermal methylphenidate patch for Attention Deficit Hyperactivity Disorder. Global rights to the developmental product are licensed to Shire Pharmaceutical Group plc (Shire). In April 2003, Noven received a not approvable letter from the FDA relating to Noven s MethyPatch New Drug Application (NDA). In May 2004, Noven and Shire met with the FDA to review Noven s and Shire s jointly prepared development plan intended to address issues raised in the not approvable letter. Based on feedback resulting from the meeting, Noven and Shire intend to proceed with the development of MethyPatch. Development efforts are expected to include additional clinical studies, including another Phase 3 study. Pursuant to the agreements between the parties, Shire will manage these studies and Noven has committed to fund them. Noven estimates that the additional studies will cost up to $13.0 million, and Noven expects to incur additional costs, which may include clinical supply costs, consulting costs and other costs associated with our pursuit of marketing approval for MethyPatch. Noven s direct costs incurred in pursuit of approval are expected to be deferred and offset against a portion of the $25.0 million deferred revenue previously received from Shire. Such expenses are not expected to impact Noven s research and development expenses in 2004, although the direct expenses incurred in pursuit of MethyPatch approval will reduce Noven s cash position and will have the effect of reducing the amount of deferred revenues that Noven may recognize in future periods. As of June 30, 2004, the amount of deferred revenues was $17.7 million (which excludes the $5.0 million of deferred revenues related to the repurchase right described below) and Noven does not expect its cost in pursuit of approval to exceed this amount. If the additional studies are successful and completed on schedule, the parties would intend to file an amendment to the pending MethyPatch NDA during 2005. The amendment is expected to receive a six-month review by the FDA, and there is no assurance that the data to be obtained from the additional studies will address the FDA s issues or that the FDA may not raise additional issues following any submission of an amendment to the MethyPatch NDA. Under Noven s agreements with Shire, Shire continues to have certain rights to terminate the MethyPatch license, including if Shire determines that submission of the results of the additional clinical studies to the FDA would not result in approval of a commercially-viable product. If Shire were to terminate on this basis, all product rights would revert to Noven, and Noven would retain the $25.0 million previously paid by Shire in April 2003. Shire continues to have the right to require Noven to repurchase the product rights to MethyPatch for $5.0 million under certain circumstances.

In June 2004, Noven entered into an agreement with Shire for the development of a transdermal amphetamine patch for Attention Deficit Hyperactivity Disorder. The agreement provides for the payment to us of up to $5.0 million if certain development milestones are achieved. The product is in pre-clinical development.

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 and six months ended June 30, 2004 and 2003, Noven had the following transactions with Novogyne (in thousands):

	Three Months		Six Months	
	2004	2003	2004	2003
Revenues:				
Product sales	$4,886	$6,086	$10,694	$ 9,016
Royalties	1,608	968	2,498	2,199
	$6,494	$7,054	$13,192	$11,215
Reimbursed expenses	$5,973	$6,358	$12,262	$12,541

As of June 30, 2004 and December 31, 2003, Noven had amounts due from Novogyne of $3.5 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 and six months ended June 30, 2004 and 2003 are as follows (in thousands):

	Three Months		Six Months	
	2004	2003	2004	2003
Gross revenues	$35,015	$22,146	$60,149	$52,738
Sales allowances	3,517	2,332	6,289	5,796
Sales return allowances (reductions)	(717)	(1,995)	292	669
Sales allowances and returns	2,800	337	6,581	6,465
Net revenues	32,215	21,809	53,568	46,273
Cost of sales	6,697	4,460	11,532	10,225
Selling, general and administrative expenses	6,937	7,621	14,562	15,504
Amortization of intangible assets	1,545	1,545	3,090	3,090
Income from operations	17,036	8,183	24,384	17,454

Interest income	13	17	53	102
Net income	$17,049	$ 8,200	$24,437	$17,556
Noven s equity in earnings of Novogyne	$ 8,228	$ 3,795	$ 8,865	$ 5,320

The activity in the Investment in Novogyne account for the six months ended June 30, 2004 is as follows (in thousands):

Investment in Novogyne, beginning of period	$ 28,368
Equity in earnings of Novogyne	8,865
Cash distributions from Novogyne	(12,263)
Non-cash distribution from Novogyne (Note 7)	(1,692)
Investment in Novogyne, end of period	$ 23,278

Subject to the approval of Novogyne s management committee, Novogyne may, from time to time, distribute cash to Novartis and Noven based upon a contractual formula. For the three and six months ended June 30, 2004, Noven received cash distributions of $6.3 million and

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$12.3 million, respectively, from Novogyne. For the three and six months ended June 30, 2003, Noven received cash distributions of $1.3 million and $12.0 million, respectively, from Novogyne. In addition, as discussed in Note 7, a $1.7 million tax payment to the New Jersey Department of Revenue made by Novogyne on Noven s behalf in each of April 2004 and 2003 were deemed distributions from Novogyne to Noven. 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. Noven 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 six months ended June 30, 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, Noven s combination estrogen/progestin patch, continue to decline in the post-WHI environment. Novogyne recorded the acquisition of the marketing rights for Noven s CombiPatch product at cost and tests this asset for impairment on a periodic basis. Further adverse change in the market for HT products could have a material adverse impact on the ability of Novogyne to recover its investment in these rights, which could require Novogyne to record an impairment loss on the CombiPatch intangible asset. Impairment of the CombiPatch intangible asset would adversely affect Novogyne s and Noven s financial results. Management cannot predict whether these or other studies will have additional adverse effects on Noven s liquidity and results of operations, or Novogyne s ability to recover the net carrying value of the CombiPatch intangible asset.

Production Issues

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. As a result of the product recall, in 2003, Noven and Novogyne established allowances for the return of recalled product, which had the effect of reducing Noven and Novogyne s net revenues by approximately $1.4 million and $6.5 million, respectively, for the year ended December 31, 2003. Based on their review of currently available information, including actual product returns and future expected returns, Noven and

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Novogyne reduced these allowances during the six months ended June 30, 2004, which had the effect of increasing net revenues for the three months ended June 30, 2004 by $0.6 million and $2.4 million for Noven and Novogyne, respectively, and by $0.6 million and $3.1 million for the six months ended June 30, 2004 for Noven and Novogyne, respectively. The effect on Noven of these adjustments by Noven and Novogyne was to increase Noven s income before income taxes by $1.7 million and $2.0 million for the three and six months ended June 30, 2004, respectively. The effect on Novogyne of Novogyne s adjustment was to increase Novogyne s income before income taxes by $1.9 million and $2.6 million for the three and six months ended June 30, 2004, respectively.

At June 30, 2004, allowances for recall related returns were $0.1 million and $0.3 million at Noven and Novogyne, respectively. In addition, Noven had $0.1 million remaining in reserves for expected costs related to the product recall.

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.

The Vivelle-Dot production issue resulted from the use of certain rolls of patch backing material provided by a raw material supplier. Noven believes that the Vivelle-Dot product currently in distribution and in its inventory will maintain required stability. If Noven s estimate concerning the scope of, or amount of, expected product returns is incorrect or if Novartis should initiate further unexpected recalls, then Noven s results of operations could be materially and adversely impacted.

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. Designation of a new supplier and approval of a new supply agreement would require the affirmative vote of four of the five members of Novogyne s Management Committee. Accordingly, both Novartis and Noven must agree on Novogyne s supplier.

Litigation, Claims and Assessments

On 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.

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On July 30, 2004, Noven became aware that an individual plaintiff and her husband filed a complaint in Superior Court of New Jersey Law Division, Atlantic County as of July 8, 2004, against Noven, Novartis, Wyeth Pharmaceuticals, Inc. and others alleging liability in connection with personal injury claims allegedly arising from the use of HT products, including CombiPatch, which is manufactured by Noven and distributed by Novogyne. The plaintiffs claim compensatory, punitive and other damages in an unspecified amount. In addition, Novartis has advised Noven that it has been named as a defendant in several additional lawsuits alleging liability in connection with personal injury claims allegedly arising from the use of HT patches distributed and sold by Novartis and Novogyne, including Noven products, Vivelle, Vivelle-Dot and CombiPatch. To date neither Noven nor Novogyne has, to Noven s knowledge, been named as a party to these additional lawsuits. Novartis has indicated that it will seek indemnification from Noven and Novogyne to the extent permitted by the agreements between and among Novartis, Novogyne and Noven. The outcome of these product liability lawsuits cannot be predicted, and it is not presently possible to determine to what extent Noven or Novogyne may ultimately be impacted by these lawsuits.

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 June 30, 2004, and the results of operations for the three and six months ended June 30, 2004 and 2003. The contents of this section include:

An overview of Noven and recent developments related to:

its menopausal hormone therapy business;

MethyPatch® and our collaboration with Shire;

our collaboration with P&G Pharmaceuticals; and

production issues and the allowances that we established for recall-related returns;

An analysis of material aspects 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 and six months ended June 30, 2004 and 2003 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 combination therapy arm of the WHI study) to the second quarter of 2004, total prescriptions dispensed in the HT market in the United States declined by 47%. For the same period, aggregate prescriptions for Noven s United States products decreased 14%. The estrogen segment of the HT market in the United States declined 42%, while our Vivelle product family decreased 7%. Vivelle-Dot, which represented 78% of our total United States prescriptions in the second quarter of 2004, increased 12% from the second quarter of 2002 to the second quarter of 2004. We believe Vivelle-Dot patch prescriptions have benefited from patient conversions from original Vivelle. At the end of the second quarter of 2004, the Vivelle family

held a 42% share of total estrogen patch prescriptions in the United States, 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.

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United States prescriptions for our CombiPatch product (which represented approximately 14% of our total United States prescriptions in the second quarter of 2004) declined 43% from the second quarter of 2002 to the second quarter of 2004, while prescriptions for the total United States market for fixed combination hormone therapy declined 67%. The combination therapy arm of WHI involved an oral combination estrogen/progestin product and, accordingly, that segment of the HT market has experienced the most significant decline. Further declines for our CombiPatch product could require Novogyne (which holds the CombiPatch marketing rights) to record an impairment loss related to these marketing rights, which would harm both our and Novogyne s results of operations.

Shire

We are developing a transdermal methylphenidate patch for Attention Deficit Hyperactivity Disorder. Global rights to the developmental product are licensed to Shire. In April 2003, we received a not approvable letter from the FDA relating to our MethyPatch New Drug Application (NDA). In May 2004, Noven and Shire met with the FDA to review Noven s and Shire s jointly prepared development plan intended to address issues raised in the not approvable letter. Based on feedback resulting from the meeting, Noven and Shire intend to proceed with the development of MethyPatch. Development efforts are expected to include additional clinical studies, including another Phase 3 study. Pursuant to the agreements between the parties, Shire will manage these studies and we have committed to fund them. We estimate that the additional studies will cost up to $13.0 million, and we expect to incur additional costs, which may include clinical supply costs, consulting costs and other costs associated with our pursuit of marketing approval for MethyPatch. Our direct costs incurred in pursuit of approval are expected to be deferred and offset against a portion of the $25.0 million deferred revenue previously received from Shire. Such expenses are not expected to impact our research and development expenses in 2004, although the direct expenses incurred in pursuit of MethyPatch approval will reduce our cash position and will have the effect of reducing the amount of deferred revenues that we may recognize in future periods. As of June 30, 2004, the amount of deferred revenues was $17.7 million (which excludes the $5.0 million of deferred revenues related to the repurchase right described below) and we do not expect our costs in pursuit of approval to exceed this amount. If the additional studies are successful and completed on schedule, the parties would intend to file an amendment to the pending MethyPatch NDA during 2005. The amendment is expected to receive a six-month review by the FDA, and there is no assurance that the data to be obtained from the additional studies will address the FDA s issues or that the FDA may not raise additional issues following any submission of an amendment to the MethyPatch NDA. Under our agreements with Shire, Shire continues to have certain rights to terminate the MethyPatch license, including if Shire determines that submission of the results of the additional clinical studies to the FDA would not result in approval of a commercially-viable product. If Shire were to terminate on this basis, all product rights would revert to us, and we would retain the $25.0 million previously paid by Shire in April 2003. Shire continues to have the right to require us to repurchase the product rights to MethyPatch for $5.0 million under certain circumstances.

In June 2004, we entered into an agreement with Shire for the development of a transdermal amphetamine patch for Attention Deficit Hyperactivity Disorder. The agreement provides for the

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payment to us of up to $5.0 million if certain development milestones are achieved. The product is in pre-clinical development.

P&G Pharmaceuticals

In April 2003, we established a collaboration with P&G Pharmaceuticals, for the development of new prescription patches. The products under development explore follow-on product opportunities for Intrinsa™, P&G Pharmaceuticals in-licensed investigational transdermal testosterone patch designed to help restore desire in menopausal women who have Hypoactive Sexual Desire Disorder. P&G Pharmaceuticals has initiated studies of the first product in humans. For the three and six months ended June 30, 2004, we recognized as contract revenues $0.8 million and $1.2 million, respectively, in development milestones under this collaboration based on P&G Pharmaceuticals determination that we had met the applicable performance criteria. No development milestones under this collaboration were recognized for the same periods in 2003. Potential development milestones totaling $3.6 million remain to be earned under the collaboration.

Production Issues

In 2003, our 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. As a result of the product recall, in 2003, Noven and Novogyne established allowances for the return of recalled product, which had the effect of reducing Noven and Novogyne s net revenues by $1.4 million and $6.5 million, respectively, for the year ended December 31, 2003. Based on their review of currently available information, including actual product returns and future expected returns, Noven and Novogyne reduced these allowances during the six months ended June 30, 2004, which had the effect of increasing net revenues for the three months ended June 30, 2004 by $0.6 million and $2.4 million for Noven and Novogyne, respectively, and by $0.6 million and $3.1 million for the six months ended June 30, 2004 for Noven and Novogyne, respectively. The effect on Noven of these adjustments by Noven and Novogyne was to increase our income before income taxes by $1.7 million and $2.0 million for the three and six months ended June 30, 2004, respectively. The effect on Novogyne of Novogyne s adjustment was to increase Novogyne s income before income taxes by $1.9 million and $2.6 million for the three and six months ended June 30, 2004, respectively.

At June 30, 2004, allowances for recall related returns were $0.1 million and $0.3 million at Noven and Novogyne, respectively. In addition, we had $0.1 million remaining in reserves for expected costs related to the product recall.

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Results of Operations

Three and six months ended June 30, 2004 compared to the three and six months ended June 30, 2003

Revenues

Total revenues for the three and six months ended June 30, 2004 and 2003 are summarized as follows (dollar amounts in thousands):

	Three Months			Six Months		
	2004	2003	% Change	2004	2003	% Change
Product revenues Novogyne:						
Product sales	$ 4,886	$ 6,086	(20%)	$10,694	$ 9,016	19%
Royalties	1,608	968	66%	2,498	2,199	14%
	6,494	7,054	(8%)	13,192	11,215	18%
Product revenues third parties:						
Product sales	3,489	3,753	(7%)	6,327	8,713	(27%)
Royalties	75	33	N/M	214	30	N/M
	3,564	3,786	(6%)	6,541	8,743	(25%)
Total product revenues	10,058	10,840	(7%)	19,733	19,958	(1%)
License and contract revenues:						
Contract	853	39	N/M	1,372	65	N/M
License	1,044	1,382	(24%)	1,980	2,263	(13%)
	1,897	1,421	33%	3,352	2,328	44%
Net revenues	$11,955	$12,261	(2%)	$23,085	$22,286	4%

N/M not meaningful

Net Revenues

As described in more detail below, the decrease in net revenues for the three months ended June 30, 2004 as compared to the same period in 2003 was primarily attributable to lower unit sales of our products and a decrease in license revenue. These decreases were partially offset by an increase in our royalties and contract revenue due to the attainment of certain product development milestones. Net revenues also benefited from a reduction in the allowances for returns related to product recalls.

As described in more detail below, the increase in net revenues for the six months ended June 30, 2004 as compared to the same period in 2003 was primarily attributable to higher unit sales of our U.S. products and an increase in contract revenue due to the attainment of certain product development milestones. Net revenues also benefited from a reduction in the allowances for returns related to product recalls. This increase was partially offset by a decline in unit sales of our international products and a decrease in our license revenue.

Product Revenues Novogyne

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

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The $0.6 million decrease in product revenues from Novogyne for the three months ended June 30, 2004 as compared to the same period in the prior year primarily related to lower unit sales of all products, of which the most significant was a $1.1 million decline in CombiPatch unit sales. CombiPatch unit sales increased in the second quarter of 2003 after we temporarily suspended shipment of this product to Novogyne in the first quarter of 2003 as a result of a production issue. The decrease in our product sales was partially offset by higher royalties of $0.6 million due to higher Novogyne sales of Vivelle family products. Product revenues also benefited from a $0.6 million reduction in allowances for returns established in the prior year related to product recalls.

The $2.0 million increase in product revenues from Novogyne for the six months ended June 30, 2004 as compared to the same period in the prior year primarily relates to $2.5 million in higher unit sales for Vivelle-Dot. This increase also included the $0.6 million reduction in allowances for returns discussed above. This increase was primarily due to lower sales in the prior period resulting from inventory reduction initiatives intended to align inventories with post-WHI demand.

Product Revenues Third Parties

Product revenues third parties consists substantially 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 $0.2 million decrease in product revenues from third parties for the three months ended June 30, 2004 as compared to the same period in the prior year primarily related to $1.7 million in lower unit sales of Estalis, our combination estrogen/progestin patch. The decline in Estalis reflected lower prescription trends following the publication of the combination therapy arm of the WHI study and other studies. This decrease in product revenues third parties was partially offset by $1.1 million in higher unit sales of Estradot. We believe this increase was primarily attributable to Novartis Pharma restocking inventory in certain countries.

The $2.2 million decrease in product revenues from third parties for the six months ended June 30, 2004 as compared to the same period in the prior year primarily related to $3.4 million in lower unit sales of Estalis, partially offset by $1.3 million in higher unit sales of Estradot, each of which was attributable to the same factors noted above for the three months ended June 30, 2004.

License and Contract Revenues

The increase in contract revenues for the three and six months ended June 30, 2004 as compared to the same period in the prior year was primarily attributable to the attainment of certain product development milestones and the completion of certain product development contracts in the current period. The decrease in license revenues for the three and six months ended June 30, 2004 as compared to the same period in the prior year was due to the recognition of license revenue in connection with the Shire transaction in the prior year. Beginning in the third quarter of 2003, we ceased amortization of the unamortized balance of license revenue received in the Shire transaction due to the planned initiation of an additional clinical trial and the significant costs expected to be incurred in pursuing MethyPatch® approval. As described above under Overview Shire our 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.

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Gross Margin

Gross margin for the three and six months ended June 30, 2004 and 2003 are summarized as follows (dollar amounts in thousands):

	Three Months			Six Months		
	2004	2003	% Change	2004	2003	% Change
Total product revenues	$10,058	$10,840	(7%)	$19,733	$19,958	(1%)
Gross profit (product revenues less cost of products sold)	5,083	4,800	6%	9,240	9,633	(4%)
Gross margin (gross profit as a percentage of product revenues)	51%	44%		47%	48%	

The increase in gross margin for the three months ended June 30, 2004 as compared to the same period in the prior year was primarily due to a decrease of $0.6 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 margin for that period. The decrease in the deferred profit on sales to Novogyne for the three months ended June 30, 2004 as compared to the prior period reflected the combined impact of Novogyne s increased sales to trade customers and our reduced sales to Novogyne in the current period in comparison to the same period in the prior year. The increase in gross margin for the three months ended June 30, 2004 was also due to a $0.6 million reduction in the reserve we established for the 2003 product recall. Additionally, an increase in product royalties had a favorable impact on gross margin when compared to prior year. Gross margin was consistent for the six months ended June 30, 2004 and 2003.

Operating Expenses

Operating expenses for the three and six months ended June 30, 2004 and 2003 are summarized as follows (dollar amounts in thousands):

	Three Months			Six Months		
	2004	2003	% Change	2004	2003	% Change
Research and development	$2,734	$2,154	27%	$4,989	$4,647	7%
Marketing, general and administrative	3,762	3,293	14%	7,666	7,474	3%

Research and Development

The $0.6 million and $0.3 million increase in research and development expenses for the three and six months ended June 30, 2004, respectively, as compared to the same period in 2003 was primarily attributable to an increase in non-clinical development expenses related to our fentanyl transdermal system and other projects.

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Marketing, General and Administrative

The $0.5 million increase in marketing, general and administrative expenses for the three months ended June 30, 2004 as compared to the same period in 2003 was primarily attributable to $0.3 million of increased consulting and professional fees primarily related to new requirements resulting from Sarbanes-Oxley.

The $0.2 million increase in marketing, general and administrative expenses for the six months ended June 30, 2004 as compared to the same period in 2003 was primarily attributable to $0.6 million of increased compensation costs, $0.5 million of increased consulting and professional fees primarily related to new requirements resulting from Sarbanes-Oxley, and $0.3 million of increased insurance costs. This increase was partially offset by a $1.3 million reduction in costs due to the elimination of pre-launch marketing expenses for MethyPatch, which ceased during the second quarter of 2003 as a result of the license of MethyPatch to Shire.

Income Taxes

Our effective tax rate was approximately 36% for each of the three and six months ended June 30, 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 June 30, 2004, we had a net deferred tax asset of $21.8 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 and six months ended June 30, 2004 and 2003 are summarized as follows (dollar amounts in thousands):

	Three Months			Six Months		
	2004	2003	% Change	2004	2003	% Change
Gross revenues[1]	$35,015	$22,146	58%	$60,149	$52,738	14%
Sales allowances	3,517	2,332	51%	6,289	5,796	9%
Sales returns allowances (reductions)	(717)	(1,995)	(64%)	292	669	(56%)
Sales allowances and returns	2,800	337	731%	6,581	6,465	2%
Net revenues	32,215	21,809	48%	53,568	46,273	16%
Cost of sales	6,697	4,460	50%	11,532	10,225	13%
Gross profit	25,518	17,349	47%	42,036	36,048	17%
Gross margin percentage	79%	80%		78%	78%	
Selling, general and administrative expenses	6,937	7,621	(9%)	14,562	15,504	(6%)
Amortization of intangible asset	1,545	1,545		3,090	3,090	
Income from operations	17,036	8,183	108%	24,384	17,454	40%
Interest income	13	17	(24%)	53	102	(48%)
Net income	$17,049	$ 8,200	108%	$24,437	$17,556	39%
Noven s equity in earnings of Novogyne	$ 8,228	$ 3,795	117%	$ 8,865	$ 5,320	67%

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

Novogyne Net Revenues

Gross revenues increased $12.9 million for the three months ended June 30, 2004 compared to the prior year, primarily due to $12.0 million in increased sales of Vivelle-Dot. The Vivelle-Dot increase was primarily due to increased unit sales. Because underlying prescriptions for Vivelle-Dot increased only slightly from period to period, we believe the increase in Vivelle-Dot sales was related to the timing of orders from trade customers. Novogyne sells its products to trade customers, including wholesalers, distributors and chain pharmacies. As has historically been the case, the timing of purchases by trade customers is driven by the inventory needs of each customer and other factors, and does not necessarily track underlying prescription trends in any given period or coincide with Novogyne s quarterly financial reporting periods. As a result, the timing of orders by trade customers is difficult to predict and can lead to significant variability in Novogyne s quarterly results. We believe Novogyne s revenues in the second quarter of 2004 may have benefited as trade customers replenished inventories depleted during the first quarter of 2004.

Gross revenues increased $7.4 million for the six months ended June 30, 2004 compared to the prior year, primarily due to $6.6 million in increased sales of Vivelle-Dot and $2.7 million in increased sales of Estradot to Canada. We believe the increase in Estradot sales to Canada was due to Novartis Pharma restocking inventory. Approximately $4.4 million of the Vivelle-Dot increase was due to price, while the remaining $2.2 million increase related to increased unit sales. This increase in sales was partially offset by a $1.0 million decrease in sales of Vivelle, our first generation estrogen patch, and $0.8 million decrease in sales of CombiPatch due to a continuing decline in the market for combination therapies after the publication of the combination arm of the WHI study.

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Sales allowances consist of chargebacks, Medicaid rebates, managed healthcare rebates, cash discounts and other allowances, which tend to fluctuate based on changes in gross revenues. These sales allowances were 10% and 11% of gross revenues for the three months ended June 30, 2004 and 2003, respectively, and 10% and 11% of gross revenues for the six months ended June 30, 2004 and 2003, respectively.

Sales returns allowances consist of: (i) allowances for returns of expiring product, and (ii) allowances for returns for product recalls. For the three months ended June 30, 2004, there was a net reduction in sales return allowances of $0.7 million, consisting of an increase in allowances for expiring product of $1.7 million, offset by a $2.4 million decrease in the allowances for returns for product recalls. Novogyne increased its allowances for returns of expiring product primarily due to higher unit sales of Vivelle-Dot. Unit sales are one of the significant factors considered in assessing the adequacy of allowances for returns of expiring product. Novogyne decreased its allowances for returns for product recalls in the quarter ended June 30, 2004 based on an analysis of currently available information relating to the product recalls initiated in 2003, including actual returns received in the recalls to date and an estimate of remaining returns expected to be received in the recalls. At June 30, 2004, Novogyne s remaining product recall allowances were $0.3 million. For the three months ended June 30, 2003, there was a net reduction in sales return allowances of $2.0 million, all of which was related to allowances for returns of expiring product due to the analysis of actual returns and other factors at the time.

For the six months ended June 30, 2004, there was a net increase in sales return allowances of $0.3 million, consisting of an increase in allowances for expiring product of $3.4 million offset by a $3.1 million decrease in allowances for returns for product recalls. Novogyne increased its allowances for expiring product primarily due to higher sales of Vivelle-Dot. Novogyne decreased its allowances for returns for product recalls in the six months ended June 30, 2004 based on its on-going analysis of available information relating to the product recalls initiated in 2003. For the six months ended June 30, 2003, there was a net increase in sales return allowances of $0.7 million, all of which was related to allowances for expiring product due to the analysis of actual returns and other factors at the time.

Novogyne Gross Margin

The decline in gross margin for the three months ended June 30, 2004 as compared to the same period in 2003 was primarily due to higher sales allowances and returns, which decreased net revenues without affecting cost of goods sold. Gross margin was consistent for the six months ended June 30, 2004 and 2003, respectively.

Novogyne Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three and six months ended June 30, 2004 decreased $0.7 million and $0.9 million, respectively, which was primarily attributable to lower samples expense due to timing of orders.

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 June 30, 2004 and 2003 and $3.1 million for each of the six month periods ended June 30, 2004 and 2003. Our CombiPatch product was licensed by Novogyne in March 2001.

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Liquidity and Capital Resources

As of June 30, 2004 and December 31, 2003, we had $106.8 million and $83.4 million in cash and cash equivalents, and working capital of $94.6 million and $76.7 million, respectively.

Cash provided by (used in) operating, investing and financing activities for the six months ended June 30, 2004 and 2003 is summarized as follows (amounts in thousands):

	2004	2003
Cash flows:		
Operating activities	$20,732	$29,528
Investing activities	(2,575)	(3,277)
Financing activities	5,272	(1,146)

Operating Activities

Net cash provided by operating activities for the six months ended June 30, 2004 primarily resulted from the receipt of an $8.0 million payment upon the closing of the Endo transaction in February 2004 and $12.3 million in distributions from Novogyne.

Net cash provided by operating activities for the six months ended June 30, 2003 primarily resulted from the receipt of a $25.0 million license payment from Shire and a $12.0 million distribution from Novogyne. The increase was partially offset by changes in working capital due to the timing and amount of product shipments, payment of Director s and Officer s insurance premiums and payment of income taxes.

Investing Activities

Net cash used in investing activities for the six months ended June 30, 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 six months ended June 30, 2004 was primarily attributable to $5.3 million received in connection with the issuance of common stock from the exercise of stock options.

Net cash used in financing activities for the six months ended June 30, 2003 was primarily attributable to the repurchase of 105,000 shares of our common stock for $1.3 million, 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. In February 2004, Endo paid us $8.0 million upon closing of the fentanyl patch licensing transaction. For the six months ended June 30, 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.

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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, and there is no assurance that the additional studies that Noven and Shire propose to conduct will address the FDA s issues or that the FDA may not raise additional issues following any submission of an amendment to the MethyPatch NDA. Additionally, even if the FDA approves MethyPatch, we cannot assure that 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 with respect to MethyPatch. Our short-term liquidity will be affected in 2004 as we expect to incur up to $5.2 million in capital expenditures during the remainder of 2004 primarily in preparation for the expected launch of new products, including our fentanyl patch. Such amount includes purchase obligations at June 30, 2004 for fentanyl of $3.7 million. In addition, in the remainder of 2004 we expect that we may incur up to $10.0 million for the cost of pre-launch inventories for our fentanyl patch. If launch supplies are manufactured prior to receipt of FDA approval of our fentanyl patch and approval is delayed or not ultimately received, our agreement with Endo provides that we will share with Endo the cost of manufacturing product that cannot be sold by Endo, in accordance with an agreed-upon formula. In that case, we cannot assure that Endo would be able to sell any of the product that had been produced. Accordingly, we cannot assure that we would be able to offset all of our up-front production costs of launch inventories with sales of the product.

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 plant and equipment to expand production capacity for new products. If our products under development, including those being developed with Shire and P&G Pharmaceuticals, are successful, these expenditures, which may include a new manufacturing plant, may be significant. We cannot assure that we will successfully complete the development of such products, that we will obtain regulatory approval for any such products, that any approved product may be produced in commercial quantities, at reasonable costs, and be successfully marketed, or that we will successfully negotiate future licensing or product acquisition arrangements. Because much of the cost associated with product development 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.

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

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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 prove incorrect or 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 June 30, 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, technological 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 have been launched in 2004);

changes in our business relationships/collaborations; or

changes in the economy or the health care sector generally.

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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.

As has historically been the case, Novogyne s operating results are expected to continue to fluctuate by quarter, in part due to the timing of orders placed by trade customers, which we believe is driven by the inventory needs of each customer and other factors, and does not necessarily track underlying prescription trends or coincide with Novogyne s quarterly financial reporting period.

For full year 2004, we expect that a decline in Noven s international product revenues will be approximately offset by an increase in Noven s other revenue sources. We expect capital expenditures in 2004 to increase by up to $3.1 million over 2003 levels as we prepare for the possible launch of our fentanyl patch. We expect that capital expenditures will increase significantly beginning in 2005 in connection with the development of other new products, including MethyPatch and products under our P&G Pharmaceuticals collaboration.

In the second quarter of 2004, we recognized as contract revenues a $0.8 million development milestone under our collaboration with P&G Pharmaceuticals. Potential development milestones totaling $3.6 million remain to be earned under the P&G Pharmaceuticals collaboration.

In May 2004, Noven and Shire met with the FDA to review a jointly prepared development plan intended to address issues raised in the MethyPatch not approvable letter. Based on feedback resulting from the meeting, Noven and Shire intend to proceed with the development of MethyPatch. Development efforts are expected to include additional clinical studies, including another Phase 3 study. We estimate that the additional studies will cost up to $13.0 million, and we expect to incur additional costs which may include clinical supply costs, consulting costs and other costs associated with our pursuit of MethyPatch approval. Under our agreements 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 $25.0 million deferred revenue that we previously received from Shire. Such expenses are not expected to impact our research and development expenses in 2004, although the direct expenses incurred in pursuit of MethyPatch approval will reduce our cash position and will have the effect of reducing the amount of deferred revenues that we may recognize in future periods. As of June 30, 2004, the amount of deferred revenues was $17.7 million (which excludes the $5 million of deferred revenues related to Shire s right to require us to repurchase product rights under certain circumstances) and we do not expect our costs in pursuit of approval to exceed this amount. If the additional studies are successful and completed on schedule, the parties would intend to file an amendment to the pending MethyPatch NDA during 2005. The amendment is expected to receive a six-month review by the FDA, and there is no assurance that the data to be obtained from the additional studies will address the FDA s issues or that the FDA may not raise additional issues following any submission of an amendment to the MethyPatch NDA. 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.

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In June 2004, we signed an agreement with Shire for the development of a transdermal amphetamine patch for ADHD. The agreement provides for payments to us of up to $5.0 million if certain development milestones are achieved. The product is in pre-clinical development.

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 give any assurance 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.

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; the European HT market may be limited due to pricing pressures and delayed Estradot launches in certain countries due to labeling issues; and the risk of product liability claims resulting from the use of HT products such as the lawsuits presently pending against Noven and Novartis with respect to our products, as well as any indemnification or contribution obligations that we may have to Novartis or Novogyne related to product liability claims.

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

Production Matters, risks related to our reliance on suppliers for the availability and quality of raw materials used in our products; risks related to our reliance on a single supplier for certain raw

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materials and compounds used in our products; uncertainties regarding the timing and magnitude of any product recalls; the impact of the recalls or related issues on Novartis or other partners strategy for the commercialization of our products; the possibility that our estimates of the impact of future returns and charges may prove inaccurate, incomplete or otherwise incorrect; the impact of detected or undetected product stability failures or other product defects on our ability to estimate our reserves for sales returns and other associated accounting consequences.

Our Partners, the risk that our development partners may have different or conflicting priorities than ours which may adversely impact their ability or willingness to assist in the development and commercialization of our products or to continue the development programs in which they and we have partnered; uncertainties regarding our ability to attract additional development partners; the possibility that our technologies may not be approvable or suitable for use in additional therapeutic categories, including those categories addressed through products developed with our development partners; the possibility that we may be unsuccessful in achieving milestone objectives under our development programs and may not receive any further payments; the possibility that our development programs may not proceed on schedule or as expected, which could, among other things, prevent us from achieving milestone objectives under our development programs and/or cause delays or cancellations of programs; the possibility that our current development priorities could render us unable to advance our other development projects or increase the cost of advancing those projects; risks related to our dependence on Novartis to perform Novogyne s financial, accounting, inventory, distribution, revenues and sales deductions functions (including any asset impairment decisions for Novogyne), including the risk that Novartis may perform these functions differently than we would have, inadequately or incorrectly; 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 protocols and/or clinical strategies do not address the FDA s concerns regarding the approval of the MethyPatch product NDA; the risk that planned additional studies may not be commenced or completed in a timely manner, due to an inability to enroll a sufficient number of subjects for the additional studies or otherwise, which could delay the filing of an amendment to the MethyPatch product NDA past 2005; the possibility that planned 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 timing of FDA s review of any amended NDA for MethyPatch as well as any product approval, which are outside Noven s control and which may impact the success of product launch and market penetration; Shire s control over the management of the planned additional MethyPatch product clinical trials, including the risk that Shire may elect to manage such studies differently than Noven might have, incorrectly or inadequately; the possibility that the additional studies may be more extensive, lengthier or more costly than anticipated and may exceed the total amount of license revenues available to offset such costs and expenses; any exercise of Shire s right to terminate the agreement following its review of the results of the additional studies, including the risk that, in such event, our right to receive a $50 million approval milestone would terminate, and that we may be unable or unwilling to proceed with the project or may be unable to license MethyPatch to a third party or to a party with the resources of Shire on commercially reasonable terms; the possibility that our method of accounting for the $25 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

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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 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, distribution, revenues and sales deductions functions are performed by Novartis, our disclosure controls and procedures with respect to Novogyne are necessarily more limited than those we maintain with respect to ourselves. No significant changes were made in our internal controls or in other factors that could significantly affect these controls subsequent to the date of the Chief Executive Officer s and Chief Financial Officer s evaluation.

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

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

On July 30, 2004, we became aware that an individual plaintiff and her husband filed a complaint in Superior Court of New Jersey Law Division, Atlantic County as of July 8, 2004, against Noven, Novartis, Wyeth Pharmaceuticals, Inc. and others alleging liability in connection with personal injury claims allegedly arising from the use of HT products, including CombiPatch, which is manufactured by us and distributed by Novogyne. The plaintiffs claim compensatory, punitive and other damages in an unspecified amount.

In addition, Novartis has advised us that it has been named as a defendant in several additional lawsuits alleging liability in connection with personal injury claims allegedly arising from the use of HT patches distributed and sold by Novartis and Novogyne, including our products, Vivelle, Vivelle-Dot and CombiPatch. To date neither Noven, nor Novogyne has, to our knowledge, been named as a party to these additional lawsuits. Novartis has indicated that it will seek indemnification from Noven and Novogyne to the extent permitted by the agreements between and among Novartis, Novogyne and Noven.

The outcome of these lawsuits cannot be predicted, and it is not presently possible to determine to what extent Noven or Novogyne may ultimately be impacted by these lawsuits.

Item 2. Changes in Securities and Use of Proceeds

The following table provides information with respect to our stock repurchases during the second 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]
April 1, 2004 to April 30, 2004				$23,711,040
May 1, 2004 to May 31, 2004				$23,711,040
June 1, 2004 to June 30, 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 4. Submission of Matters to a Vote of Security Holders

The following proposals were approved at our Annual Meeting of Stockholders held on May 18, 2004:

1. Election of Directors

	For	Withheld
Sidney Braginsky	20,927,342	179,859
John G. Clarkson, M.D.	20,932,502	174,699
Donald A. Denkhaus	20,932,402	174,799
Robert G. Savage	20,932,502	174,699
Robert C. Strauss	20,912,582	194,619
Wayne P. Yetter	20,917,002	190,199

2. Amendments to the Noven Pharmaceuticals, Inc. 1999 Long-Term Incentive Plan

For	Against	Abstained	Broker Non-Votes[a]
13,922,492	3,416,912	31,565	3,736,232

a. Brokers lacked discretionary voting power for the proposal to amend the 1999 Long-Term Incentive Plan. Broker Non-Votes represent those shares that brokers did not receive voting instructions from the beneficial owner and for which such brokers did not vote because they lacked discretionary voting power.

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3. Ratification of the Appointment of Deloitte & Touche LLP as our Independent Accountant for 2004

For	Against	Abstained
20,860,805	231,936	14,460

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

10.1	Agreement between Shire U.S. Inc. and Noven, dated June 15, 2004 (with certain provisions omitted pursuant to Rule 24b-2)
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

(b) Reports on Form 8-K

We did not file any reports on Form 8-K during the three months ended June 30, 2004.

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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: August 3, 2004

By: /s/ Diane M. Barrett
Diane M. Barrett
Vice President and Chief Financial Officer

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