NOVEN PHARMACEUTICALS INC
Form 10-Q
November 09, 2004

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, 2004

Commission file number 0-17254

NOVEN PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

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

(Address of principal executive offices) (Zip Code)

(305) 253-5099

(Registrant s telephone number, including area code)

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

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

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

Class	Outstanding at October 29, 2004
Common stock $.0001 par value	23,443,053

NOVEN PHARMACEUTICALS, INC.

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Cautionary Factors: This report contains forward-looking statements. Our actual results, performance and achievements may be materially different from those expressed or implied by such statements and readers should consider the risks and uncertainties associated with our business that are listed, by category, starting on page 27 of this report. For additional information regarding these and other risks and uncertainties, readers should refer to our Annual Report on Form 10-K for the year ended December 31, 2003, as well as other reports filed from time to time with the Securities and Exchange Commission.

Trademark Information: Vivelle, Vivelle-Dot, Estalis, Estradot and Menorest are trademarks of Novartis AG or its affiliated companies; CombiPatch is a registered trademark of Vivelle Ventures, LLC; MethyPatch is a registered trademark of Noven Pharmaceuticals, Inc.; Duragesic is a registered trademark of Johnson & Johnson; Intrinsa is a trademark of Procter & Gamble Pharmaceuticals, Inc.

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	
	2004	**2003**	**2004**	**2003**
Revenues:				
Product revenues Novogyne:				
Product sales	$ 4,364	$ 2,756	$15,058	$11,772
Royalties	1,411	1,182	3,909	3,381
Total product revenues Novogyne	5,775	3,938	18,967	15,153
Product revenues third parties	3,287	4,045	9,828	12,788
Total product revenues	9,062	7,983	28,795	27,941
License and contract revenues	1,039	1,113	4,391	3,441
Net revenues	10,101	9,096	33,186	31,382
Expenses:				
Cost of products sold	4,984	3,936	15,477	14,261
Research and development	2,741	1,916	7,730	6,563
Marketing, general and administrative	4,358	4,791	12,024	12,265
Total expenses	12,083	10,643	35,231	33,089
Loss from operations	(1,982)	(1,547)	(2,045)	(1,707)
Equity in earnings of Novogyne	6,232	4,529	15,097	9,849
Interest income, net	279	159	619	505

Income before income taxes	4,529	3,141	13,671	8,647
Provision for income taxes	1,895	1,130	5,201	3,113
Net income	$ 2,634	$ 2,011	$ 8,470	$ 5,534
Basic earnings per share	$ 0.11	$ 0.09	$ 0.36	$ 0.25
Diluted earnings per share	$ 0.11	$ 0.09	$ 0.35	$ 0.24
Weighted average number of common shares outstanding:				
Basic	23,416	22,506	23,290	22,526
Diluted	24,361	22,949	24,344	22,935

The accompanying notes are an integral part of these statements.

NOVEN PHARMACEUTICALS, INC.

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

	September 30, 2004	December 31, 2003
Assets		
Current Assets:		
Cash and cash equivalents	$ 100,347	$ 83,381
Accounts receivable trade (less allowance for doubtful accounts of $72 in 2004 and $84 in 2003)	2,083	3,809
Accounts receivable Novogyne, net	4,488	6,320
Inventories	5,324	5,200
Net deferred income tax asset, current portion	9,900	8,000
Prepaid income taxes and other current assets	8,766	3,219
	130,908	109,929
Property, plant and equipment, net	22,005	18,354
Other Assets:		
Investment in Novogyne	29,510	28,368
Net deferred income tax asset	7,290	12,175
Patent development costs, net	2,114	1,977
Deposits and other assets	21	181
	38,935	42,701
	$ 191,848	$ 170,984
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable	$ 9,576	$ 4,060
Capital lease obligations current portion	102	
Accrued compensation and related liabilities	5,202	3,734
Other accrued liabilities	1,618	3,590
Deferred contract revenues	2,532	772
Deferred license revenues current portion	17,033	21,112
	36,063	33,268

Long-Term Liabilities:		
Capital lease obligations	136	
Deferred license revenues	29,767	28,893
	65,966	62,161
Commitments and Contingencies (Note 11)		
Stockholders Equity:		
Preferred stock authorized 100,000 shares of $.01 par value; no shares issued or outstanding		
Common stock authorized 80,000,000 shares, par value $.0001 per share; issued and outstanding 23,439,768 at September 30, 2004 and 22,722,060 at December 31, 2003	2	2
Additional paid-in capital	87,833	79,244
Retained earnings	38,047	29,577
	125,882	108,823
	$ 191,848	$ 170,984

The accompanying notes are an integral part of these statements.

NOVEN PHARMACEUTICALS, INC.

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

	2004	2003
Cash flows from operating activities:		
Net income	$ 8,470	$ 5,534
Adjustments to reconcile net income to net cash flows provided by operating activities:		
Depreciation and amortization	1,665	1,683
Amortization of patent costs	285	252
Amortization of non-competition agreement	167	300
Income tax benefits on exercise of stock options	3,007	67
Deferred income tax provision (benefit)	2,985	(3,315)
Non-cash expense related to issuance of stock to outside directors	30	31
Recognition of deferred contract revenues	(1,415)	(296)
Amortization of deferred license revenues	(2,976)	(3,145)
Equity in earnings of Novogyne	(15,097)	(9,849)
Distributions from Novogyne	12,263	16,894
Changes in operating assets and liabilities:		
Decrease in accounts receivable trade, net	1,726	1,076
Decrease (increase) in accounts receivable Novogyne, net	1,832	(537)
(Increase) decrease in inventories	(124)	419
Increase in prepaid income taxes and other current assets	(3,855)	(3,504)
Increase in deposits and other assets	(7)	
Increase in accounts payable	5,516	647
Increase (decrease) in accrued compensation and related liabilities	1,468	(95)
(Decrease) increase in other accrued liabilities	(1,972)	1,440
Increase in deferred contract revenue	3,175	768
Increase in deferred license revenue	6,500	25,000
Direct expenses incurred in pursuit of MethyPatch® product regulatory approval	(6,729)	
Cash flows provided by operating activities	16,914	33,370
Cash flows from investing activities:		
Purchases of property, plant and equipment, net	(5,004)	(3,869)
Payments for patent development costs	(422)	(235)
Cash flows used in investing activities	(5,426)	(4,104)
Cash flows from financing activities:		
Issuance of common stock from exercise of stock options	5,552	258
Purchase and retirement of common stock		(1,289)

Repayments of capital leases and notes payable	(74)	(6)
Cash flows provided by (used in) financing activities	5,478	(1,037)
Net increase in cash and cash equivalents	16,966	28,229
Cash and cash equivalents, beginning of period	83,381	58,684
Cash and cash equivalents, end of period	$100,347	$86,913

The accompanying notes are an integral part of these statements.

NOVEN PHARMACEUTICALS, INC.

Notes to Unaudited Condensed Financial Statements

1. DESCRIPTION OF BUSINESS:

Noven Pharmaceuticals, Inc. (Noven) was incorporated in Delaware in 1987 and is engaged in the research, development, manufacture and marketing of advanced transdermal drug delivery technologies and prescription transdermal products.

Noven and Novartis Pharmaceuticals Corporation (Novartis) entered into a joint venture, Vivelle Ventures LLC (d/b/a Novogyne Pharmaceuticals) (Novogyne), effective May 1, 1998, to market and sell women s prescription healthcare products in the United States and Canada. These products include Noven s transdermal estrogen delivery systems marketed under the brand names Vivelle® and Vivelle-Dot® and Noven s transdermal combination estrogen/progestin delivery system marketed under the brand name CombiPatch®. Noven accounts for its 49% investment in Novogyne under the equity method and reports its share of Novogyne s earnings as Equity in earnings of Novogyne on its Statements of Operations. Noven defers the recognition of 49% of its profit on products sold to Novogyne until the products are sold by Novogyne to third party customers.

2. BASIS OF PRESENTATION:

In management s opinion, the accompanying unaudited condensed financial statements of Noven contain all adjustments (consisting of only normal recurring adjustments) necessary to present fairly, in all material respects, the financial position of Noven as of September 30, 2004, and the results of its operations and its cash flows for the three and nine months ended September 30, 2004 and 2003. Noven s business is subject to numerous risks and uncertainties including, but not limited to, those set forth in Noven s Annual Report on Form 10-K, as amended, for the year ended December 31, 2003 (Form 10-K), and in Part I 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, 2004 and 2003 are not, and should not be construed as, necessarily indicative of the results of operations or cash flows which may be reported for the remainder of 2004 or for periods thereafter.

The accompanying unaudited condensed financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission for reporting on Form 10-Q. Pursuant to such rules and regulations, certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted. The unaudited condensed financial statements should be read in conjunction with the financial statements and the notes to the financial statements included in Noven s Form 10-K. The accounting policies followed for interim financial reporting are the same as those disclosed in Note 2 of the notes to the financial statements included in Noven s Form 10-K.

3. RECENT ACCOUNTING PRONOUNCEMENTS:

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

the entity to finance its activities without additional subordinated financial support from other parties, which is provided through other interests that will absorb some or all of the expected losses of the entity, and (ii) the equity investors lack one or more of the characteristics of a controlling financial interest. This interpretation applies immediately to variable interest entities created after January 31, 2003, and to variable interest entities in which an enterprise obtains an interest after that date. It applies no later than the first reporting period ending after March 15, 2004 to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. Noven s investment in Novogyne is not considered a variable interest in a Variable Interest Entity (VIE) under the provisions of FIN 46. Therefore, the consolidation and disclosure rules of FIN 46 are not applicable to Noven and the adoption of this interpretation has had no impact on Noven s financial statements. These conclusions are based on currently available information and require Noven to periodically assess its investment interest and ownership rights in Novogyne. If Noven s conclusions or underlying assumptions of factual information concerning its investment in Novogyne prove incorrect or were to change, Novogyne may be considered a VIE and Noven s investment in Novogyne could become subject to the consolidation and disclosure rules of FIN 46. In that case, a determination would have to be made as to the primary beneficiary of Novogyne s interest. The primary beneficiary would then consolidate Novogyne. Noven believes that, even if a determination were made that Novogyne was a VIE at September 30, 2004, Novartis is the primary beneficiary due to its preferred return and 51% equity interest in Novogyne and would continue to consolidate Novogyne.

4. RECLASSIFICATIONS:

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

5. INVENTORIES:

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

	September 30, 2004	December 31, 2003
Finished goods	$ 737	$ 806
Work in process	1,427	1,722
Raw materials	3,160	2,672
Total	$5,324	$5,200

Included in the amounts above as of September 30, 2004 were approximately $0.5 million in raw materials inventories to manufacture launch supplies of Noven s fentanyl patch for which FDA approval is pending. See Note 8 License and Contract Agreements Endo Collaboration.

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.

The following table illustrates the effect on net income and earnings per share for the three and nine months ended September 30, 2004 and 2003 if Noven had applied the fair value recognition provisions of SFAS 123, as amended by SFAS 148 (in thousands, except per share amounts):

	Three Months		Nine Months	
	2004	**2003**	**2004**	**2003**
Net income:				
As reported	$ 2,634	$ 2,011	$ 8,470	$ 5,534
Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(1,565)	(1,054)	(3,289)	(3,163)
Pro forma	$ 1,069	$ 957	$ 5,181	$ 2,371
Basic earnings per share:				
As reported	$ 0.11	$ 0.09	$ 0.36	$ 0.25
Pro forma	$ 0.05	$ 0.04	$ 0.22	$ 0.11
Diluted earnings per share:				
As reported	$ 0.11	$ 0.09	$ 0.35	$ 0.24
Pro forma	$ 0.04	$ 0.04	$ 0.21	$ 0.10

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 ended September 30, 2004 and 2003, respectively, may not be representative of the effects for future years because outstanding options vest over a period of several years and additional awards are generally made during each year.

7. CASH FLOW INFORMATION:

Cash payments for income taxes were $5.4 million and $8.5 million for the nine months ended September 30, 2004 and 2003, respectively. Cash payments for interest were not material for the nine months ended September 30, 2004

and 2003.

Non-cash Operating Activities

In 2002, the State of New Jersey enacted legislation that requires Novogyne to remit estimated state income tax payments on behalf of its owners, Noven and Novartis. In April 2004 and 2003, Novogyne paid $1.7 million to the New Jersey Department of Revenue, representing Noven s portion of Novogyne s estimated state income tax payment. These payments were deemed a distribution to Noven.

Non-cash Investing Activities

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

8. LICENSE AND CONTRACT AGREEMENTS:

Endo Collaboration

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

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

Based on the current patent and exclusivity status of Johnson & Johnson s Duragesic patch, the earliest its generic fentanyl patch could be launched is January 24, 2005, assuming Food and Drug Administration (FDA) approval is received by that time, but Noven cannot give any assurance that it will receive FDA approval by that time or at all. Noven has begun manufacturing launch supplies. If approval is not ultimately received or is delayed, the agreement provides that Noven and Endo will share the cost of manufacturing product that cannot be sold by Endo in accordance with an agreed-upon formula. Noven estimates that its share of such costs could be up to approximately $5.0 million. If the product has not been approved or Noven has not supplied Endo s launch requirements by May 2005, Endo may have the right to terminate the license, depending on the number of generic competitors in the market.

In addition to the fentanyl license, Noven has established a collaboration with Endo to identify and develop new transdermal therapies. Of the $8.0 million up-front payment, $1.5 million has been allocated to fund feasibility studies to determine whether certain compounds identified by the parties can be delivered using Noven s transdermal technology. Noven believes the $1.5 million represents the fair value of such services. Endo is expected to fund and manage clinical development of those compounds proceeding into clinical trials.

Of the $8.0 million received at signing, $6.5 million will be recognized as revenues as earned over a 10-year period, which is the estimated product life cycle. The remaining $1.5 million is expected to be recognized as revenues over the course of feasibility development of any additional patches developed under the Noven/Endo collaboration.

P&G Pharmaceuticals Collaboration

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

collaboration were recognized for the three months ended September 30, 2004 or for the three and nine months ended September 30, 2003. Potential development milestones totaling $3.6 million remain available to be earned under the collaboration.

Shire

Noven is developing a transdermal methylphenidate patch for Attention Deficit Hyperactivity Disorder. Global rights to the developmental product are licensed to Shire Pharmaceutical Group plc (Shire). In April 2003, Noven received a not approvable letter from the FDA relating to Noven s MethyPatch New Drug Application (NDA). In May 2004, Noven and Shire met with the FDA to review Noven s and Shire s jointly prepared development plan intended to address issues raised in the not approvable letter. Based on feedback resulting from the meeting, Noven and Shire are proceeding with the development of MethyPatch. Development efforts are expected to include additional clinical studies, including another Phase 3 study. Pursuant to the agreements between the parties, Shire will manage these studies and Noven has committed to fund them. Noven s direct costs incurred in pursuit of approval are expected to be deferred and offset against a portion of the $25.0 million deferred revenue previously received from Shire. Such expenses are not expected to impact Noven s research and development expenses in 2004, although the direct expenses incurred in pursuit of MethyPatch approval will reduce Noven s cash position and will have the effect of reducing the amount of deferred revenues that Noven may recognize in future periods. As of September 30, 2004, the amount of deferred revenues was $12.4 million (which excludes the $5.0 million of deferred revenues related to the repurchase right described below) and Noven does not expect its cost in pursuit of approval to exceed this amount. If the additional studies are successful and completed on schedule, the parties would intend to file an amendment to the pending MethyPatch NDA during 2005. The amendment is expected to receive a six-month review by the FDA, and there is no assurance that the data to be obtained from the additional studies will address the FDA s issues or that the FDA may not raise additional issues following any submission of an amendment to the MethyPatch NDA. Under Noven s agreements with Shire, Shire continues to have certain rights to terminate the MethyPatch license, including if Shire determines that submission of the results of the additional clinical studies to the FDA would not result in approval of a commercially-viable product. If Shire were to terminate on this basis, all product rights would revert to Noven, and Noven would retain the $25.0 million previously paid by Shire. Shire continues to have the right to require Noven to repurchase the product rights to MethyPatch for $5.0 million under certain circumstances.

In June 2004, Noven entered into an agreement with Shire for the development of a transdermal amphetamine patch for Attention Deficit Hyperactivity Disorder. The agreement provides for the payment to Noven of up to $5.0 million if certain development milestones are achieved. The product is in pre-clinical development. Noven received $0.3 million from Shire related to this agreement for the nine months ended September 30, 2004.

9. INVESTMENT IN VIVELLE VENTURES LLC (d/b/a NOVOGYNE):

Noven shares in the earnings of Novogyne, after satisfaction of an annual preferred return of $6.1 million to Novartis, according to an established formula. Noven s share of Novogyne s earnings increases as Novogyne s product sales increase, subject to a cap of 49%. Novogyne produced sufficient income in the first quarter of 2004 and 2003 to meet Novartis annual preferred return for those years and for Noven to recognize earnings from Novogyne under the formula.

During the three and nine months ended September 30, 2004 and 2003, Noven had the following transactions with Novogyne (in thousands):

	Three Months		Nine Months	
	2004	2003	2004	2003
Revenues:				
Product sales	$4,364	$2,756	$15,058	$11,772
Royalties	1,411	1,182	3,909	3,381
	$5,775	$3,938	$18,967	$15,153
Reimbursed expenses	$6,657	$6,350	$18,919	$18,891

As of September 30, 2004 and December 31, 2003, Noven had amounts due from Novogyne of $4.5 million and $6.3 million, respectively, for products sold to, and marketing expenses reimbursable by, Novogyne.

The unaudited condensed Statements of Operations of Novogyne for the three and nine months ended September 30, 2004 and 2003 are as follows (in thousands):

	Three Months		Nine Months	
	2004	2003	2004	2003
Gross revenues	$34,314	$31,584	$94,463	$84,321
Sales allowances	3,123	2,969	9,412	8,764
Sales return allowances	3,676	4,586	3,968	5,255
Sales allowances and returns	6,799	7,555	13,380	14,019
Net revenues	27,515	24,029	81,083	70,302
Cost of sales	5,394	4,568	16,926	14,793
Selling, general and administrative expenses	7,957	8,113	22,519	23,617
Amortization of intangible assets	1,545	1,545	4,635	4,635
Income from operations	12,619	9,803	37,003	27,257

Interest income	50	33	103	135
Net income	$12,669	$ 9,836	$37,106	$27,392
Noven s equity in earnings of Novogyne	$ 6,232	$ 4,529	$15,097	$ 9,849

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

Investment in Novogyne, beginning of period	$ 28,368
Equity in earnings of Novogyne	15,097
Cash distributions from Novogyne	(12,263)
Deemed distribution by Novogyne for state income tax payment	(1,692)
Investment in Novogyne, end of period	$ 29,510

Subject to the approval of Novogyne s management committee, Novogyne may, from time to time, distribute cash to Novartis and Noven based upon a contractual formula. There were no distributions from Novogyne for the three months ended September 30, 2004. For the

nine months ended September 30, 2004, Noven received cash distributions of $12.3 million. For the three and nine months ended September 30, 2003, Noven received cash distributions of $4.9 million and $16.9 million, respectively, from Novogyne. In addition, as discussed in Note 7, a $1.7 million tax payment to the New Jersey Department of Revenue made by Novogyne on Noven s behalf in each of April 2004 and 2003 were deemed distributions from Novogyne to Noven. These amounts were recorded as reductions in the investment in Novogyne when deemed received.

10. SHARE REPURCHASE PROGRAM:

In the first quarter of 2003, Noven s Board of Directors authorized a share repurchase program under which Noven may acquire up to $25.0 million of its common stock. Noven repurchased 105,000 shares of its common stock at an aggregate price of approximately $1.3 million during the three months ended March 31, 2003. These shares were retired on March 31, 2003. No shares were repurchased during the nine months ended September 30, 2004.

11. COMMITMENTS AND CONTINGENCIES:

HT Studies

In July 2002, the National Institutes of Health (NIH) released data from its Women s Health Initiative (WHI) study on the risks and benefits associated with the use of oral combination hormone therapy (HT). The study revealed an increase in the risk of developing breast cancer and increased risks of stroke, heart attack and blood clots. The WHI study was followed by the publication during 20