NOVEN PHARMACEUTICALS INC
Form 10-Q
August 14, 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 June 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 o

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

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

Class	Outstanding at July 31, 2003
Common stock $.0001 par value	22,497,917

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

NOVEN PHARMACEUTICALS, INC.

Condensed Statements of Operations
Three and Six Months Ended June 30,
(in thousands, except per share amounts)
(unaudited)

	Three Months		Six Months	
	2003	2002	2003	2002
Revenues:				
Product revenues Novogyne	$ 7,054	$ 8,420	$11,215	$16,079
Product revenues third parties	3,786	6,058	8,743	9,835
Total product revenues	10,840	14,478	19,958	25,914
License and contract revenues	1,421	1,678	2,328	2,977
Total revenues	12,261	16,156	22,286	28,891
Expenses:				
Cost of products sold	6,040	6,021	10,325	11,921
Research and development	2,154	3,313	4,647	6,682
Marketing, general and administrative	3,293	3,679	7,474	6,612
Total expenses	11,487	13,013	22,446	25,215
Income (loss) from operations	774	3,143	(160)	3,676
Equity in earnings of Novogyne	3,795	7,132	5,320	8,647
Interest income, net	198	195	346	402
Income before income taxes	4,767	10,470	5,506	12,725
Provision for income taxes	1,717	3,827	1,983	4,629
Net income	$ 3,050	$ 6,643	$ 3,523	$ 8,096
Basic earnings per share	$ 0.14	$ 0.29	$ 0.16	$ 0.36
Diluted earnings per share	$ 0.13	$ 0.28	$ 0.15	$ 0.34

Weighted average number of common shares outstanding:				
Basic	22,493	22,528	22,536	22,510
Diluted	22,937	23,687	22,928	23,571

The accompanying notes are an integral part of these statements.

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NOVEN PHARMACEUTICALS, INC.

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

	June 30, 2003	December 31, 2002
Assets		
Current Assets:		
Cash and cash equivalents	$ 83,789	$ 58,684
Accounts receivable trade (less allowance for doubtful accounts of $54 in 2003 and $79 in 2002)	4,172	4,359
Accounts receivable Novogyne	5,973	2,581
Inventories	4,251	5,613
Net deferred income tax asset	2,000	2,600
Prepaid and other current assets	1,951	541
	102,136	74,378
Property, plant and equipment, net	18,195	16,232
Other Assets:		
Investment in Novogyne	26,353	34,684
Net deferred income tax asset	19,213	9,831
Patent development costs, net	1,998	1,996
Deposits and other assets	381	581
	47,945	47,092
	$168,276	$ 137,702
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable	$ 5,251	$ 5,062
Notes payable current portion	9	8
Accrued compensation and related liabilities	2,251	3,549
Other accrued liabilities	1,405	1,350
Current tax payable	6,579	713
Deferred contract revenues	1,429	829
Deferred license revenues current portion	10,526	3,525
	27,450	15,036
Long-Term Liabilities:		
Notes payable		5
Deferred license revenues	41,656	25,920
	69,106	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 22,495,942 shares at June 30, 2003 and 22,579,112 at December 31, 2002	2	2

Additional paid-in capital	77,264	78,358
Retained earnings	21,904	18,381
	99,170	96,741
	$168,276	$ 137,702

The accompanying notes are an integral part of these statements.

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NOVEN PHARMACEUTICALS, INC.

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

	2003	2002
Cash flows from operating activities:		
Net income	$ 3,523	$ 8,096
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,146	1,063
Amortization of patent costs	166	154
Amortization of non-competition agreement	200	200
Deferred income tax (benefit) expense	(8,782)	1,873
Non-cash expense related to issuance of stock to charitable organization	31	
Recognition of deferred contract revenues	(65)	(1,354)
Amortization of deferred license revenues	(2,263)	(1,623)
Distributed earnings in excess of equity in earnings of Novogyne	6,660	3,080
Changes in assets and liabilities:		
Decrease (increase) in accounts receivable trade, net	187	(4,555)
Increase in accounts receivable Novogyne	(3,392)	(4,323)
Decrease (increase) in inventories	1,362	(1,340)
Increase in prepaid and other current assets	(1,410)	(814)
Decrease in deposits and other assets		26
Increase in accounts payable	189	1,602
(Decrease) increase in accrued compensation and related liabilities	(1,298)	1,394
Increase in other accrued liabilities	55	936
Increase in current tax payable	7,554	161
Increase in deferred contract revenues	665	58
Increase in deferred license revenues	25,000	
Cash flows provided by operating activities	29,528	4,634
Cash flows from investing activities:		
Purchase of property, plant and equipment, net	(3,109)	(873)
Payments for patent development costs	(168)	(93)
Cash flows used in investing activities	(3,277)	(966)
Cash flows from financing activities:		
Issuance of common stock	147	593
Purchase and retirement of common stock	(1,289)	
Repayments of notes payable	(4)	(249)
Cash flows (used in) provided by financing activities	(1,146)	344
Net increase in cash and cash equivalents	25,105	4,012
Cash and cash equivalents, beginning of period	58,684	49,389
Cash and cash equivalents, end of period	$83,789	$53,401

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 June 30, 2003, and the results of its operations for the three and six months ended June 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), as well as the risk that the results of recent and ongoing studies on the adverse health effects of certain forms of hormone replacement therapy (HRT) may result in lower sales by Noven or Novogyne in future periods, the risk that MethyPatch® may not be approved by the United States Food and Drug Administration (FDA), particularly in light of Noven s receipt of a not approvable letter from the FDA in April 2003, and the risk that Shire Pharmaceuticals Group plc. (Shire) may elect to require Noven to repurchase the MethyPatch® rights for $5 million. Accordingly, the results of operations and cash flows for the three and six months ended June 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.

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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):

	June 30, 2003	December 31, 2002
Finished goods	$ 224	$ 830
Work in process	1,746	1,390
Raw materials	2,281	3,393
Total	$4,251	$5,613

5. REVENUE RECOGNITION:

Substantially all of Noven s product revenues were to its licensees, Novogyne, Novartis Pharma AG (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 would 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. 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 fees 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

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specific drug into a transdermal drug delivery system, studies to address the ongoing stability of 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.

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. 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 revenues recognized may vary from contract to contract.

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 six months ended June 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		Six Months	
	2003	2002	2003	2002
Net income:				
As reported	$ 3,050	$ 6,643	$ 3,523	$ 8,096
Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(997)	(1,138)	(2,109)	(2,229)
Pro forma	$ 2,053	$ 5,505	$ 1,414	$ 5,867
Basic earnings per share:				
As reported	$ 0.14	$ 0.29	$ 0.16	$ 0.36
Pro forma	$ 0.09	$ 0.24	$ 0.06	$ 0.26
Diluted earnings per share:				
As reported	$ 0.13	$ 0.28	$ 0.15	$ 0.34
Pro forma	$ 0.09	$ 0.23	$ 0.06	$ 0.25

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

The effect of applying the fair value method of accounting for stock options on reported net income and earnings per share for the three and six months ending June 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 $3.2 million and $2.6 million for the six months ended June 30, 2003 and 2002, respectively. Cash payments for interest were not material for the six months ended June 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.

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,

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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 $17,000 and $165,000 in income tax benefits to additional paid-in capital for the six months ended June 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 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.

Under the terms of the transaction, Noven remains responsible for securing final regulatory approval for MethyPatch®. On April 25, 2003, Noven received a not approvable letter from the FDA relating to its MethyPatch® New Drug Application (NDA). A not approvable letter is issued if the FDA 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. Pursuant to the agreement, under certain circumstances Shire has the right to require Noven to repurchase the product rights for $5 million. For accounting purposes, $20 million of the initial $25 million payment has been deferred and is being recognized as revenues over 10 years beginning in the second quarter of 2003. The remaining $5 million has been deferred and is expected to be recognized as revenues beginning at the time Shire s right to require us to repurchase the product rights expires. However, this accounting treatment would be expected to change if Shire were to exercise its right to require Noven to repurchase the product rights and Noven had no further obligations to Shire.

On the closing date, Noven entered into a long-term supply agreement under which it will manufacture and supply MethyPatch® to Shire. The agreement gives Shire the right to qualify a second manufacturing source and purchase a portion of its requirements from the second source.

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.

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

	Three Months		Six Months	
	2003	2002	2003	2002
Revenues:				
Product sales	$6,086	$6,920	$ 9,016	$13,297
Royalties	968	1,500	2,199	2,782
	$7,054	$8,420	$11,215	$16,079
Reimbursed expenses	$6,358	$5,946	$12,541	$13,628

As of June 30, 2003 and December 31, 2002, Noven had amounts due from Novogyne of $6.0 million and $2.6 million, respectively, for products sold to, and marketing expenses reimbursable by, Novogyne.

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

	Three Months		Six Months	
	2003	2002	2003	2002
Net revenues	$22,249	$32,972	$46,713	$60,429
Cost of sales	4,460	7,769	10,225	14,245
Selling, general and administrative expenses	8,061	8,220	15,944	18,157
Amortization of intangible assets	1,545	1,545	3,090	3,090
Income from operations	8,183	15,438	17,454	24,937
Interest income	17	94	102	164
Net income	$ 8,200	$15,532	$17,556	$25,101
Noven s equity in earnings of Novogyne	$ 3,795	$ 7,132	$ 5,320	$ 8,647

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 six months ended June 30, 2003, Noven received distributions of $1.3 million and $12.0 million from Novogyne, respectively. For the three and six months ended June 30, 2002, Noven received a distribution of $11.7 million from Novogyne. In addition, as discussed in Note 6, 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.

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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 June 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.

11. COMMITMENTS AND CONTINGENCIES:

HRT Studies

In July 2002, the National Institutes of Health released data on studies concerning the risks and benefits associated with use of oral hormone replacement therapy. The study revealed an increase in the risk of developing breast cancer and increased risk of stroke, heart attacks and blood clots. Also in July 2002, results of an observational study sponsored by the National Cancer Institute on the effects of estrogen replacement therapy were announced. The main finding of the study was that postmenopausal women who used estrogen replacement therapy for 10 or more years had a higher risk of developing ovarian cancer than women who never used hormone replacement therapy. In June 2003, a new analysis of study data indicated that use of combination HRT 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 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. These studies and others have caused the hormone replacement therapy market, and the market for Noven s products, to significantly decline. Management can not predict whether the studies or other studies will have additional adverse effects on Noven s results of operations, or Novogyne s ability to recover the value of the CombiPatch® intangible asset.

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. Noven expects that the agreement will be extended on satisfactory terms.

Litigation, Claims and Assessments

On August 7, 2003, a law firm issued a press release announcing that it had filed a complaint on behalf of Miller Donovan (Plaintiff), who, the law firm claimed, represents a purported class of purchasers of Noven s common stock during the period from October 29, 2001 through April 28, 2003. Noven has not been served with a complaint in this matter. According to the law firm s press release, 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

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and misleading statements regarding Noven s rationale and marketing strategies for approval of its MethyPatch® product. The press release states that Plaintiff is seeking to recover damages on behalf of all purchasers of Noven common stock during the subject period.

If served in the above-referenced matter, Noven intends to vigorously defend it, but its outcome cannot be predicted. Noven s ultimate liability with respect to the foregoing matter, if any, is not presently determinable.

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

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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, expects, intends, may plans, could, should, will, would and similar words. These statements are based on our current expectations and beliefs concerning future ev 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 HRT market of published studies regarding the adverse health effects of certain forms of HRT; uncertainties associated with future prescription trends for CombiPatch®, Vivelle® family products, Estalis® and Estradot®, including risks relating to declining physician or patient preference for HRT 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 HRT 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 (HIPAA); risks and uncertainties associated with the impact of a Novogyne competitor s strategy of increasing market share by heavily discounting product sales to managed care organizations; risks associated with the expected launches in 2003 and 2004 of estrogen cream and gel products, which are new dosage forms in this category; risks associated with higher than desired Vivelle® returns to Novogyne; risks and uncertainties relating to our dependence on Novartis to monitor trade inventory levels for Novogyne 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 coincide with prescription trends; uncertainties concerning the timing and extent of Estradot® regulatory approvals and launch orders and Estalis® orders and commercialization efforts by Novartis AG, particularly in light of the significant pricing and reimbursement issues faced by Novartis AG in Europe; our limited ability to accurately forecast international product orders from Novartis AG; the risk that MethyPatch® may not be approved by the FDA, particularly in light of the FDA s issuance of a not approvable letter; uncertainties associated with the timing, cost and outcomes of clinical trials, product development and product launch, including the regulatory review process for MethyPatch® (together with any additional clinical trials that may be required or advisable in connection with that review process) and any future generations of our combination estrogen/progestin patch; risks and uncertainties associated with product liability claims that may be brought against us as a result of published studies regarding the adverse health effects of HRT; our dependence on strategic alliances and our relationships with our

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licensees, and our vulnerability to the risks and uncertainties of our licensees businesses, inventory requirements and marketing strategies; the risk that our licensees may favor their own competitive products over the products licensed from us; the risk that Shire may seek to exercise its right to require us to repurchase the rights to MethyPatch® for $5 million, and the risk that such an exercise would change our method of accounting for the initial amount received from Shire; risks associated with the availability of a non-stimulant therapy to treat children with Attention Deficit Hyperactivity Disorder (ADHD); risks associated with our ability to meet Shire s manufacturing requirements for MethyPatch®; 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 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.

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, and we expect that the supply agreement will be extended on satisfactory terms. However, we cannot assure that the agreement will be extended on satisfactory terms or at all. Failure to extend the supply agreement could have a material adverse effect on our business, results of operations, financial conditions and prospects. Designation of a new supplier and approval of a new supply agreement would require the affirmative vote of 4 of the 5 members of Novogyne s Management Committee. Accordingly, both Novartis and Noven must agree on Novogyne s supplier.

In November 2000, we entered into an exclusive license agreement with Novartis AG pursuant to which we granted Novartis AG the right to market Vivelle-Dot® 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. Novartis AG markets several other transdermal HRT products in addition to our products, which may limit the efforts Novartis AG devotes to our products. In some countries, including the United Kingdom and France, Novartis AG is seeking a marketing partner to launch the product, but to date has been unsuccessful. We cannot assure that Novartis AG will be successful in securing a marketing partner or in launching Estradot® in those countries, and we do not expect additional major market launches of Estradot® in the remainder of 2003.

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HRT 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 long-term use of oral HRT by healthy women. The NIH announced that it was discontinuing the arm of the study investigating the use of oral estrogen/progestin combination HRT products after an average follow-up period of 5.2 years because the oral HRT product used in the study was shown to cause an increase in the risk of invasive breast cancer. The study also found an increased risk of stroke, heart attacks and blood clots and concluded that overall health risks exceeded benefits from use of the orally delivered combined estrogen plus progestin product among healthy postmenopausal women. Also in July 2002, results of an observational study sponsored by the National Cancer Institute (NCI) on the effects of estrogen replacement therapy (ERT) were announced. The main finding of the NCI study was that postmenopausal women who used ERT for 10 or more years had a higher risk of developing ovarian cancer than women who never used HRT. In June 2003, a further analysis of data from the discontinued combination therapy arm of the WHI study indicated that use of combination HRT 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 HRT products, either as physicians withdraw their patients from HRT or as women elect to discontinue HRT on their own. In addition, the market growth that would have been expected if HRT had been found safe and effective for additional indications, such as heart disease, is now unlikely to materialize. In January 2003, the FDA announced that marketers of HRT products, including Novogyne, are required to modify their HRT product labels to include additional safety information and warnings. Among other things, the labels must indicate that HRT should be used for short-term therapy only and that, in the absence of clinical studies demonstrating that HRT products other than the oral product studied in the WHI study are safe, physicians should assume that all HRT products carry the same risks. Novartis has informed us that it has submitted proposed revised labeling to the FDA and will begin using the revised label 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 HRT products, such as those presently under development by Novartis AG and us, or require that any new HRT products be subject to more extensive or more rigorous study and testing prior to being approved. Further, because these studies show that certain uses of certain HRT products may result in a higher likelihood of certain adverse health effects, it is possible that we could be named as a defendant in product liability lawsuits relating to our HRT products.

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Other studies evaluating HRT are currently underway or in the planning stages. In particular, the estrogen-only arm of the WHI study is ongoing. We are unable to predict the effect of new study results, once available, on the short and long-term prospects for the HRT market or on the market for our transdermal HRT products. Since publication of the WHI and NCI study data, United States prescriptions have declined for substantially all HRT products, including our products, although Vivelle® family total monthly prescriptions have returned to approximately pre-WHI levels. 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 HRT 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 HRT study is halted, or if ongoing analyses yield additional safety concerns, the market for HRT products, including ours, both in the United States and abroad, could be further adversely impacted. The HRT label changes mandated by the FDA may also negatively impact our products, particularly with physicians and patients who may believe that transdermal HRT products are safer than orally delivered HRT products. Currently, our results of operations and business prospects are dependent on sales, license royalties and fees associated with transdermal HRT products. Accordingly, any further adverse change in the market for HRT products (including any adverse changes resulting from the foregoing studies) could have a material adverse impact on our liquidity, results of operations and business prospects.

MethyPatch®

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

In the first quarter of 2003, we signed an agreement to license the exclusive global rights to market MethyPatch® to Shire for payments of up to $150 million and ongoing manufacturing 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 will manufacture and supply MethyPatch® to Shire. The agreement gives Shire the right to qualify a second manufacturing source and purchase a portion of its requirements from the second source.

Under the terms of the transaction, we remain responsible for securing final regulatory approval for MethyPatch®. On April 25, 2003, we received a not approvable letter from the FDA relating to our MethyPatch® NDA. A not approvable letter is issued if the FDA does not consider the application approvable because one or more deficiencies in the application preclude the FDA from approving it.

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Pursuant to the agreement, under certain circumstances Shire has the right to require us to repurchase the product rights for $5 million. For accounting purposes, $20 million of the initial $25 million payment has been deferred and is being recognized as revenues over 10 years beginning in the second quarter of 2003. The remaining $5 million has been deferred and is expected to be recognized as revenues beginning at the time Shire s right to require us to repurchase the product rights expires. However, this accounting treatment would be expected to change if Shire were to exercise its right to require Noven to repurchase the product rights.

The FDA cited clinical and other issues as the basis for non-approval. We are working with the FDA to clarify its concerns and to determine what additional studies, analyses or other actions would resolve the issues raised in the letter. We are presently conducting additional analyses of data from MethyPatch® clinical studies in an effort to address the FDA s clinical issues regarding the MethyPatch® NDA without undertaking an additional Phase III clinical study. In parallel with that analysis, we also expect to begin a large-scale clinical trial before year-end, reflecting our belief that an additional pre-approval study will likely be required. We cannot assure that we will develop a strategy for approval that will be acceptable to the FDA, that we will successfully execute any strategy we develop or that successfully executing any strategy will result in approval. We also cannot assure that any additional requirements imposed by the FDA will not be cost-prohibitive, impair the commercial value of MethyPatch®, or otherwise cause us and/or Shire to elect not to pursue commercialization of the product. Therefore, we cannot assure that MethyPatch® will ever be approved by the FDA or ultimately commercialized.

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Results of Operations

Three and six months ended June 30, 2003 compared to three and six months ended June 30, 2002

Revenues:

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

	Three Months			Six Months		
	2003	2002	% Change	2003	2002	% Change
Product revenues Novogyne:						
Product sales	$ 6,086	$ 6,920	(12%)	$ 9,016	$13,297	(32%)
Royalties	968	1,500	(35%)	2,199	2,782	(21%)
	7,054	8,420	(16%)	11,215	16,079	(30%)
Product revenues third parties:						
Product sales	3,753	6,029	(38%)	8,713	9,806	(11%)
Royalties	33	29	14%	30	29	3%
	3,786	6,058	(38%)	8,743	9,835	(11%)
Total product revenues	10,840	14,478	(25%)	19,958	25,914	(23%)
License and contract revenues:						
Contract	39	799	(95%)	65	1,354	(95%)
License	1,382	879	57%	2,263	1,623	39%
	1,421	1,678	(15%)	2,328	2,977	(22%)
Total revenues	$12,261	$16,156	(24%)	$22,286	$28,891	(23%)

Total Revenues

The decline in total revenues for the three and six months ended June 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, and lower royalties due to lower Novogyne sales of Vivelle® family products.

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

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Product Revenues Novogyne

The decline in revenues from Novogyne for the three months ended June 30, 2003 as compared to the prior year primarily relates to a volume decline for Vivelle®, which reflects lower prescription trends due to product maturity and the impact of inventory reduction initiatives intended to align inventories with post-WHI demand. Since the 1999 launch of Vivelle-Dot®, which is a newer, improved version of Vivelle®, Vivelle® prescriptions and sales have been steadily declining. In addition, royalty revenues declined due to lower unit sales by Novogyne of Vivelle® family products. These declines were partially offset by an increase in volume of CombiPatch® sold to Novogyne. In the first three months of 2003, a production issue relating to material supplied by one vendor caused us to temporarily suspend shipments of CombiPatch® to Novogyne. We believe we have resolved this production issue, and we resumed shipments of CombiPatch® late in the second quarter of 2003.

The decline in revenues from Novogyne for the six months ended June 30, 2003 as compared to the prior year primarily relates to volume declines of all products sold to Novogyne and lower royalty payments from Novogyne, which reflects lower prescription trends following the publication of the HRT studies.

Product Revenues Third Parties

The decline in revenues from third parties for the three and six months ended June 30, 2003 as compared to the prior year primarily related to lower unit sales of Menorest® and, to a lesser extent, Estradot®. The decline in sales of Estradot® compared to the prior year is primarily a result of the effect of the sale to Novartis AG of launch quantities for Germany in 2002. Germany remains the only major European country in which Novartis AG has launched Estradot®.

License and Contract Revenues

The increase in license revenues for the three and six months ended June 30, 2003 as compared to the prior year is due to the closing of the MethyPatch® license transaction with Shire and Noven s receipt of $25 million, of which $20 million is being recognized as revenues over 10 years beginning in the second quarter of 2003. The reduction in contract revenues is primarily attributable to the attainment of certain milestones and the completion of certain contracts in the prior year.

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Gross Margin:

	Three Months			Six Months		
	2003	2002	% Change	2003	2002	% Change
Total product revenues	$10,840	$14,478	(25%)	$19,958	$25,914	(23%)
Gross profit (product revenues less cost of products sold)	4,800	8,457	(43%)	9,633	13,993	(31%)
Gross margin (as a percentage of product revenues)	44%	58%		48%	54%	

The declines in gross margin for the three and six months ended June 30, 2003 were primarily due to (i) lower overhead absorption due to lower production volumes, (ii) lower royalty revenues from Novogyne, and (iii) an increase in deferred profit on sales to Novogyne. Novogyne had higher end-of-period inventories as a result of lower sales for the three and six months ended June 30, 2003. We defer 49% of the profit on product we sell to Novogyne until that product is sold by Novogyne to trade customers. We did not ship CombiPatch to Novogyne in the 2003 first quarter due to a production issue. Shipping resumed late in the second quarter. Because much of this product did not sell through to trade customers in the second quarter, our deferred profit increased, contributing to the decline in Noven s quarterly gross margin.

Operating Expenses:

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

	Three Months			Six Months		
	2003	2002	% Change	2003	2002	% Change
Research and development	$2,154	$3,313	(35%)	$4,647	$6,682	(30%)
Marketing, general and administrative	3,293	3,679	(10%)	7,474	6,612	13%

Research and Development

The declines in research and development expenses for the three and six months ended June 30, 2003, as compared to the same periods in 2002, were primarily attributable to lower research and development expenses for MethyPatch® due to the completion of Phase III clinical trials 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 decline in marketing, general and administrative expenses for the three months ended June 30, 2003 as compared to the same period in 2002 was primarily attributable to lower pre-launch marketing expenses for MethyPatch®, which ceased as a result of the Shire transaction.

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The increase in marketing, general and administrative expenses for the six months ended June 30, 2003 as compared to the same period in 2002 was primarily attributable to pre-launch marketing expenses incurred during the first quarter of 2003 for MethyPatch®, and increased legal fees incurred in connection with the Shire transaction.

Interest Income:

Interest income, net, increased $3,000, or 2%, for the three months ended June 30, 2003 as compared to the same period in 2002 as a result of an increase in our overall cash balance due to the $25 million received in April 2003 in connection with the Shire transaction, partially offset by lower interest rates.

Interest income, net, decreased $56,000, or 14%, for the six months ended June 30, 2003 as compared to the same period in 2002 primarily due to lower interest rates in 2003, partially offset by an increased cash balance as noted above.

Income Taxes:

Our effective tax rate decreased to 36.0% for the three months ended June 30, 2003 from 36.6% for the three months ended June 30, 2002, and 36.0% for the six months ended June 30, 2003 from 36.4% for the six months ended June 30, 2002. The provision for income taxes is based on the Federal statutory and state income tax rates. Net deferred income tax assets are measured using the average graduated tax rate for the estimated amount of annual taxable income in the years that the liability is expected to be settled or the asset recovered. The effect of adjusting the expected tax rate related to the net deferred income tax assets is included in the provision for income taxes. As of June 30, 2003, we had a net deferred tax asset of $21.2 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 Condensed Statements of Operations.

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

	Three Months			Six Months		
	2003	2002	% Change	2003	2002	% Change
Novogyne s Summary Results:						
Gross revenues	$22,586	$38,742	(42%)	$53,178	$71,395	(26%)
Sales allowances and returns	337	5,770	(94%)	6,465	10,966	(41%)
Net revenues	22,249	32,972	(33%)	46,713	60,429	(23%)
Cost of sales	4,460	7,769	(43%)	10,225	14,245	(28%)
Gross profit	17,789	25,203	(29%)	36,488	46,184	(21%)
Gross margin percentage	80%	76%		78%	76%	
Selling, general and administrative expenses	8,061	8,220	(2%)	15,944	18,157	(12%)
Amortization of intangible assets	1,545	1,545		3,090	3,090	
Income from operations	8,183	15,438	(47%)	17,454	24,937	(30%)
Interest income	17	94	(82%)	102	164	(38%)
Net income	$ 8,200	$15,532	(47%)	$17,556	$25,101	(30%)
Noven s equity in earnings of Novogyne	$ 3,795	$ 7,132	(47%)	$ 5,320	$ 8,647	(38%)

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

The declines in gross revenues were primarily due to lower unit sales of each of Novogyne s products. Vivelle® family total monthly prescriptions have returned to approximately pre-WHI levels. Based on prescription data for recent periods demonstrating increased demand for Vivelle-Dot®, we believe that the declines in Vivelle-Dot® sales were primarily due to the timing of orders from trade customers, partially offset by a price increase. The declines in volume of Vivelle® during the relevant periods were the result of lower prescription trends due to product maturity and the inventory initiatives intended to align inventories with post-WHI demand. The lower volume sales of CombiPatch® were due to the continuing effect of the HRT studies described above.

The declines in sales allowances and returns were primarily attributable to lower unit sales of all products, lower returns for Vivelle®, 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.

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Gross Margin

The increase in gross margin for the three and six months ended June 30, 2003 as compared to the prior periods was primarily due to lower sales allowances and returns, which increased net sales without affecting cost of goods sold.

Selling, General and Administrative

Novogyne s selling, general and administrative expenses declined for the three and six months ended June 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. This decline was partially offset by higher sales force expenses due to the addition of sales personnel.

Amortization of Intangible Asset

Novogyne amortized $1.5 million related to the CombiPatch® acquisition cost for each of the three month periods ended June 30, 2003 and 2002 and $3.1 million for each of the six month periods ended June 30, 2003 and 2002. CombiPatch® was licensed by Novogyne in March 2001.

Liquidity and Capital Resources

As of June 30, 2003 and December 31, 2002, we had $83.8 million and $58.7 million in cash and cash equivalents, and working capital of $74.7 million and $59.3 million, respectively.

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

	2003	2002
Cash flows:		
Operating activities	$29,528	$4,634
Investing activities	(3,277)	(966)
Financing activities	(1,146)	344

Operating Activities:

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

Net cash provided by operating activities for the six months ended June 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.

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Investing Activities:

Net cash used in investing activities for the six months ended June 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 six months ended June 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 six months ended June 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 six months ended June 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 HRT products. Any decrease in sales of those products by us or our licensees or any increase in returns of products to Novogyne (including any such changes resulting from the results of the recent or ongoing HRT studies or the pending product label changes), the failure of the transdermal HRT market to resume its prior growth trends, or the inability or failure of Novogyne to pay distributions would have a material adverse effect on our short-term cash flow and require us to rely more heavily on our existing cash reserves or on borrowings to support our operations and business. Although we expect to receive distributions from Novogyne, there can be no assurance that Novogyne will have sufficient profits or cash flow to pay distributions or that Novogyne s Management Committee will authorize such distributions. We cannot assure that MethyPatch® 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.

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 June 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

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equipment to expand production capacity. We cannot assure that we will successfully complete the development of such products, that we will obtain regulatory approval for any such products, that any approved product may be produced in commercial quantities, at reasonable costs, and be successfully marketed, or that we will successfully negotiate future licensing or product acquisition arrangements. Because much of the cost associated with product development is incurred prior to product launch, if we are unable to launch additional commercially viable products that we develop or that we license or acquire from others, we will have incurred the up-front costs associated with product development or acquisition without the benefit of the liquidity generated by sales of those products, which could adversely affect our long-term liquidity needs.

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

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

Critical Accounting Policies

For a discussion of our critical accounting policies, see Management s Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies , which is included in our Form 10-K. In addition to the matters discussed in the Form 10-K, the following items should be added to the Revenue Recognition policy: (i) Noven accrues royalties from Novogyne s product sales each quarter based on Novogyne s net sales for that quarter; and (ii) contract revenues are now being included in License and contract revenues instead of product sales. Also, the following item should be added to the Investment in Novogyne policy: The methodology used by Novogyne to estimate product returns is based on (i) the historical experience of actual product returns and (ii) the estimated lag time between when an actual sale takes place in relation to when the products are physically returned by a customer. The historical actual returns rate is then applied to product sales during the estimated lag period to develop the returns estimate. However, because Novogyne s return history includes periods of higher and lower trade inventory levels and varying levels of demand, in making its final estimations of expected product return, Novogyne also considers trends and expectations for future demand and trade inventory levels. Novogyne does not accept returns due to short-dating until the product has less than a certain amount of shelf-life remaining. Also, Novogyne does not accept returns due to expiration later than a certain period after the product has expired. These policies cause a significant lag time between when a product is sold and the latest date on which a return could occur. Novogyne believes this is a reasonable basis on which to estimate returns exposure and incorporates the key factors that contribute to returns.

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Outlook

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

U.S. HRT

During the fourth quarter of 2002 and first half of 2003, we undertook inventory reduction initiatives intended to align inventories for our U.S. HRT products with the reduced demand that followed the early termination of the combination therapy arm of the WHI study. 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.

International HRT

We do not expect international sales to grow in 2003 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 remainder of 2003.

MethyPatch®

In light of our April 2003 receipt of a not approvable letter from the FDA for MethyPatch®, we are unable to assure either product approval or launch, nor can we predict when, if ever, we will receive additional milestone payments or manufacturing revenues from Shire.

We are conducting additional analyses of data from MethyPatch® clinical studies in an effort to address the FDA s clinical issues regarding the MethyPatch® NDA without undertaking an additional Phase III clinical study. In parallel with that analysis, we also expect to begin a large-scale clinical trial before year-end, reflecting our belief that an additional pre-approval study will likely be required. Noven expects to fund the cost of the study, which we expect will cost $5-8 million, and associated expenses are expected to be reflected in our financial results beginning in the second half of 2003 and extending into 2004. Depending on final study design, the number of subjects and other factors, the actual cost may be greater and the trial may commence later and/or last longer than we anticipate. The FDA could require additional studies and/or activities as a condition of approval, and the total cost may exceed our estimate. In light of the expected MethyPatch® clinical trial, we have postponed clinical studies of our developmental dextroamphetamine patch for ADHD.

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Financial Guidance

For full-year 2003, we expect to report revenues in the low $40 million range. The expected decline in 2003 revenues compared to 2002 reflects: (i) the continuing impact of WHI; (ii) inventory reduction efforts; (iii) strong U.S. HRT sales in the first half of 2002; and (iv) lower international HRT sales in 2003 due to launch delays for Estradot® and declines in volume of our other products. Depending on the cost and timing of expected MethyPatch® clinical trials, our diluted earnings per share for 2003 could be as low as $0.30. This earnings forecast incorporates (i) our internal estimates of MethyPatch and other clinical spending in the 2003 second half, and (ii) our belief that Novogyne sales will re-align with prescription trends, permitting Novogyne to report results for 2003 that approach 2002 results.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Noven had no variable rate debt outstanding during the six months ended June 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 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

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procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. Furthermore, our level of historical and current equity participation in Novogyne may substantially impact the effectiveness of our disclosure controls and procedures. Because we do not control Novogyne, and Novogyne s financial, accounting, inventory and sales deductions functions are performed by Novartis, our disclosure controls and procedures with respect to Novogyne are necessarily more limited than those we maintain with respect to ourselves. No significant changes were made in our internal controls or in other factors that could significantly affect these controls subsequent to the date of the Chief Executive Officer s and Chief Financial Officer s evaluation.

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

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PART II. OTHER INFORMATION

Item 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.

On August 7, 2003, a law firm issued a press release in which it announced that it filed a complaint in the above-referenced matter on behalf of Plaintiff, who, the law firm claimed, represents a purported class of purchasers of Noven s common stock during the period from October 29, 2001 through April 28, 2003. Noven has not been served with a complaint in this matter. According to the law firm s press release, 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 and marketing strategies for approval of its MethyPatch® product. The press release states that Plaintiff is seeking to recover damages on behalf of all purchasers of Noven common stock during the subject period.

If served in the above-referenced matter, Noven intends to vigorously defend it, but its outcome cannot be predicted. Noven s ultimate liability with respect to the foregoing matter, if any, is not presently determinable.

Item 4. Submission of Matters to a Vote of Security Holders

Annual Meeting of Stockholders held on May 14, 2003.

(i) Election of Directors

	For	Withheld
Sidney Braginsky	21,160,196	82,371
John G. Clarkson, M.D.	21,160,296	82,271
Lawrence J. DuBow	21,160,296	82,271
Regina E. Herzlinger	21,160,346	82,221
Robert C. Strauss	20,762,779	479,788
Wayne P. Yetter	21,160,246	82,321

(ii) The ratification of the appointment of Deloitte & Touche LLP as Noven s independent certified public accountants for 2003 was approved by an affirmative vote of 20,245,354 shares to a negative vote of 974,877 shares, with 22,336 shares abstaining.

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Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

31.1	Certification of Robert C. Strauss, President, Chief Executive Officer and Chairman of the Board pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Diane M. Barrett, Vice President and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Robert C. Strauss, President, Chief Executive Officer and Chairman of the Board, pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Diane M. Barrett, Vice President and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(b) Reports on Form 8-K

On April 25, 2003, Noven filed a current report on Form 8-K relating to the receipt of a not approvable letter received from the FDA relating to the NDA for its methylphenidate transdermal system.

On April 30, 2003, Noven furnished a current report on Form 8-K relating to the issuance of a press release announcing its financial results for the three months ended March 31, 2003.

On July 31, 2003, Noven furnished a current report on Form 8-K relating to the issuance of a press release announcing its financial results for the three and six months ended June 30, 2003.

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Signatures

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

NOVEN PHARMACEUTICALS, INC.

Date: August 14, 2003

By: /s/ Diane M. Barrett

Diane M. Barrett
Vice President and
Chief Financial Officer