NOVEN PHARMACEUTICALS INC
Form 10-Q
November 13, 2003

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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 September 30, 2003

Commission file number 0-17254

NOVEN PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

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

(Address of principal executive offices) (Zip Code)
(305) 253-5099

(Registrant s telephone number, including area code)

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

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

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

Class	**Outstanding at October 31, 2003**
Common stock $.0001 par value	22,521,813

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

NOVEN PHARMACEUTICALS, INC.
Condensed Statements of Operations
Three and Nine Months Ended September 30,
(in thousands, except per share amounts)
(unaudited)

	Three Months		Nine Months	
	2003	2002	2003	2002
Revenues:				
Product revenues Novogyne	$ 3,938	$ 7,604	$ 15,153	$ 23,683
Product revenues third parties	4,045	4,610	12,788	14,445
Total product revenues	7,983	12,214	27,941	38,128
License and contract revenues	1,113	984	3,441	3,961
Total revenues	9,096	13,198	31,382	42,089
Expenses:				
Cost of products sold	3,936	5,111	14,261	17,032
Research and development	1,916	2,585	6,563	9,267
Marketing, general and administrative	4,791	3,492	12,265	10,104
Total expenses	10,643	11,188	33,089	36,403
Income (loss) from operations	(1,547)	2,010	(1,707)	5,686
Equity in earnings of Novogyne	4,529	2,010	9,849	10,657
Interest income, net	159	223	505	625
Income before income taxes	3,141	4,243	8,647	16,968
Provision for income taxes	1,130	1,480	3,113	6,109
Net income	$ 2,011	$ 2,763	$ 5,534	$ 10,859
Basic earnings per share	$ 0.09	$ 0.12	$ 0.25	$ 0.48
Diluted earnings per share	$ 0.09	$ 0.12	$ 0.24	$ 0.46
Weighted average number of common shares outstanding:				
Basic	22,506	22,549	22,526	22,523
Diluted	22,949	23,127	22,935	23,424

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)

	September 30, 2003	December 31, 2002
Assets		
Current Assets:		
Cash and cash equivalents	$ 86,913	$ 58,684
Accounts receivable trade (less allowance for doubtful accounts of $84 in 2003 and $79 in 2002)	3,283	4,359
Accounts receivable Novogyne	4,243	2,581
Inventories	5,194	5,613
Net deferred income tax asset	5,400	2,600
Prepaid income taxes and other current assets	5,716	541
	110,749	74,378
Property, plant and equipment, net	18,418	16,232
Other Assets:		
Investment in Novogyne	25,968	34,684
Net deferred income tax asset	9,646	9,831
Patent development costs, net	1,979	1,996
Deposits and other assets	281	581
	37,874	47,092
	$ 167,041	$ 137,702
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable	5,709	5,062
Notes payable current portion	7	8
Accrued compensation and related liabilities	3,454	3,549
Other accrued liabilities	1,953	1,578
Allowance for returns	1,975	485
Deferred contract revenues	1,301	829
Deferred license revenues current portion	20,526	3,525
	34,925	15,036
Long-Term Liabilities:		
Notes payable		5
Deferred license revenues	30,774	25,920
	65,699	40,961
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 22,517,430 shares at September 30, 2003 and 22,579,112 at December 31, 2002	2	2
Additional paid-in capital	77,425	78,358
Retained earnings	23,915	18,381

101,342	96,741
$ 167,041	$ 137,702

The accompanying notes are an integral part of these statements.

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NOVEN PHARMACEUTICALS, INC.
Condensed Statements of Cash Flows
Nine Months Ended September 30,
(in thousands)
(unaudited)

	2003	2002
Cash flows from operating activities:		
Net income	$ 5,534	$10,859
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,683	1,623
Amortization of patent costs	252	231
Amortization of non-competition agreement	300	300
Deferred income tax (benefit) expense	(2,615)	2,099
Non-cash expense related to issuance of stock to charitable organization	31	
Recognition of deferred contract revenues	(296)	(1,457)
Recognition of deferred license revenues	(3,145)	(2,504)
Distributed earnings in excess of equity in earnings of Novogyne	7,045	1,070
Changes in operating assets and liabilities:		
Decrease (increase) in accounts receivable trade, net	1,076	(2,213)
(Increase) decrease in accounts receivable Novogyne	(1,662)	2,830
Decrease (increase) in inventories	419	(2,856)
Increase in prepaid income taxes and other current assets	(3,504)	(728)
Decrease in deposits and other assets		26
Increase in accounts payable	647	4
(Decrease) increase in accrued compensation and related liabilities	(95)	2,567
Increase (decrease) in other accrued liabilities	442	(304)
Increase in allowance for returns	1,490	
Increase in deferred contract revenues	768	132
Increase in deferred license revenues	25,000	73
Cash flows provided by operating activities	33,370	11,752
Cash flows from investing activities:		
Purchase of property, plant and equipment, net	(3,869)	(1,642)
Payments for patent development costs	(235)	(154)
Cash flows used in investing activities	(4,104)	(1,796)
Cash flows from financing activities:		
Issuance of common stock	258	665
Purchase and retirement of common stock	(1,289)	
Repayments of notes payable	(6)	(250)
Cash flows (used in) provided by financing activities	(1,037)	415
Net increase in cash and cash equivalents	28,229	10,371
Cash and cash equivalents, beginning of period	58,684	49,389
Cash and cash equivalents, end of period	$86,913	$59,760

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.

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 September 30, 2003, and the results of its operations for the three and nine months ended September 30, 2003 and 2002. Noven s business is subject to numerous risks and uncertainties including, but not limited to, those set forth in Noven s Annual Report on Form 10-K/A for the year ended December 31, 2002 (Form 10-K), 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 nine months ended September 30, 2003 and 2002 are not, and should not be construed as, necessarily indicative of the results of operations or cash flows which may be reported for the remainder of 2003.

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

The accounting policies followed for interim financial reporting are the same as those disclosed in Note 2 of the notes to the financial statements included in Noven s Form 10-K and in Note 5 Revenue Recognition .

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3. RECLASSIFICATIONS:

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

4. INVENTORIES:

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

	September 30, 2003	December 31, 2002
Finished goods	$ 824	$ 830
Work in process	1,905	1,390
Raw materials	2,465	3,393
Total	$5,194	$5,613

5. REVENUE RECOGNITION:

Substantially all of Noven s product revenues were to its licensees, Novogyne, Novartis Pharma AG and its affiliates (Novartis AG) and Aventis Pharma AG. Revenues from product sales are recognized at the time of shipment when both title and the risks and rewards of ownership have been transferred to the buyer. Certain of our license agreements provide that the ultimate supply price is based on a percentage of the licensee s net selling price. Each of those agreements also establishes a fixed minimum supply price per unit that represents the lowest price Noven could receive on sales to the licensee. Noven receives the minimum price at the time of shipment with the possibility of an upward adjustment later when the licensee s net selling price is known. Revenues under these agreements are recorded at the minimum price at the time of shipment. Noven records any upward adjustments to revenues at the time that the information necessary to make the determination is received from the licensee. If the upward adjustments are not determinable, Noven records the adjustments (which historically have not been significant) on a cash basis. These amounts are included in product revenues.

Royalty revenues consist of royalties payable by Novogyne and Novartis AG from sales of Vivelle® and Vivelle-Dot®/Estradot® in the United States and Canada. Noven accrues royalties from Novogyne s and Novartis AG s product sales each quarter based on Novogyne s and Novartis AG s net sales for that quarter. Royalties are included in product revenues.

License revenues consist of up-front, milestone and similar payments under license agreements and are recognized when earned under the terms of the applicable agreements. In most cases, license revenues are deferred and recognized over the estimated product life cycle or the length of relevant patents, whichever is shorter.

Contract revenues consist of contract payments related to research and development projects performed for third parties. The work performed by Noven includes feasibility studies to determine if a specific drug is amenable to transdermal drug delivery, the actual formulation of a specific drug into a transdermal drug delivery system, studies to address the ongoing stability of

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the drug in a transdermal drug delivery system, and manufacturing of batches of product that can be used in human clinical trials. Noven receives contract payments for the work it performs in the following forms:

nonrefundable up-front payments prior to commencing the work (or certain phases of the work);

additional payments upon completion of additional phases; and

in some cases, success milestone payments based on achievement of specified performance criteria.

As prescribed by EITF 00-21 Accounting for Revenue Arrangements with Multiple Deliverables , Noven analyzes each contract in order to separate each deliverable into separate units of accounting and then recognizes revenues for those separated units at their fair value, as delivered, based on the proportionate share of the work performed by Noven as it performs the specified acts under the contract. If each deliverable does not qualify as a separate unit of accounting, the deliverables are combined and the amounts under the contract are allocated to the combined deliverables. The appropriate recognition of revenue is then determined for the combined deliverables as a single unit of accounting. The difference between the amount of the payments received and the amount recognized is recorded as deferred revenues until that amount is earned in accordance with Staff Accounting Bulletin 101, Revenue Recognition in Financial Statements (SAB 101).

Milestone payments are recorded when the specified performance criteria are achieved, as determined by the customer. Each contract may have different payment terms. Therefore, the timing of revenue recognition may vary from contract to contract.

Revenues are net of an allowance for returns. Noven establishes allowances for returns for product that has been recalled or that it believes is probable of being recalled. The methodology used by Noven to estimate product recall returns is based on the distribution and expiration dates of the affected product and overall trade inventory levels. These estimates are based on currently available information, and the ultimate outcome may be significantly different than the amounts estimated given the subjective nature and complexities inherent in this area and in the pharmaceutical industry.

Noven s revenue recognition policy is in compliance with the requirements of SAB 101.

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 nine months ended September 30, 2003 and 2002 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		Nine Months	
	2003	2002	2003	2002
Net income:				
As reported	$ 2,011	$ 2,763	$ 5,534	$10,859
Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(1,138)	(1,270)	(3,247)	(3,499)
Pro forma	$ 873	$ 1,493	$ 2,287	$ 7,360
Basic earnings per share:				
As reported	$ 0.09	$ 0.12	$ 0.25	$ 0.48
Pro forma	$ 0.04	$ 0.07	$ 0.10	$ 0.33
Diluted earnings per share:				
As reported	$ 0.09	$ 0.12	$ 0.24	$ 0.46
Pro forma	$ 0.04	$ 0.06	$ 0.10	$ 0.31

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 nine months ending September 30, 2003 and 2002, respectively, may not be representative of the effects for future years because outstanding options vest over a period of several years and additional awards are generally made during each year.

7. CASH FLOW INFORMATION:

Cash payments for income taxes were $8.5 million and $4.8 million for the nine months ended September 30, 2003 and 2002, respectively. Cash payments for interest were not material for the nine months ended September 30, 2003 and 2002.

Non-cash Operating Activities

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

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In 2002, the State of New Jersey enacted legislation that requires Novogyne to remit estimated state tax payments on behalf of its owners, Noven and Novartis. In April 2003, Novogyne paid $1.7 million to the New Jersey Department of Revenue, representing Noven s portion of Novogyne s estimated state tax payment. This payment was deemed a distribution to Noven.

Noven recorded $67,000 and $163,000 in income tax benefits to additional paid-in capital for the nine months ended September 30, 2003 and 2002, respectively, which were derived from the exercise of non-qualified stock options and disqualifying dispositions of incentive stock options.

8. LICENSE AGREEMENTS:

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

In April 2003, Noven received a not approvable letter from the FDA relating to its MethyPatch® New Drug Application (NDA). A not approvable letter is issued if the FDA does not consider the application approvable because one or more deficiencies in the application preclude the FDA from approving it. The letter cited clinical and other issues as the basis for non-approval. In October 2003, Noven and Shire submitted a jointly prepared protocol for an additional clinical study for MethyPatch® to the FDA for review and comment, and Noven expects the FDA to respond to the protocol during the 2003 fourth quarter. Noven believes this study is necessary to amend the NDA. In November 2003, Noven and Shire signed a letter agreement relating to this additional study. Under the letter agreement, if the study protocol is acceptable to the FDA, Shire will manage the new clinical study and Noven will fund it, up to a maximum of $10.9 million. Noven will also incur certain additional expenses in pursuit of regulatory approval. At the conclusion of the trial, if Shire determines that submission of the study results to the FDA would not result in a commercially viable product, Shire will have the right to terminate the original transaction agreement. If Shire exercises its termination right under these circumstances, however, Shire will forfeit its right to require Noven to repurchase the product rights, and the product rights will revert to Noven without payment to Shire. If Shire elects to proceed after reviewing the study results, the parties are expected to cooperate in submitting the new study results to the FDA and pursuing regulatory approval of MethyPatch®.

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Noven cannot assure that the submitted protocol or any further revised study design will be acceptable to the FDA. If the parties are unable to reach agreement with the FDA on a study design, the parties may not continue to pursue regulatory approval of MethyPatch®.

Of the $25 million received from Shire at closing, $5 million has been deferred and is expected to be recognized as license revenues over time beginning at the time Shire s right to require Noven to repurchase MethyPatch® rights expires. A portion of the remaining $20 million was recognized as revenues in the 2003 second quarter using a 10-year amortization period. Beginning in the 2003 third quarter, Noven ceased amortization of the balance of the $20 million due to the planned initiation of an additional clinical trial and the significant costs expected to be incurred in pursuing MethyPatch® approval.

Beginning in the 2003 third quarter Noven determined it cannot yet estimate the total cost of pursuing MethyPatch® approval, but Noven expects that the total cost will not exceed the deferred revenue balance. Noven expects to offset expenses incurred in pursuit of MethyPatch® regulatory approval (including the cost of any clinical studies) against the deferred revenue balance. License revenue recognized under this arrangement will be recorded net of the expenses incurred in pursuing regulatory approval. Once Noven can estimate the expected total cost or how much Noven is willing to commit in pursuit of approval, Noven expects to recognize any unused portion of the deferred revenue balance over the remainder of the initial 10-year period. The accounting treatment of amounts received from Shire would be expected to change if Shire were to exercise its right to require Noven to repurchase the product rights or if MethyPatch® development were abandoned.

9. INVESTMENT IN NOVOGYNE:

Noven shares in the earnings of Novogyne, after satisfaction of an annual preferred return of $6.1 million to Novartis, according to an established formula. Noven s share of Novogyne s earnings increases as Novogyne s product sales increase, subject to a cap of 49%. Novogyne produced sufficient income in the first quarter of 2003 and 2002 to meet Novartis annual preferred return for those years and for Noven to recognize earnings from Novogyne under the formula.

During the three and nine months ended September 30, 2003 and 2002, Noven had the following transactions with Novogyne (in thousands):

	Three Months		Nine Months	
	2003	2002	2003	2002
Revenues:				
Product sales	$2,756	$6,796	$11,772	$20,093
Royalties	1,182	808	3,381	3,590
	$3,938	$7,604	$15,153	$23,683
Reimbursed expenses	$6,350	$6,720	$18,891	$20,348

As of September 30, 2003 and December 31, 2002, Noven had amounts due from Novogyne of $4.2 million and $2.6 million, respectively, for products sold to, and marketing expenses reimbursable by, Novogyne.

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The unaudited condensed Statements of Operations of Novogyne for the three and nine months ended September 30, 2003 and 2002 are as follows (in thousands):

	Three Months		Nine Months	
	2003	2002	2003	2002
Net revenues	$24,284	$21,507	$70,997	$81,936
Cost of sales	4,568	7,079	14,793	21,324
Selling, general and administrative expenses	8,368	8,709	24,312	26,866
Amortization of intangible assets	1,545	1,545	4,635	4,635
Income from operations	9,803	4,174	27,257	29,111
Interest income	33	73	135	237
Net income	$ 9,836	$ 4,247	$27,392	$29,348
Noven s equity in earnings of Novogyne	$ 4,529	$ 2,010	$ 9,849	$10,657

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

Subject to the approval of Novogyne s management committee, cash may be distributed to Novartis and Noven based upon a contractual formula. For the three and nine months ended September 30, 2003, Noven received distributions of $4.9 million and $16.9 million from Novogyne, respectively. For the nine months ended September 30, 2002, Noven received a distribution of $11.7 million from Novogyne. There were no distributions from Novogyne for the three months ended September 30, 2002. 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 April 2003 was deemed a distribution 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. As of September 30, 2003, Noven had repurchased 105,000 shares of its common stock at an aggregate price of approximately $1.3 million. These shares were retired on March 31, 2003.

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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 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. Also in July 2002, results of an observational study sponsored by the National Cancer Institute (NCI) on the effects of estrogen therapy (ET) were announced. The main finding of the study was that postmenopausal women who used ET for 10 or more years had a higher risk of developing ovarian cancer than women who never used HT. In June 2003, a new analysis of study data indicated that use of combination HT may increase the frequency of abnormal mammograms beginning in the first year of therapy and/or may cause tumors at the time of diagnosis to be more advanced. In August 2003, further WHI data analysis suggested that the use of combination therapy increased the risk of heart disease beginning in the first year of therapy, and a large study in the United Kingdom suggested that the use of both estrogen-only and combination therapy increased the risk of breast cancer, and the risk of death from breast cancer, whether administered orally, transdermally or via implant.

These studies and others have caused the HT market, and the market for Noven s products, to significantly decline. Prescriptions for CombiPatch®, our combination estrogen/progestin patch, continue to decline in the post-WHI environment. Novogyne recorded the acquisition of CombiPatch® marketing rights 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 can not 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 carrying value of the CombiPatch® intangible asset.

Production Issues

In October 2003, Noven s product stability testing program revealed that certain CombiPatch® and Vivelle-Dot® product did not maintain required specifications throughout the products shelf lives, resulting in product recalls. Third quarter revenues are net of approximately $900,000 and $5.0 million in allowances for returns at Noven and Novogyne, respectively, related to the announced and expected recalls. In addition, Noven s third quarter marketing, selling and administrative expenses include $850,000 in estimated costs associated with these recalls.

The CombiPatch® recalls resulted from a previously disclosed production issue related to a raw material supplied by one vendor. This issue caused Noven to temporarily suspend shipments of CombiPatch® to Novogyne in the 2003 first quarter, and caused Novartis to recall one lot of CombiPatch® in July 2003. Since identifying the issue, Noven has been monitoring all lots of CombiPatch® product manufactured with the material. Even

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though interim testing indicated that these additional lots were expected to maintain specifications throughout their shelf lives, one additional lot unexpectedly tested out of specifications. In light of this event, Novartis initiated a recall of all lots of CombiPatch® product remaining in distribution that are potentially affected by this problematic raw material. Noven continues to manufacture and ship CombiPatch® to Novogyne and expects no interruption of trade supplies.

Noven is working to identify the root cause of the Vivelle-Dot® issue, and in the interim has initiated more rigorous testing of Vivelle-Dot® and Estradot® product. In October 2003, a quantity of Vivelle-Dot® tested out of specification. In November 2003, an additional quantity tested out of specification, and Noven notified Novartis of the failure. Novartis has announced a recall of the Vivelle-Dot® product that tested out of specification in October 2003 and is expected to initiate a recall shortly of the product that tested out of specification in November 2003. Noven has identified additional Vivelle-Dot® product that demonstrates adverse stability trends but remains within required specifications. Based on Noven s testing and analysis to date, Noven does not believe that any additional Vivelle-Dot® product that is currently in distribution or in its inventory is probable of being recalled. Noven has established allowances for estimated sales returns for product that has been recalled or will be recalled as a result of testing out of specification. Novogyne has increased its allowance for sales returns in light of the same issue. Noven has suspended shipments of Vivelle-Dot® to Novogyne and Estradot® to Novartis AG until Noven identifies a root cause and/or confirms that the issue does not impact product to be shipped. Noven hopes that it will complete testing and resume shipping within a timeframe that avoids interruption of trade supplies. Based on Noven s current information, Noven believes that Novogyne has approximately one to two months of Vivelle-Dot® inventory on hand. If a root cause determination or additional testing indicates that the production issue affects more product than Noven s current testing and analysis suggests, additional recalls may be required, Noven s allowances may prove insufficient and/or Noven may be unable to resume shipping. If Noven is unable to resume shipments of Vivelle-Dot® and/or Estradot®, Novogyne and/or Novartis AG would be unable to supply its customers, which would result in lost sales and potentially lost market share, and Noven s results of operations and prospects would be materially adversely affected.

The FDA inspected Noven s facilities earlier this year, and recently initiated a follow-up inspection. The recent and expected product recalls may result in additional FDA inspections of Noven s facilities and procedures. Noven cannot assure that the FDA will be satisfied with Noven s operations and procedures, which could result in more frequent and stringent inspections and monitoring. If the FDA were to conclude that Noven s manufacturing controls and procedures are not sufficient, Noven could be required to suspend production until it demonstrates to the FDA that Noven s controls and procedures are sufficient.

Supply Agreement

Noven s supply agreement with Novogyne for Vivelle® and Vivelle-Dot® expired in January 2003. The parties are negotiating an extension to the agreement. Since expiration, the parties have continued to operate in accordance with the supply agreement s commercial terms. Failure to extend the agreement could have a material adverse effect on Noven s financial statements.

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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 regarding Noven s rationale for approval of its MethyPatch® product and marketing strategies. The press release states that Plaintiff is seeking to recover damages on behalf of all purchasers of Noven common stock during the subject period. 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. A joint motion was filed with the Court in October 2003 seeking to consolidate all of the six actions into a single consolidated action. 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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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read in conjunction with the financial statements, the related notes and management s discussion and analysis of financial condition and results of operations included in our Form 10-K for the year ended December 31, 2002 and the condensed financial statements and related notes included in Item 1 of this Quarterly Report on Form 10-Q. Except for historical information contained herein, the matters discussed in this report are forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements about our and our licensees respective plans, objectives, expectations, estimates, strategies, prospects, product approvals and development plans, and anticipated financial results. These statements are typically identified by the use of terms such as anticipates, believes, estimates, hopes, expects, intend may, plans, could, should, will, would and similar words. These statements are based on our current expectations and beliefs concerning f events and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed herein. We do not undertake to update any of these forward-looking statements or to announce the results of any revisions to these forward-looking statements except as required by law.

In addition to the important factors described in our Form 10-K, the following important factors, among others, could cause our actual results to differ materially from those expressed in any forward-looking statements: uncertainties associated with the impact on the HT market of published studies regarding the adverse health effects of certain forms of HT; uncertainties associated with future prescription trends for CombiPatch®, Vivelle® family products, Estalis® and Estradot®, including risks relating to declining physician or patient preference for HT as a result of the published studies and label changes mandated by the FDA; uncertainties related to the FDA s willingness to permit us, Novogyne and trade participants to deplete HT product inventory bearing the old labels; risks associated with the commercialization of Noven s products; risks and uncertainties associated with the potential impact on our business of the effectiveness as of April 2003 of the privacy regulations issued by the Department of Health and Human Services under the Health Insurance Portability and Accountability Act of 1996, risks and uncertainties associated with the impact of a Novogyne competitor s strategy of increasing market share by heavily discounting product sales to managed care organizations; risks associated with increased competition in the estrogen market as a result of the 2003 launch of a vaginal estrogen delivery system and the expected launches in 2003 and 2004 of estrogen cream and gel products, each of which is a new dosage form in this category, as well as the recent filing by a competitor of an NDA for an ultra-low dose estrogen patch; risks associated with increased competition in the estrogen/progestin market as a result of the expected approval in 2003 of a combination estrogen/progestin patch; risks associated with higher than desired Vivelle® returns to Novogyne; risks and uncertainties relating to our dependence on Novartis to monitor trade inventory levels for Novogyne (including levels of Vivelle-Dot®) and to perform Novogyne s financial, accounting, inventory and sales deductions functions; the risk that Novogyne s revenues could fluctuate based on trade customer buying patterns, which may not correlate with prescription trends; uncertainties concerning the timing and extent of Estradot® regulatory approvals (including any delays that may arise if any Estradot® product should be required to be recalled) and launch orders and Estalis® orders and commercialization efforts by Novartis AG, particularly in light of the significant pricing, reimbursement and regulatory issues faced by Novartis AG in Europe; our limited ability to accurately forecast international product orders from Novartis AG; the risk that MethyPatch® may not be approved by the FDA, particularly in light of the FDA s issuance of a not approvable letter; the risk that the FDA may not approve the proposed study protocol for MethyPatch®; uncertainties associated with the

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timing, cost and outcomes of clinical trials, product development and product launch, including the regulatory review process for MethyPatch® (together with expected clinical trials in connection with that review process), our generic fentanyl patch, and any future generations of our combination estrogen/progestin patch; risks and uncertainties associated with product liability claims that may be brought against us as a result of published studies regarding the adverse health effects of HT, especially in light of claims that have been brought against Wyeth Pharmaceuticals; our dependence on strategic alliances and our relationships with our licensees, and our vulnerability to the risks and uncertainties of our licensees businesses, inventory requirements and marketing strategies; the risk that our licensees may favor their own competitive products over the products licensed from us; the risk that Shire may elect to terminate our agreement after completion of our additional clinical study, and that therefore we would lose the opportunity to receive our milestone payments and manufacturing revenue from Shire; the risk that Shire may seek to exercise its right to require us to repurchase the rights to MethyPatch® for $5 million, and the risk that such an exercise would change our method of accounting for the initial amount received from Shire; risks associated with the availability of a non-stimulant therapy to treat children with Attention Deficit Hyperactivity Disorder (ADHD) and the market penetration of that product; expected fluctuations in quarterly revenues and research and development expenses, including fluctuations in revenues resulting from factors not within our control and the timing of royalty reconciliations and payments under our license agreements; risks and uncertainties relating to the fact that a majority of our cash flow is dependent upon Novogyne s ability to pay distributions to us; our reliance on Shire s marketing efforts and success to achieve the MethyPatch® sales levels necessary to trigger our milestone payments; the risk that we may be unable to resume shipments of Vivelle-Dot® and Estradot® in time to avoid inventory depletion in the trade or at all and the risk that our products may lose market share in that event; the risk that the product recall allowances we have established may not be adequate; 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 accounting consequences associated therewith; the risk that recalls may result in more frequent or stringent inspections of our facilities and processes by the FDA; the effect of changes in taxation or accounting principles generally accepted in the United States (including changes in accounting principles relating to the accounting treatment for employee stock options); and economic, competitive, governmental and technological factors affecting our operations, markets, products, prices and prospects.

Supply Agreement

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

International HT

In November 2000, we entered into an exclusive license agreement with Novartis AG pursuant to which we granted Novartis AG the right to market Vivelle-Dot® under the name Estradot® in all countries other than the United States, Canada and Japan. Under the terms of the agreement, Novartis AG is responsible for seeking approval to market Estradot® in its territories. Novartis AG has launched the product in Germany and a number of smaller countries. However, Novartis AG has informed us that pricing, reimbursement and post-WHI regulatory issues are adversely impacting its launch plans in many countries, including the United Kingdom, France, and Italy. Accordingly, we cannot assure that Novartis AG, will launch Estradot® in any particular country within its territory.

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Novartis AG markets several other transdermal HT products in addition to our products, which may limit the efforts Novartis AG devotes to our products. In some countries, including the United Kingdom and France, Novartis AG has informed us that it is seeking a marketing partner to launch the product, but to date has been unsuccessful. We cannot assure that Novartis AG will be successful in securing a marketing partner or in launching Estradot® in those countries, and we do not expect additional major market launches of Estradot® in the near term.

Production Issues

In October 2003, our product stability testing program revealed that certain lots of CombiPatch® and Vivelle-Dot® did not maintain required specifications throughout the products shelf lives, resulting in product recalls. Third quarter revenues are net of approximately $900,000 and $5.0 million in allowances for returns at Noven and Novogyne, respectively, related to the announced and expected recalls. In addition, our third quarter marketing, selling and administrative expenses include $850,000 in estimated costs associated with these recalls.

The CombiPatch® issue resulted from a previously disclosed production issue related to a problematic raw material supplied by one vendor. This issue caused us to temporarily suspend shipments of CombiPatch® to Novogyne in the 2003 first quarter, and caused Novartis to recall one lot of CombiPatch® in July 2003. Since identifying the issue, we have been monitoring all lots of CombiPatch® product manufactured with the problematic material. Even though interim testing indicated that these additional lots were expected to maintain specifications throughout their shelf lives, we experienced an unexpected stability failure in one additional lot. In light of this event, Novartis initiated a recall of all lots of CombiPatch® product remaining in distribution that are potentially affected by this problematic raw material. We continue to manufacture and ship CombiPatch® to Novogyne and expect no interruption of trade supplies.

We are working to identify the root cause of the Vivelle-Dot® issue, and in the interim have initiated more rigorous testing of Vivelle-Dot® and Estradot® product. In October 2003, a quantity of Vivelle-Dot® tested out of specification. In November 2003, an additional quantity tested out of specification, and we notified Novartis of the failure. Novartis has announced a recall of the Vivelle-Dot® product that tested out of specification in October 2003 and is expected to initiate a recall shortly of the product that tested out of specification in November 2003. We have identified additional Vivelle-Dot® product that demonstrates adverse stability trends but remains within required specifications. Based on results of our testing and analysis to date, we do not believe that any additional Vivelle-Dot® product that is currently in distribution or in our inventory is probable of being recalled. We have established allowances for estimated sales returns for product that has been recalled or will be recalled as a result of testing out of specification. Novogyne has increased its allowance for sales returns in light of the same issue. We have suspended shipments of Vivelle-Dot® to Novogyne and Estradot® to Novartis until our testing identifies a root cause and/or confirms that the issue does not impact product to be shipped. We hope that we will complete testing and resume shipping within a timeframe that avoids interruption of trade supplies. Based on our current information, we believe that Novogyne has approximately one to two months of inventory on hand. If a root cause determination or additional testing indicates that the production issue affects more product than our current testing and analysis suggests, additional recalls may be required, our allowances may prove insufficient and/or we may be unable to resume shipping. If we are unable to resume shipments of Vivelle-Dot® and/or Estradot®, Novogyne and/or Novartis would be unable to supply its customers, which would result in lost sales and potentially lost market share, and our results of operations and prospects would be materially adversely affected.

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The FDA inspected our facilities earlier this year, and recently initiated a follow-up inspection. The recent and expected product recalls may result in additional FDA inspections of our facilities and procedures. We cannot assure that the FDA will be satisfied with our operations and procedures, which could result in more frequent and stringent inspections and monitoring. If the FDA were to conclude that our manufacturing controls and procedures are not sufficient, we could be required to suspend production until we demonstrate to the FDA that our controls and procedures are sufficient.

HT Studies

In July 2002, the NIH released data from its WHI study on the risks and benefits associated with use of oral combination HT by healthy women. The NIH announced that it was discontinuing the arm of the study investigating the use of oral estrogen/progestin combination HT products after an average follow-up period of 5.2 years because the oral HT product used in the study was shown to cause an increase in the risk of invasive breast cancer. The study also found an increased risk of stroke, heart attacks and blood clots and concluded that overall health risks exceeded benefits from use of the orally delivered combined estrogen plus progestin product among healthy postmenopausal women. Also in July 2002, results of an observational study sponsored by the NCI on the effects of ET were announced. The main finding of the NCI study was that postmenopausal women who used ET for 10 or more years had a higher risk of developing ovarian cancer than women who never used HT. In June 2003, a further analysis of data from the discontinued combination therapy arm of the WHI study indicated that use of combination HT may also increase the frequency of abnormal mammograms beginning in the first year of therapy and/or may cause tumors to be more advanced at the time of diagnosis. In August 2003, further WHI data analysis suggested that the use of combination therapy increased the risk of heart disease beginning in the first year of therapy, and a large U.K. study suggested that the use of both estrogen-only and combination therapy increased the risk of breast cancer, and the risk of death from breast cancer, whether administered orally, transdermally or via implant. The data from the WHI and other studies continue to be analyzed and we cannot predict what further findings, if any, those analyses may yield.

Although the range of consequences of these studies cannot be predicted, they have to date significantly and adversely impacted our results of operations. It is possible that these studies could result in a significant permanent decrease in the market for our HT products, either as physicians withdraw their patients from HT or as women elect to discontinue HT on their own. In addition, the market growth that would have been expected if HT had been found safe and effective for additional indications, such as heart disease, is now unlikely to materialize. In January 2003, the FDA announced that marketers of HT products, including Novogyne, are required to modify their HT product labels to include additional safety information and warnings. Among other things, the labels must indicate that HT should be used for short-term therapy only and that, in the absence of clinical studies demonstrating that HT products other than the oral product studied in the WHI study are safe, physicians should assume that all HT products carry the same risks. Novartis has informed us that it has submitted proposed revised labeling to the FDA and will begin using the revised label after reaching agreement with the FDA on label language. Based on industry practice, we expect that Noven, Novogyne and trade participants will be permitted to deplete product inventory bearing the old label concurrently with the introduction of product with revised labeling. If depletion of inventory with old labeling is not permitted or does not otherwise occur, revised labeling could cause an increase in sales returns to Novogyne, and could have a material adverse impact on the financial results of Noven and Novogyne. Healthcare regulators also could delay the approval of new HT

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products, such as those presently under development by Novartis AG and us, including Estradot®, or require that any new HT products be subject to more extensive or more rigorous study and testing prior to being approved. Further, because these studies show that certain uses of certain HT products may result in a higher likelihood of certain adverse health effects, it is possible that we could be named as a defendant in product liability lawsuits relating to our HT products, especially in light of pending claims against Wyeth Pharmaceuticals.

Other studies evaluating HT are currently underway or in the planning stages. In particular, the estrogen-only arm of the WHI study is ongoing. We are unable to predict the effect of new study results, once available, on the short and long-term prospects for the HT market or on the market for our transdermal HT products. Since publication of the WHI and NCI study data, United States prescriptions have declined for substantially all HT products, including our products in the aggregate. Demand for our products in Europe has declined as well. Any increase in returns of products to Novogyne (including any such changes resulting from the results of the recent or ongoing HT studies or the pending product label changes) would have a material adverse effect on our results of operations and financial condition.

The WHI safety board re-evaluates the risk/benefit profile of the estrogen-only arm as frequently as twice per year. In addition, researchers continue to analyze data from the discontinued arm of the WHI study and other studies. If the estrogen-only study or any other currently ongoing HT study is halted, or if ongoing analyses yield additional safety concerns, the market for HT products, including ours, both in the United States and abroad, could be further adversely impacted. The HT label changes mandated by the FDA may also negatively impact our products, particularly with physicians and patients who may believe that transdermal HT products are safer than orally delivered HT products. Currently, our results of operations and business prospects are dependent on sales, license royalties and fees associated with transdermal HT products. Accordingly, any further adverse change in the market for HT products (including any adverse changes resulting from the foregoing studies) could have a material adverse impact on our liquidity, results of operations and business prospects.

MethyPatch®

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

In the first quarter of 2003, we signed an agreement to license the exclusive global rights to market MethyPatch® to Shire for payments of up to $150 million and ongoing manufacturing revenues. Consideration for the transaction is as follows: (a) $25 million was paid upon closing of the transaction in April 2003; (b) $50 million is payable upon receipt of final marketing approval for MethyPatch® by the FDA; and (c) three installments of $25 million each are payable upon Shire s achievement of $25 million, $50 million and $75 million in annual net sales of MethyPatch®, respectively. Shire s annual net sales will be measured quarterly on a trailing 12-month basis, with each milestone payment due 45 days after the end of the first quarter during which trailing 12-month sales exceed the applicable threshold. Shire has agreed that it will not sell any other product containing methylphenidate as an active ingredient until the earlier of (a) five years from the closing date or (b) payment of all of the sales milestones. On the closing date, we entered into a long-term supply agreement under which we expect to manufacture and supply MethyPatch® to Shire at fair value for such services. The agreement gives Shire the right to qualify a second manufacturing

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source and purchase a portion of its requirements from the second source. Pursuant to the agreement, under certain circumstances Shire has the right to require us to repurchase the product rights for $5 million.

In April 2003, we received a not approvable letter from the FDA relating to our MethyPatch® NDA. A not approvable letter is issued if the FDA does not consider the application approvable because one or more deficiencies in the application preclude the FDA from approving it. The letter cited clinical and other issues as the basis for non-approval. In October 2003, we submitted with Shire a jointly prepared study protocol for an additional clinical study for MethyPatch® to the FDA for review and comment, and Noven expects the FDA to respond to the protocol during the 2003 fourth quarter. We believe this study is necessary to amend the NDA. In November 2003, we signed a letter agreement with Shire relating to this additional study. Under the letter agreement, if the study protocol is acceptable to the FDA, Shire will manage the new clinical study and we will fund it, up to a maximum of $10.9 million. We may also incur certain additional expenses in pursuit of regulatory approval. At the conclusion of the trial, if Shire determines that submission of the study results to the FDA would not result in a commercially viable product, Shire will have the right to terminate the original transaction agreement. If Shire exercises its termination right under these circumstances, however, Shire will forfeit its right to require us to repurchase the product rights, and the product rights will revert to us without payment to Shire. If Shire elects to proceed after reviewing the study results, the parties are expected to cooperate in submitting the new study results to the FDA and pursuing regulatory approval of MethyPatch®. We cannot assure that the submitted protocol or any further revised study design will be acceptable to the FDA. If the parties are unable to reach agreement with the FDA on a study design, the parties may not continue to pursue regulatory approval of MethyPatch®.

Of the $25 million received from Shire at closing, $5 million has been deferred and is expected to be recognized as license revenues over time beginning at the time Shire s right to require us to repurchase MethyPatch® rights expires. A portion of the remaining $20 million was recognized as revenues in the 2003 second quarter using a 10-year amortization period. Beginning in the 2003 third quarter, we ceased amortization of the balance of the $20 million due to the planned initiation of an additional clinical trial and the significant costs expected to be incurred in pursuing MethyPatch® approval.

Beginning in the 2003 third quarter we determined we cannot yet estimate the total cost of pursuing MethyPatch® approval, but we expect that the total cost will not exceed the deferred revenue balance. We expect to offset expenses incurred in pursuit of MethyPatch® regulatory approval (including the cost of any clinical studies) against the deferred revenue balance. License revenue recognized under this arrangement will be recorded net of expenses incurred in pursuing regulatory approval. Once we can estimate the expected total cost or how much we are willing to commit in pursuit of approval, we expect to recognize any unused portion of the deferred revenue balance over the remainder of the initial 10-year period. The accounting treatment of amounts received from Shire would be expected to change if Shire were to exercise its right to require Noven to repurchase the product rights or if MethyPatch® development were abandoned.

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Results of Operations

Three and nine months ended September 30, 2003 compared to three and nine months ended September 30, 2002

Revenues:

Total revenues for the three and nine months ended September 30, 2003 and 2002 are summarized as follows (dollar amounts in thousands):

	Three Months			Nine Months		
	2003	2002	% Change	2003	2002	% Change
Product revenues Novogyne:						
Product sales	$2,756	$ 6,796	(59%)	$11,772	$20,093	(41%)
Royalties	1,182	808	46%	3,381	3,590	(6%)
	3,938	7,604	(48%)	15,153	23,683	(36%)
Product revenues third parties:						
Product sales	4,035	4,467	(10%)	12,748	14,273	(11%)
Royalties	10	143	(93%)	40	172	(77%)
	4,045	4,610	(12%)	12,788	14,445	(11%)
Total product revenues	7,983	12,214	(35%)	27,941	38,128	(27%)
License and contract revenues:						
Contract	231	103	124%	296	1,457	(80%)
License	882	881		3,145	2,504	26%
	1,113	984	13%	3,441	3,961	(13%)
Total revenues	$9,096	$13,198	(31%)	$31,382	$42,089	(25%)

Total Revenues

The decline in total revenues for the three and nine months ended September 30, 2003 as compared to the same periods in 2002 was primarily attributable to lower unit sales for both our U.S. and international products, as well as approximately $900,000 in an allowance for returns established in the third quarter related to announced and expected product recalls.

Product Revenues Novogyne

The decline in revenues from Novogyne for the three months ended September 30, 2003 as compared to the same period in the prior year primarily relates to a volume decline for the Vivelle® family products, as well as an allowance for returns established in the 2003 third quarter related to announced and expected product recalls. The decline in Vivelle® reflects lower prescription trends due to product maturity. Since the 1999 launch of Vivelle-Dot®, which is a newer, improved version of Vivelle®, Vivelle® prescriptions and sales have been steadily declining. The decline in Vivelle-Dot® reflects the timing of shipments to Novogyne based on Novogyne s inventory requirements and the effect of the announced and expected product recalls. These declines were partially offset by an increase in royalties, primarily related to increased sales revenue of Vivelle-Dot® by Novogyne.

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The decline in revenues from Novogyne for the nine months ended September 30, 2003 as compared to the same period in the prior year primarily relates to volume declines of product sold to Novogyne, which reflect lower prescription trends following the publication of the HT studies and the impact of inventory reduction initiatives intended to align inventories with post-WHI demand. An allowance for returns related to announced and expected product recalls established in the third quarter also contributed to the decline.

Product Revenues Third Parties

The decline in revenues from third parties for the three months ended September 30, 2003 as compared to the same period in the prior year primarily relates to lower unit sales of Estalis®, partially offset by higher unit sales of Estradot®. The declines in Estalis® reflect lower prescription trends following the publication of the HT studies.

The decline in revenues from third parties for the nine months ended September 30, 2003 as compared to the same period in the prior year primarily relates to volume declines of Menorest®. Novartis AG has indicated that it has reduced orders for Menorest® in certain countries in anticipation of planned transitions to Estradot® and as a result of declines in the estrogen patch market in Europe following the publication of the HT studies.

License and Contract Revenues

The decrease in contract revenues for the nine months ended September 30, 2003 as compared to the same period in the prior year is primarily attributable to the attainment of certain product development milestones and the completion of certain product development contracts in the prior year. The increase in license revenues for the nine months ended September 30, 2003 as compared to the prior year is due to the recognition of license revenue in connection with the Shire transaction. Beginning in the third quarter, 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.

Gross Margin:

Gross margin for the three and nine months ended September 30, 2003 and 2002 are summarized as follows (dollar amounts in thousands):

	Three Months			Nine Months		
	2003	2002	% Change	2003	2002	% Change
Total product revenues	$7,983	$12,214	(35%)	$27,941	$38,128	(27%)
Gross profit (product revenues less cost of products sold)	4,047	7,103	(43%)	13,680	21,096	(35%)
Gross margin (as a percentage of product revenues)	51%	58%		49%	55%	

The declines in gross margin for the three and nine months ended September 30, 2003 were primarily due to lower overhead absorption due to lower production volumes, as well as an allowance for returns

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established in the third quarter related to announced and expected product recalls, which decrease product revenues without affecting cost of goods sold.

Operating Expenses:

Operating expenses for the three and nine months ended September 30, 2003 and 2002 are summarized as follows (dollar amounts in thousands):

	Three Months			Nine Months		
	2003	2002	% Change	2003	2002	% Change
Research and development	$1,916	$2,585	(26%)	$ 6,563	$ 9,267	(29%)
Marketing, general and administrative	4,791	3,492	37%	12,265	10,104	21%

Research and Development

The decline in research and development expenses for the three months ended September 30, 2003, as compared to the same period in 2002 was primarily attributable to the purchase of fentanyl active ingredient for development purposes in the prior year. The decline for the nine months ended September 30, 2003, as compared to the same period in 2002, was primarily attributable to lower research and development expenses for MethyPatch® due to the completion of a Phase III clinical trial in the prior year, partially offset by increases in research and development expenses associated with our fentanyl transdermal delivery system.

Marketing, General and Administrative

The increase in marketing, general and administrative expenses for the three and nine months ended September 30, 2003 as compared to the same period in 2002 was primarily attributable to the $850,000 in costs associated with product recalls, increased consulting and professional fees and increased insurance costs. For the three months ended September 30, 2003, the increase was partially offset by the elimination of pre-launch marketing expenses for MethyPatch®, which ceased as a result of the Shire transaction.

Interest Income:

Interest income, net, decreased $64,000, or 29%, and $120,000 or 19%, for the three and nine months ended September 30, 2003 as compared to the same period in 2002, primarily due to lower interest rates in 2003, partially offset by an increase in our overall cash balance due to the $25 million received in April 2003 in connection with the Shire transaction.

Income Taxes:

Our effective tax rate increased to 36.0% for the three months ended September 30, 2003 from 34.9% for the three months ended September 30, 2002, and was 36.0% for the nine months ended September 30, 2003 and 2002. The provision for income taxes is based on the Federal statutory and state income tax rates. Net deferred income tax assets are measured using the average graduated tax rate for the estimated amount of annual taxable income in the years that the liability is expected to be settled or the asset recovered. The effect of adjusting the expected tax rate related to

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the net deferred income tax assets is included in the provision for income taxes. As of September 30, 2003, we had a net deferred tax asset of $15.0 million. Realization of this deferred tax asset depends upon the generation of sufficient future taxable income. Although realization is not assured, we believe it is more likely than not that the deferred income tax asset will be realized based upon estimated future taxable income.

Equity in Earnings of Novogyne:

We share in the earnings of Novogyne, after satisfaction of an annual preferred return of $6.1 million to Novartis, according to an established formula. Novogyne produced sufficient income in the first quarters of 2003 and 2002 to meet Novartis annual preferred return for those years and for us to recognize earnings from Novogyne under the formula. We report our share of Novogyne s earnings as Equity in earnings of Novogyne on our unaudited Condensed Statements of Operations.

The financial results of Novogyne for the three and nine months ended September 30, 2003 and 2002 are summarized as follows (dollar amounts in thousands):

	Three Months			Nine Months		
	2003	2002	% Change	2003	2002	% Change
Novogyne s Summary Results:						
Gross revenues	$31,839	$30,936	3%	$85,016	$102,332	(17%)
Sales allowances and returns	7,555	9,429	(20%)	14,019	20,396	(31%)
Net revenues	24,284	21,507	13%	70,997	81,936	(13%)
Cost of sales	4,568	7,079	(35%)	14,793	21,324	(31%)
Gross profit	19,716	14,428	37%	56,204	60,612	(7%)
Gross margin percentage	81%	67%		79%	74%	
Selling, general and administrative expenses	8,368	8,709	(4%)	24,312	26,866	(10%)
Amortization of intangible assets	1,545	1,545		4,635	4,635	
Income from operations	9,803	4,174	135%	27,257	29,111	(6%)
Interest income	33	73	(55%)	135	237	(43%)
Net income	$ 9,836	$ 4,247	132%	$27,392	$ 29,348	(7%)
Noven s equity in earnings of Novogyne	$ 4,529	$ 2,010	125%	$ 9,849	$ 10,657	(8%)

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

Revenues

Gross revenues increased for the three months ended September 30, 2003 compared to the prior year, primarily due to increased unit sales of Vivelle-Dot®, which we believe related to the timing of orders from trade customers. The increase was partially offset by declines in unit sales of Vivelle® in the U.S. and Vivelle® family products to Canada. Vivelle® is in a declining trend due to

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product maturity. The decline in volume of sales to Canada resulted from launch quantities of Estradot® sold in the prior year.

Gross revenues declined for the nine months ended September 30, 2003 compared to the prior year, primarily due to lower unit sales of Vivelle® and CombiPatch® in the U.S. The lower volume sales of Vivelle® were attributable to the same factors described above. The lower sales of CombiPatch® were due to the continuing effect of the HT studies described above. These declines were partially offset by increased sales of Vivelle-Dot®, primarily attributable to price increases.

The declines in sales allowances and returns for each of the three and nine months ended September 30, 2003 were attributable to declines in the reserves for expiration dating related returns, primarily attributable to lower unit sales of Vivelle®, lower returns for the Vivelle® family, and lower overall trade inventory levels. These factors caused Novogyne to reduce its estimate of future returns and correspondingly reduce its reserve for sales allowances and returns by $6.9 million and $11.0 million, respectively, for the three and nine months ended September 30, 2003. In each period, these declines were partially offset by $5 million in allowances for sales returns established in the third quarter related to announced and expected product recalls.

Gross Margin

The increases in gross margin for the three and nine months ended September 30, 2003 as compared to the prior periods were primarily due to lower sales allowances and returns, which increased net sales without affecting cost of goods sold, and lower inventory obsolescence reserves.

Selling, General and Administrative

Novogyne s selling, general and administrative expenses declined for the three and nine months ended September 30, 2003 as compared to the same periods in the prior year, primarily due to lower CombiPatch® promotion expenses and lower sample expenses in 2003.

Amortization of Intangible Asset

Novogyne amortized $1.5 million related to the CombiPatch® acquisition cost for each of the three month periods ended September 30, 2003 and 2002 and $4.6 million for each of the nine month periods ended September 30, 2003 and 2002. CombiPatch® was licensed by Novogyne in March 2001.

Liquidity and Capital Resources

As of September 30, 2003 and December 31, 2002, we had $86.9 million and $58.7 million in cash and cash equivalents, and working capital of $75.8 million and $59.3 million, respectively.

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Cash provided by (used in) operating, investing and financing activities for the nine months ended September 30, 2003 and 2002 is summarized as follows (amounts in thousands):

	2003	2002
Cash flows:		
Operating activities	$33,370	$11,752
Investing activities	(4,104)	(1,796)
Financing activities	(1,037)	415

Operating Activities:

Net cash provided by operating activities for the nine months ended September 30, 2003 primarily resulted from the receipt of a $25.0 million license payment upon the closing of the Shire transaction in April 2003 and $16.9 million in distributions 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.

Net cash provided by operating activities for the nine months ended September 30, 2002 primarily resulted from an $11.7 million distribution from Novogyne. This was partially offset by changes in working capital due to the timing and amount of product shipments and payments for inventory and income taxes.

Investing Activities:

Net cash used in investing activities for the nine months ended September 30, 2003 and 2002 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 used in financing activities for the nine months ended September 30, 2003 was primarily attributable to the repurchase of 105,000 shares of our common stock, partially offset by cash received in connection with the issuance of common stock from the exercise of stock options.

Net cash provided by financing activities for the nine months ended September 30, 2002 was primarily attributable to cash received in connection with the issuance of common stock from the exercise of stock options, partially offset by the payoff of all borrowings under a master lease facility in March 2002.

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 April 2003, Shire paid us $25 million upon closing of the MethyPatch® transaction. For the nine months ended September 30, 2003, all of our income before income taxes was comprised of equity in earnings of Novogyne, a non-cash item. Our short-term cash flow is dependent on sales, royalties and license fees associated with transdermal 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 results of the recent or ongoing HT studies

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or the pending product label changes), the failure of the transdermal HT market to resume its prior growth trends, or the inability or failure of Novogyne to pay distributions would have a material adverse effect on our short-term cash flow and require us to rely more heavily on our existing cash reserves or on borrowings to support our operations and business. Although we expect to receive distributions from Novogyne, there can be no assurance that Novogyne will have sufficient profits or cash flow to pay distributions or that Novogyne s Management Committee will authorize such distributions. We also expect our funding of an additional MethyPatch® clinical study to have a negative impact on our short-term liquidity. We cannot assure that MethyPatch® will be approved by the FDA, particularly in light of the not approvable letter we received from the FDA in April 2003, or that Shire will generate MethyPatch® sales at levels that would trigger our milestone payments; therefore, we cannot assure that we will receive any further payments from Shire. If, as a result of our product stability issues we are unable to manufacture and ship Vivelle-Dot® and Estradot® or the FDA requires us to suspend production, our liquidity would be materially and adversely affected.

In the first quarter of 2003, our Board of Directors authorized a share repurchase program under which we may acquire up to $25 million of our common stock. As of September 30, 2003, we had repurchased 105,000 shares of our common stock at an aggregate price of approximately $1.3 million. Any repurchases of common stock under our share repurchase program could adversely affect our short-term liquidity.

We believe that we will have sufficient cash available to meet our operating needs and anticipated short-term capital requirements. For our long-term operating needs, we intend to utilize funds derived from the above sources, as well as funds generated through sales of products under development or products that we may license or acquire from others. We expect that such funds will be comprised of payments received pursuant to future development and licensing arrangements, as well as direct sales of our own products. We expect that our cash requirements will continue to increase, primarily to fund clinical studies for products under development and for plant and equipment to expand production capacity. We cannot assure that we will successfully complete the development of such products, that we will obtain regulatory approval for any such products, that any approved product may be produced in commercial quantities, at reasonable costs, and be successfully marketed, or that we will successfully negotiate future licensing or product acquisition arrangements. Because much of the cost associated with product development is incurred prior to product launch, if we are 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.

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

To the extent that capital requirements exceed available capital, we will seek alternative sources of financing to fund our operations. We did not extend our credit facility, which expired in April 2003. No assurance can be given that alternative financing will be available, if at all, in a timely manner, or on favorable terms. If we are unable to obtain satisfactory alternative financing, we may be required to delay or reduce our proposed expenditures, including expenditures for research and development and plant and equipment, in order to meet our future cash requirements.

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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 and in our Form 10-Q as of June 30, 2003. In addition to the matters discussed in the Form 10-K and Form 10-Q, the following items should be added to the Revenue Recognition and Investment in Novogyne policies: Noven and Novogyne establish sales returns allowances for product that has been recalled or that they believe is probable of being recalled. The methodology used to estimate product returns is based on the distribution and expiration dates of the affected product and overall trade inventory levels. These estimates are based on currently available information, and the ultimate outcome may be significantly different than the amounts estimated given the subjective nature and complexities inherent in this area and in the pharmaceutical industry.

Outlook

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

U.S. HT:

During the fourth quarter of 2002 and first half of 2003, we undertook inventory reduction initiatives intended to align inventories for our U.S. HT products with the reduced demand that followed the publication of the WHI and other HT studies. Based on information received from Novartis, we now believe that inventories at Novogyne and in the trade channel have reached desired levels, subject to normal fluctuations.

In October 2003, we announced recalls of CombiPatch® and Vivelle-Dot® product that had tested out of specification, and indicated that other Vivelle-Dot® product was expected to be recalled following additional testing and analysis. We have undertaken additional testing of Estradot® to determine whether it is affected. Noven s and Novogyne s 2003 third quarter revenues are net of allowances for returns of approximately $900,000 and $5.0 million, respectively, related to these recalls. In addition, Noven s expenses include approximately $850,000 in costs associated with such recalls. Our results would be materially adversely affected if further analysis indicates that additional recalls are required or that additional allowances are necessary, if trade supplies are interrupted, or if Estradot® is affected to any material degree.

International HT:

We do not expect international sales of our HT products to increase in future periods unless Estradot® is launched in additional major markets. Estradot® has been launched in Germany and in several other countries, but, according to Novartis AG, significant pricing, reimbursement and post-WHI regulatory issues are adversely impacting further launch plans in many countries, including the United Kingdom, France, and Italy. Due to these issues and Novartis failure to date in securing a marketing partner in the United Kingdom and France for Estradot®, we do not expect additional major market launches of Estradot® in the near term.

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MethyPatch®:

In the second quarter of 2003, we received notification from the FDA that our pending NDA for MethyPatch® (methylphenidate transdermal system) was not approvable. In light of this development, we cannot assure either product approval or launch, nor can we predict when, if ever, we will receive additional milestone payments or manufacturing revenues from Shire.

Since receipt of the FDA notice, Noven and Shire have met with the FDA and have worked together on strategies to advance MethyPatch® toward approval. Noven and Shire have developed a draft protocol for an additional clinical study that Noven believes is necessary to amend the NDA, and we submitted the protocol to the FDA in October 2003 for review and comment. We expect the FDA to respond to our protocol in the fourth quarter of 2003. If the FDA agrees with our protocol and clinical strategy, we expect to proceed with the additional study. If they do not, development of MethyPatch® could be discontinued.

In November 2003, Noven and Shire signed a letter agreement defining certain rights and obligations of the parties. Under the letter agreement, Shire has agreed to supervise and manage the additional study, and we have agreed to fund it, up to a maximum of $10.9 million, and to provide clinical supplies of the product. We may also incur additional expenses in pursuit of approval. Our costs incurred in pursuit of approval are expected to be offset against a portion of the $25 million previously received from Shire and previously deferred.

Fentanyl Transdermal System:

In the 2003 third quarter, we submitted an Abbreviated New Drug Application (ANDA) to the FDA seeking approval to market a generic version of Duragesic® (fentanyl transdermal system). Duragesic®, distributed by Janssen Pharmaceutica L.P. (a division of Johnson & Johnson), is a Schedule II transdermal patch containing fentanyl, an opioid analgesic. Duragesic® is indicated for the management of chronic pain.

Duragesic® is expected to come off patent in mid-2004, but Janssen has been granted a six-month extension to the patent term due to completion of pediatric studies. We are in the process of negotiating with a potential industry partner to assist with commercialization. We believe that another company has first-to-file status with respect to a generic Duragesic® product, and that other companies are also developing generic versions of Duragesic®.

The FDA has communicated to us that, based on its preliminary review of our ANDA, our fentanyl patch formulation appears to contain three inactive ingredients that have not been previously approved in a drug product by the same route of administration. As a condition to further review, they requested examples of approved drug products that use these ingredients or other information demonstrating that they do not affect safety. We have provided, and the FDA is reviewing, our response to this request. Our response references listings in the FDA s Inactive Ingredient Guide, Drug Master File authorizations, usage of these ingredients in approved products and other information supporting the safety of the ingredients. If the FDA determines, however, that our response is insufficient, approval of our fentanyl patch could be delayed or prevented.

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Procter & Gamble Pharmaceuticals Development Program:

In the second quarter of 2003, we signed an agreement to develop new prescription transdermal delivery systems for P&G Pharmaceuticals, Inc. (P&GP), a subsidiary of The Procter & Gamble Company. Under the agreement, we are entitled to receive up to $7.8 million, payable in installments if certain development milestones are achieved. At P&GP s request, we have not disclosed the compounds incorporated in the new patches or the therapeutic category at which they are directed.

Financial Guidance:

Noven s revenues for 2003 are expected to decline from 2002. This decline reflects: (i) the continuing impact of WHI and other HT studies; (ii) inventory reduction efforts in the first half of 2003; (iii) strong U.S. HT sales in the first half of 2002; (iv) lower international HT sales in 2003 due to launch delays for Estradot® and declines in volume of our other products; and (v) the establishment of an allowance for returns for announced and expected product recalls. Due to uncertainties presented by the product recalls relating to production issues with CombiPatch® and Vivelle-Dot®, we are not providing 2003 fourth quarter revenue or earnings guidance.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Noven had no variable rate debt outstanding during the nine months ended September 30, 2003. Therefore, changes in interest rates did not affect interest expense, earnings or cash flows in 2003. We cannot predict market fluctuations in interest rates and their impact on any variable rate debt that we may have outstanding from time to time, nor can there be any assurance that fixed rate long-term debt will be available at favorable rates, if at all.

Item 4. Controls and Procedures

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

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can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Further, the design of any system of controls also is based in part upon assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. Furthermore, our level of historical and current equity participation in Novogyne may substantially impact the effectiveness of our disclosure controls and procedures. Because we do not control Novogyne, and Novogyne s financial, accounting, inventory and sales deductions functions are performed by Novartis, our disclosure controls and procedures with respect to Novogyne are necessarily more limited than those we maintain with respect to ourselves. No significant changes were made in our internal controls or in other factors that could significantly affect these controls subsequent to the date of the Chief Executive Officer s and Chief Financial Officer s evaluation.

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

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

Miller Donovan v. Noven Pharmaceuticals, Inc., Robert C. Strauss, James B. Messiry, and Juan A. Mantelle, United States District Court, Southern District of Florida; August 7, 2003.

Plaintiff filed the above referenced action 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 regarding Noven s rationale for approval of its MethyPatch® product and marketing strategies. The press release states that Plaintiff is seeking to recover damages on behalf of all purchasers of Noven common stock during the subject period. 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. A joint motion was filed with the Court in October 2003 seeking to consolidate all of the six actions into a single consolidated action. 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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Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

10.1	Agreement between Shire US, Inc. and Noven Pharmaceuticals, Inc. dated November 5, 2003*
10.2	Amended and Restated Employment Agreement between Robert C. Strauss and Noven Pharmaceuticals, Inc. dated as of November 5, 2003**
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

No reports on Form 8-K were filed by the Registrant during the three months ended September 30, 2003.

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* Certain exhibits and schedules to this document have not been filed. The registrant agrees to furnish a copy of any omitted schedule or exhibit to the Securities and Exchange Commission upon request.

** Compensation Plan or Agreement.

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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: November 13, 2003

By: /s/ Diane M. Barrett

Diane M. Barrett
Vice President and
Chief Financial Officer

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