NOVEN PHARMACEUTICALS INC
Form 10-Q
November 04, 2005

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q
Quarterly Report Pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934
For the quarterly period ended September 30, 2005
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 the filing requirements for at least the past 90 days. Yes þ No o.

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No þ.

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 28, 2005
Common stock $.0001 par value	23,598,085

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 35 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, 2004, as well as other reports filed from time to time with the Securities and Exchange Commission.

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

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PART I. FINANCIAL INFORMATION
Item 1. Financial Statements

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

	Three Months		Nine Months	
	2005	2004	2005	2004
Revenues:				
Product revenues Novogyne:				
Product sales	$ 4,740	$ 4,364	$ 14,432	$ 15,058
Royalties	1,790	1,411	4,617	3,909
Total product revenues Novogyne	6,530	5,775	19,049	18,967
Product revenues third parties	3,917	3,287	11,888	9,828
Total product revenues	10,447	9,062	30,937	28,795
Contract and license revenues:				
Contract	769	43	1,793	1,415
License	1,024	996	3,017	2,976
Contract and license revenues	1,793	1,039	4,810	4,391
Net revenues	12,240	10,101	35,747	33,186
Expenses:				
Cost of products sold	15,289	4,984	26,170	15,477
Research and development	3,953	2,741	10,108	7,730
Marketing, general and administrative	4,237	4,358	12,481	12,024
Total expenses	23,479	12,083	48,759	35,231
Loss from operations	(11,239)	(1,982)	(13,012)	(2,045)
Equity in earnings of Novogyne	8,081	6,232	17,094	15,097
Interest income, net	512	279	1,608	619
Income (loss) before income taxes	(2,646)	4,529	5,690	13,671

Provision (benefit) for income taxes	(1,224)	1,895	1,780	5,201
Net income (loss)	$ (1,422)	$ 2,634	$ 3,910	$ 8,470
Basic earnings (loss) per share	$ (0.06)	$ 0.11	$ 0.17	$ 0.36
Diluted earnings (loss) per share	$ (0.06)	$ 0.11	$ 0.16	$ 0.35
Weighted average number of common shares outstanding:				
Basic	23,586	23,416	23,554	23,290
Diluted	23,586	24,361	24,021	24,344

The accompanying notes are an integral part of these statements.

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NOVEN PHARMACEUTICALS, INC.
Condensed Balance Sheets
(in thousands, except share data)
(unaudited)

	September 30, 2005	December 31, 2004
Assets		
Current Assets:		
Cash and cash equivalents	$ 32,340	$ 93,958
Short-term investments	50,825	
Accounts receivable trade (less allowance for doubtful accounts of $53 in 2005 and $64 in 2004)	2,965	5,395
Accounts receivable Novogyne, net	6,779	10,098
Accounts receivable Endo	4,467	
Inventories	6,420	15,988
Net deferred income tax asset, current portion	7,900	6,700
Prepaid income taxes	6,814	9,344
Prepaid and other current assets	2,368	1,238
	120,878	142,721
Property, plant and equipment, net	32,069	22,587
Other Assets:		
Investment in Novogyne	23,778	26,233
Net deferred income tax asset	7,728	8,239
Patent development costs, net	2,250	2,174
Deposits and other assets	18	21
	33,774	36,667
	$ 186,721	$ 201,975
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable and accrued expenses	$ 6,830	$ 12,176
Capital lease obligations current portion	119	114
Accrued liability Shire	4,979	10,587
Accrued compensation and related liabilities	4,167	5,762
Other accrued liabilities	3,126	3,015
Deferred rent credit	89	
Deferred contract revenues	1,335	2,076
Deferred license revenues current portion	9,670	11,642
	30,315	45,372
Long-Term Liabilities:		
Capital lease obligations	30	121
Deferred rent credit	770	

Deferred license revenues	21,228	27,443
	52,343	72,936
Commitments and Contingencies (Note 12)		
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 23,597,785 at September 30, 2005 and 23,481,264 at December 31, 2004	2	2
Additional paid-in capital	89,665	88,236
Retained earnings	44,711	40,801
	134,378	129,039
	$ 186,721	$ 201,975

The accompanying notes are an integral part of these statements.

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

	2005	2004
Cash flows from operating activities:		
Net income	$ 3,910	$ 8,470
Adjustments to reconcile net income to net cash flows (used in) provided by operating activities:		
Depreciation and amortization	1,892	1,665
Write-off of fentanyl inventories deemed non-saleable	9,475	
Amortization of patent costs	334	285
Amortization of non-competition agreement		167
Amortization of deferred rent credit	(53)	
Income tax benefits on exercise of stock options	228	3,007
Deferred income tax expense (benefit)	(689)	2,985
Non-cash expense related to issuance of stock to outside directors		30
Recognition of deferred license revenues	(3,017)	(2,976)
Equity in earnings of Novogyne	(17,094)	(15,097)
Distributions from Novogyne	18,092	12,263
Changes in operating assets and liabilities:		
Decrease in accounts receivable trade, net	2,430	1,726
Decrease in accounts receivable Novogyne, net	3,319	1,832
Increase in accounts receivable Endo	(4,467)	
Decrease (increase) in inventories	93	(124)
Decrease (increase) in prepaid income taxes	3,987	(2,891)
Increase in prepaid and other current assets	(1,130)	(964)
Decrease (increase) in deposits and other assets	3	(7)
(Decrease) increase in accounts payable and accrued expenses	(5,346)	1,602
(Decrease) increase in accrued liability Shire	(5,608)	3,914
(Decrease) increase in accrued compensation and related liabilities	(1,595)	1,468
Increase (decrease) in other accrued liabilities	111	(1,972)
(Decrease) increase in deferred contract revenue	(741)	1,760
Increase in deferred license revenue		6,500
Direct expenses incurred in pursuit of methylphenidate patch regulatory approval	(5,170)	(6,729)
Cash flows (used in) provided by operating activities	(1,036)	16,914
Cash flows from investing activities:		
Purchases of property, plant and equipment, net	(10,462)	(5,004)
Payments for patent development costs, net	(410)	(422)
Purchases of short-term investments	(340,590)	
Proceeds from sale of short-term investments	289,765	
Cash flows used in investing activities	(61,697)	(5,426)

Cash flows from financing activities:		
Issuance of common stock from exercise of stock options	1,201	5,552
Repayments of capital leases and notes payable	(86)	(74)
Cash flows provided by financing activities	1,115	5,478
Net (decrease) increase in cash and cash equivalents	(61,618)	16,966
Cash and cash equivalents, beginning of period	93,958	83,381
Cash and cash equivalents, end of period	$ 32,340	$ 100,347

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 hormone therapy products delivery systems marketed under the brand names Vivelle®, Vivelle-Dot and 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, 2005, and the results of its operations and its cash flows for the three and nine months ended September 30, 2005 and 2004. Noven s business is subject to numerous risks and uncertainties including, but not limited to, those set forth in Noven s Annual Report on Form 10-K for the year ended December 31, 2004 (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, 2005 and 2004 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 2005 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. CASH AND CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS:

Cash and cash equivalents includes all highly liquid investments with an original maturity of three months or less at the date of purchase. Cash and cash equivalents as of September 30, 2005, and December 31, 2004, consisted primarily of overnight money market accounts, time deposits, and money market funds with original maturities of three months or less at the date of purchase. Beginning in the first quarter of 2005, Noven invested a portion of its cash in short-term investments, which primarily consist of investment grade, asset backed, variable rate debt obligations and municipal auction rate securities, which are categorized as available-for-sale under the provisions of Statement of Financial Accounting Standards (SFAS) No. 115

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Accounting for Certain Investments in Debt and Equity Securities . Despite the long-term nature of their stated contractual maturities, these securities have provisions that allow for liquidation in the short-term. Accordingly, the short-term investments are reported at fair value, with any related unrealized gains and losses included in comprehensive income as a separate component of stockholder s equity, net of applicable taxes. As of September 30, 2005, the cost of all short-term investments approximated fair value. Therefore, no unrealized gains and losses have been recognized for the quarter ended September 30, 2005. Realized gains and losses and interest and dividends are included in interest income or interest expense, as appropriate.

4. RECENT ACCOUNTING PRONOUNCEMENTS:

In November 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 151 Inventory Costs an amendment of ARB No. 43, Chapter 4 (SFAS 151), to clarify the accounting for abnormal amounts of idle facility expense, freight or wasted material (spoilage). SFAS 151 requires that those items be recognized as current-period charges regardless of whether they meet the so abnormal criterion outlined in Accounting Research Bulletin 43, Chapter 4, Inventory Pricing . SFAS 151 also introduces the concept of normal capacity and requires the allocation of fixed production overheads to inventory based on the normal capacity of the production facilities. Unallocated overheads must be recognized as an expense in the period in which they are incurred. This statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Noven currently accounts for abnormal amounts of idle facility expense, freight or wasted material (spoilage) as current-period charges, allocates fixed production overheads to inventory based on the normal capacity of the production facilities and recognizes unallocated overheads as an expense in the period in which they are incurred. For the foregoing reasons, Noven does not anticipate that implementation of this statement will have a material impact on its results of operations and financial condition.

In December 2004, the FASB issued SFAS No. 123(R) Share-Based Payment (Revised 2004) (SFAS123(R)) that will require compensation costs related to share-based payment transactions to be recognized in the financial statements. With limited exceptions, the amount of compensation cost will be measured based on the grant-date fair value of the equity or liability instruments issued. Compensation cost will be recognized over the period that an employee provides service in exchange for the award, which is generally over the vesting period. SFAS 123(R) also requires the benefits of tax deductions in excess of recognized compensation costs to be reported as financing cash flows, rather than as operating cash flows as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. While Noven cannot estimate what those amounts will be in the future, the amount of such income tax benefits on exercise of stock options was $0.2 million and $3.0 million for the nine months ended September 30, 2005 and 2004, respectively. SFAS 123(R) replaces SFAS 123, Accounting for Stock-Based Compensation (SFAS 123), and supersedes APB 25, Accounting for Stock Issued to Employees . For public companies such as Noven, the statement is effective as of the beginning of the first annual reporting period that begins after June 15, 2005 and accordingly, Noven anticipates adopting this statement in the first quarter of 2006. See Note 7 Employee Stock Plans with respect to the estimated impact SFAS 123 will have on Noven s results of operations and financial condition.

In December 2004, the FASB issued SFAS No. 153 Exchanges of Nonmonetary Assets, An Amendment of APB Opinion No. 29 (SFAS 153). SFAS 153 eliminates the exception for exchange of similar productive assets and replaces it with a general exception for exchanges of non-monetary assets that do not have commercial substance. SFAS 153 is effective for non-monetary assets and exchanges occurring in the first quarterly period beginning after June 15, 2005. As Noven has not and has no present intention to engage in exchanges of non-monetary assets, Noven does not anticipate that implementation of this statement will have a material impact on its results of operations and financial condition.

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In June 2005, the FASB issued SFAS No. 154, Accounting Changes and Error Corrections (SFAS 154). SFAS 154 replaces APB Opinion No. 20, Accounting Changes and FAS No. 3, Reporting Accounting Changes in Interim Financial Statements. SFAS 154 requires that a voluntary change in accounting principle be applied retrospectively with all prior period financial statements presented on the new accounting principle. SFAS 154 also requires that a change in method of depreciating or amortizing a long-lived non-financial asset be accounted for prospectively as a change in estimate, and correction of errors in previously issued financial statements should be termed a restatement. SFAS 154 is effective for accounting changes and correction of errors made in the first annual reporting period beginning after December 15, 2005. The implementation of SFAS 154 is not presently expected to have a material impact on Noven s results of operations and financial condition.

5. RECLASSIFICATIONS:

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

6. INVENTORIES:

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

	September 30, 2005	December 31, 2004
Finished goods	$ 915	$ 610
Work in process	1,601	6,522
Raw materials	3,904	8,856
Total	$ 6,420	$ 15,988

As of September 30, 2005 and December 31, 2004, Noven had $0 and $10.8 million in fentanyl inventories, net of inventory write-offs. Noven and Endo Pharmaceuticals Inc. (Endo) agreed that Noven would manufacture initial launch quantities of its fentanyl patch prior to receipt of final regulatory approval from the U.S. Food & Drug Administration (FDA) and that the parties would share the cost of any non-saleable fentanyl inventory in accordance with an agreed-upon formula. In September 2005, the FDA advised Noven that it did not expect to approve Noven s Abbreviated New Drug Application (ANDA) for its fentanyl patch, and was consequently ceasing its review of the ANDA. As a result of the FDA s decision to cease review of Noven s ANDA, Noven deemed the entire $14.0 million of fentanyl patch inventories to be non-saleable and recorded a $9.5 million charge to its cost of products sold for the three and nine months ended September 30, 2005. This charge represents the portion of the cost of the existing fentanyl inventories and purchasing commitments for raw material allocable to Noven under the contractual formula. Endo is responsible for the remaining $4.5 million of the fentanyl patch production costs, and Noven recorded a receivable of $4.5 million from Endo. At September 30, 2005, Noven owed Endo $2.6 million related to fentanyl raw materials. In addition, Noven expects to incur up to approximately $0.7 million in costs associated with disposal and destruction of its fentanyl inventories, substantially all of which is expected to be incurred and charged to costs of products sold in the fourth quarter of 2005.

Inventories, which include material, labor and manufacturing overhead, are stated at the lower of cost or market. Inventories as of September 30, 2005 and December 31, 2004, not including fentanyl inventories, relate to Noven s marketed products. Other than products

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produced for commercial sale, Noven s policy is to immediately recognize as expense all inventory purchased for research and development purposes. In accordance with accounting principles generally accepted in the United States, provisions have been made to reduce inventories to net realizable value, including giving effect to provisions and charges related to non-saleable product due to insufficient remaining shelf life or otherwise.

To date, Noven has not experienced any difficulty acquiring materials necessary to manufacture its marketed products. Certain materials and compounds, including essential polymers used by Noven, are available from limited sources and, in some cases, a single supplier. In addition, the Drug Enforcement Agency (DEA) controls access to controlled substances, including methylphenidate. Manufacturers of products containing controlled substances must annually apply to the DEA for procurement quota in order to obtain these substances for manufacturing. Pursuant to recent legislation, the DEA may not establish procurement quota for a product containing controlled substance until after the DEA reviews and provides public comment on the labeling, promotion, risk management plan and other documents associated with such product. In connection with Noven s 2005 request for methylphenidate procurement quota, Noven submitted certain documents to the DEA for review pursuant to this recent legislation. The DEA has indicated that it must review and comment on final versions of all required documents in order to complete its review. Accordingly, Noven may not receive procurement quota to manufacture launch supplies of its methylphenidate patch until after the DEA has reviewed and commented on final versions of the necessary documentation, which may not be available until after the FDA renders a decision on the NDA for Noven s methylphenidate patch, which could delay Noven s ability to manufacture launch supplies of the product and consequently effectively delay the product launch. The DEA s review and comment procedures are part of a new regulatory process that is still in the implementation stage, and no assurance can be given that this process will not result in delays in obtaining procurement quota for methylphenidate, a reduction in the quota awarded to Noven, or the denial of Noven s pending procurement quota request.

7. EMPLOYEE STOCK PLANS:

In accordance with the provisions of SFAS No. 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, 2005 and 2004 if Noven had applied the fair value recognition provisions of SFAS 123, as amended by SFAS 148 (in thousands, except per share amounts):

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	Three Months		Nine Months	
	2005	2004	2005	2004
Net income (loss):				
As reported	$ (1,422)	$ 2,634	$ 3,910	$ 8,470
Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(149)	(1,565)	(12,119)	(3,289)
Pro forma	$ (1,571)	$ 1,069	$ (8,209)	$ 5,181
Basic earnings (loss) per share:				
As reported	$ (0.06)	$ 0.11	$ 0.17	$ 0.36
Pro forma	$ (0.07)	$ 0.05	$ (0.35)	$ 0.22
Diluted earnings (loss) per share:				
As reported	$ (0.06)	$ 0.11	$ 0.16	$ 0.35
Pro forma	$ (0.07)	$ 0.04	$ (0.35)	$ 0.21

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 Noven s employee stock options.

As noted in Note 4 Recent Accounting Pronouncements, above, in December 2004, the FASB issued SFAS 123(R) that will require compensation costs related to share-based payment transactions to be recognized in the financial statements. Noven will be required to adopt the standards of stock option expensing under SFAS 123(R) beginning in the first quarter of 2006. In April 2005, the Compensation and Stock Option Committee of the Board of Directors of Noven approved the acceleration of vesting of unvested out-of-the-money stock options under the Noven 1999 Long-Term Incentive Plan. The affected options were those with exercise prices greater than $17.28 per share, which was the closing price of Noven s common stock on April 7, 2005 (the effective date of the modification to accelerate vesting of the out-of-the-money stock options). As a result of this action, options to purchase approximately 932,000 shares of Noven s common stock became immediately exercisable, including options held by Noven s executive officers to purchase approximately 401,000 shares. The purpose of the accelerated vesting was to eliminate the future compensation expense that Noven would otherwise recognize in its Statement of Operations with respect to these accelerated options upon the adoption of SFAS 123(R). Noven s total stock-based employee compensation expense determined under the fair value based method net of applicable income taxes (Compensation Expense) was $0.1 million and $12.1 million for the three and nine months ended September 30, 2005, respectively. Of the $12.1 million for the nine months ended September 30, 2005, $8.8 million resulted from the acceleration of vesting of unvested out-of-the-money stock options in April 2005. At September 30, 2005, unamortized Compensation Expense related to outstanding unvested options, as determined in accordance with SFAS 123(R) was $7.3 million, of which Noven expects to record during 2006 approximately $3.3 million before the effect of income taxes. Noven will incur additional expense during 2006 and in future years related to new awards granted after September 30, 2005.

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8. CASH FLOW INFORMATION:

Cash payments for income taxes were not material for the nine months ended September 30, 2005 and were $5.4 million for the nine months ended September 30, 2004. Cash payments for interest were not material for the nine months ended September 30, 2005 and 2004.

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 2005 and 2004, Novogyne paid $1.5 million and $1.7 million, respectively, 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 from Novogyne.

Non-cash Investing Activities

During the nine months ended September 30, 2005, Noven recorded approximately $0.9 million in leasehold improvements as a deferred rent credit relating to landlord-funded leasehold improvements. See Note 12 Commitments and Contingencies Facility Lease.

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

9. CONTRACT AND LICENSE AGREEMENTS:

Endo Collaboration

In July 2003, Noven submitted an ANDA to the FDA seeking approval to market a generic fentanyl transdermal system and entered into an exclusive license agreement with Endo in the first quarter of 2004 pursuant to which Noven granted Endo the right to market Noven s fentanyl patch in the United States and Canada. Noven received an up-front payment of $8.0 million from Endo, of which $6.5 million was allocated to license revenue for the fentanyl patch and the remaining $1.5 million was allocated based on fair value to fund feasibility studies that seek to determine whether certain compounds identified by the parties can be delivered through Noven s transdermal patch technology. In April 2005, Endo returned the Canadian marketing rights to Noven for no consideration.

On July 14, 2005, the FDA issued a public advisory that it is investigating reports of death and other serious side effects from overdoses involving both the branded and generic fentanyl patches. On September 27, 2005 the FDA advised Noven that it did not expect to approve Noven s ANDA and was consequently ceasing its review of Noven s ANDA, based on the FDA s assessment of potential safety concerns related to the higher drug content in Noven s generic product versus the branded product. Noven is currently evaluating available avenues from which it may continue to pursue approval of a generic fentanyl patch.

Noven and Endo agreed that Noven would manufacture initial launch quantities of its fentanyl patch prior to receipt of final regulatory approval from the FDA and that the parties would share the cost of any non-saleable fentanyl inventories in accordance with an agreed-upon formula. As a result of the FDA s decision to cease review of Noven s ANDA, Noven deemed the entire $14.0 million of fentanyl patch inventories to be non-saleable and recorded a $9.5 million charge to its cost of products sold for the three and nine months ended September 30, 2005. This charge represents the portion of the cost of the existing fentanyl inventories and purchasing commitments for raw materials allocable to Noven under the contractual formula. Endo is responsible for the remaining $4.5 million of the fentanyl patch production costs, and

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Noven recorded a receivable of $4.5 million from Endo. At September 30, 2005, Noven owed Endo $2.6 million related to fentanyl raw materials. In addition, Noven expects to incur up to approximately $0.7 million in costs associated with disposal and destruction of its fentanyl inventories, substantially all of which is expected to be incurred and charged to costs of products sold in the fourth quarter of 2005.

Noven is evaluating avenues to pursue approval of a generic fentanyl patch with Endo. If Noven determines that it has no further performance obligations or any continuing involvement relating to the Endo fentanyl patch license agreement, it expects to recognize the full balance of deferred license revenue, which was $5.7 million as of September 30, 2005, in the period the determination is made.

Long-lived assets and certain identifiable intangibles are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. If the fair value is less than the carrying amount of the asset, a loss is recognized for the difference. Fair value is determined based on market quotes, if available, or is based on valuation techniques. As a result of the FDA s decision to cease review of Noven s ANDA, Noven has reviewed for impairment all long-lived assets associated with its fentanyl patch and has determined that no impairment resulted during the three months ended September 30, 2005.

In addition to the fentanyl license, Noven has established a collaboration with Endo to seek to identify and develop new transdermal therapies. The $1.5 million allocated to feasibility studies is being recognized as contract revenues over the course of feasibility development of any additional patches developed under the collaboration. Endo is expected to fund and manage clinical development of those compounds proceeding into clinical trials.

Shire Collaboration

In the first quarter of 2003, Noven signed an agreement to license the exclusive global rights to market its methylphenidate patch for Attention Deficit Hyperactivity Disorder (ADHD) to Shire Pharmaceuticals Group plc (Shire) for payments of up to $150.0 million and ongoing manufacturing revenues. Consideration for the transaction is as follows: (i) $25.0 million was paid upon closing of the transaction in April 2003; (ii) $50.0 million is payable upon receipt of final marketing approval for the methylphenidate patch by the FDA; and (iii) three installments of $25.0 million each are payable upon Shire s achievement of $25.0 million, $50.0 million and $75.0 million in annual net sales of the methylphenidate patch, 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 (i) five years from the closing date or (ii) payment of all of the sales milestones. On the closing date, Noven entered into a long-term supply agreement under which it expects to manufacture and supply its methylphenidate patch 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. If Shire were to exercise this right, Noven s manufacturing revenues from sales of its methylphenidate patch would be adversely affected. Pursuant to the agreement, under certain circumstances Shire has the right to require Noven to repurchase the product rights for $5.0 million.

In April 2003, Noven received a not approvable letter from the FDA relating to its methylphenidate patch New Drug Application (NDA). In June 2005, Noven submitted an amendment to the NDA that included new clinical trial results, and the FDA accepted the amendment for filing in July 2005. The FDA review period for the amended NDA under the Prescription Drug User Fee Act (PDUFA) is scheduled to conclude on December 28, 2005. No assurance can be given that the amendment will in fact address the FDA s issues that resulted in the not approvable letter or that the FDA may not raise additional issues. The FDA has scheduled a December 2, 2005 meeting of its Psychopharmacologic Advisory Committee to consider Noven s pending methylphenidate patch NDA.

Noven s direct costs incurred in pursuit of approval are being deferred and offset against a portion of the $25.0 million deferred revenue previously received from Shire. Such expenses did not impact Noven s research and development expenses in 2004 or in the three and nine months

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ended September 30, 2005, although the direct expenses incurred in pursuit of FDA approval 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, 2005, the amount of available deferred revenues was $0.5 million (which excludes the $5.0 million of deferred revenues related to Shire s repurchase right) and Noven does not expect its prospective cost in pursuit of approval to exceed this amount.

In June 2004, Noven entered into an agreement with Shire for the development of a transdermal amphetamine patch for ADHD. The agreement provides for the payment to Noven of up to $5.0 million if certain development milestones are achieved. No such development milestones had been earned as of September 30, 2005. The product is in pre-clinical development and Noven is recognizing payments received as contract revenue as the work is performed.

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 withdrew its NDA for Intrinsa in December 2004 based on feedback from an FDA Advisory Committee and has indicated that it is working to identify a clinical strategy intended to address the FDA s safety concerns related to Intrinsa. During 2004, Noven earned $4.4 million under the P&G Pharmaceuticals collaboration. No development milestones under this collaboration were earned for the nine months ended September 30, 2005.

10. 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 2005 and 2004 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, 2005 and 2004, Noven had the following transactions with Novogyne (in thousands):

	Three Months		Nine Months	
	2005	2004	2005	2004
Revenues:				
Product sales	$ 4,740	$ 4,364	$ 14,432	$ 15,058
Royalties	1,790	1,411	4,617	3,909
	$ 6,530	$ 5,775	$ 19,049	$ 18,967
Reimbursed expenses	$ 6,576	$ 6,657	$ 20,196	$ 18,919

As of September 30, 2005 and December 31, 2004, Noven had amounts due from Novogyne of $6.8 million and $10.1 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, 2005 and 2004 are as follows (in thousands):

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	Three Months		Nine Months	
	2005	2004	2005	2004
Gross revenues	$ 37,974	$ 34,314	$ 100,519	$ 94,463
Sales allowances	4,007	3,123	11,078	9,412
Sales return allowances	192	3,676	1,057	3,968
Sales allowances and returns	4,199	6,799	12,135	13,380
Net revenues	33,775	27,515	88,384	81,083
Cost of sales	6,395	5,394	16,712	16,926
Selling, general and administrative expenses	9,187	7,957	25,627	22,519
Amortization of intangible assets	1,545	1,545	4,635	4,635
Income from operations	16,648	12,619	41,410	37,003
Interest income	201	50	336	103
Net income	$ 16,849	$ 12,669	$ 41,746	$ 37,106
Noven s equity in earnings of Novogyne	$ 8,081	$ 6,232	$ 17,094	$ 15,097

The activity in the Investment in Novogyne account for the nine months ended September 30, 2005 is as follows (in thousands):

Investment in Novogyne, beginning of period	$ 26,233
Equity in earnings of Novogyne	17,094
Cash distributions from Novogyne	(18,092)
Non-cash distribution from Novogyne (Note 8)	(1,457)
Investment in Novogyne, end of period	$ 23,778

Subject to the approval of Novogyne s management committee, Novogyne may, from time to time, distribute cash to Novartis and Noven based upon a contractual formula. For the three and nine months ended September 30, 2005, Noven received cash distributions of $9.2 million and $18.1 million from Novogyne, respectively. 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. In addition, as discussed in Note 8, tax payments of $1.5 million and $1.7 million were made by Novogyne on Noven s behalf to the New Jersey Department of Revenue in April 2005 and 2004, respectively. These payments were deemed distributions from Novogyne to Noven and were recorded as reductions in Noven s investment in Novogyne when deemed received.

11. 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. To date, Noven has repurchased 105,000 shares of its common stock at an aggregate price of approximately $1.3 million. No shares were repurchased during the nine months ended September 30, 2005 and 2004.

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12. 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 subsequent publication of the results of a number of other studies that found that the overall health risks from the use of certain HT products exceed the benefits from the use of those products. In the first quarter of 2004, the NIH discontinued the estrogen-only arm of the WHI study because results were showing an increased risk of stroke and because, after nearly seven years of follow-up, the NIH determined that it had sufficient data to assess the risks and benefits of estrogen use in the trial. Researchers continue to analyze data from both arms of the WHI study and other studies, and other publications may be forthcoming.

These studies and others have caused the HT market, and the market for Noven s products, to significantly decline. Prescriptions for CombiPatch®, Noven s combination estrogen/progestin patch, continue to decline in the post-WHI environment. Novogyne recorded the acquisition of the marketing rights for Noven s CombiPatch® product at cost and tests this asset for impairment on a periodic basis. Further adverse change in the market for HT products could have a material adverse impact on the ability of Novogyne to recover its investment in these rights, which could require Novogyne to record an impairment loss on the CombiPatch® intangible asset. Impairment of the CombiPatch® intangible asset would adversely affect Novogyne s and Noven s financial results. Management cannot predict whether these or other studies will have additional adverse effects on Noven s liquidity and results of operations, or Novogyne s ability to recover the net carrying value of the CombiPatch® intangible asset.

Production Issues

Noven maintains in-house product stability testing for its commercialized products. This process includes, among other things, testing samples from commercial lots under a variety of conditions to confirm that the samples remain within required specifications for the shelf-life of the product.

As a result of the 2003 recall of certain Vivelle-Dot patches, Noven initiated a series of special stability protocols to monitor commercial lots in distribution as well as future production of Vivelle-Dot. In the first quarter of 2005, a total of ten lots of Vivelle-Dot manufactured in 2003 were identified for recall when one of Noven s stability protocols revealed that these lots did not meet required specifications or were associated with lots that did not meet specifications. The recall of these lots in the first quarter of 2005 did not have a material impact on Noven s or Novogyne s results of operations because an immaterial number of patches from these lots (manufactured in 2003) remained in distribution. Based on testing and analysis to date, Noven believes that the probable cause of the Vivelle-Dot stability failures remains related to certain patch backing material that Noven obtained from a raw material supplier. Noven and Novartis have established a joint task force to identify the definitive root cause of the Vivelle-Dot stability failures. If the root cause determination or additional testing (including Noven s routine stability testing) indicates that the production issue affects more product than Noven s current testing and analysis suggests, additional recalls may be required. Noven cannot predict what action, if any, the FDA may take with respect to the recalls of Vivelle-Dot. Although Noven and Novartis are working together in assessing the Vivelle-Dot production issues, the decision to recall product resides with Novartis as the holder of the Vivelle-Dot NDA and is not within Noven s control. Among other risks, the 2005 recall, or any additional recalls, of Vivelle-Dot

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could result in a decision to: recall all or a significant portion of the product in distribution until a definitive root cause has been identified and any required corrective action has been completed; cease production or shipment of new product until a definitive root cause has been identified and any required corrective action has been completed; or reduce the shelf-life of Vivelle-Dot. Vivelle-Dot represented 84% of Noven s United States prescriptions in the third quarter of 2005 and Noven s and Novogyne s results of operations and prospects would be materially and adversely affected in the event these or similar actions were to occur.

In October 2004, Noven s product stability testing program indicated that one commercial lot of CombiPatch® product did not maintain required specifications throughout the product s shelf-life due to the formation of crystals. Novartis recalled the affected lot. The 2004 recall of this lot did not have a material impact on Noven s or Novogyne s financial statements.

As previously disclosed, Noven continues to maintain special stability protocols involving its combination-therapy products related to the October 2004 stability failure. In October 2005, one of these protocols indicated that one commercial lot of Estalis® (a product substantially similar to CombiPatch® and manufactured for sale outside the United States) did not maintain required specifications throughout the product s shelf-life due to the formation of crystals. This special stability protocol also indicates that two additional lots of Estalis®, while within specifications, are trending adversely. Noven is investigating the cause of the stability failure. While Noven plans to work together with Novartis regarding these issues, the decision to recall product and/or suspend shipment of new product resides with Novartis as the holder of the various regulatory authorizations to market Estalis® outside the United States and CombiPatch® in the United States and is not within Noven s control. Noven s and Novogyne s business and results of operations could be materially and adversely impacted if these stability failures lead to the recall of a significant amount of Estalis®/CombiPatch® or the suspension of shipments of the product. Among other things, any CombiPatch® recalls could have a material adverse impact on the ability of Novogyne to recover its investment in its CombiPatch® marketing rights.

The recalls and stability failures may result in an FDA inspection of Noven s facilities and procedures and Noven cannot assure that the FDA will be satisfied with Noven s operations and procedures, which could result in more frequent and stringent inspections and monitoring. If the FDA were to conclude that Noven s manufacturing controls and procedures are not sufficient, Noven could be required to suspend production until Noven demonstrates to the FDA that Noven s controls and procedures are sufficient.

Supply Agreement

Noven s supply agreement with Novogyne for Vivelle® and Vivelle-Dot patches expired in January 2003. Since expiration, the parties have continued to operate in accordance with the supply agreement s commercial terms. There is no assurance that the agreement s non-commercial terms would be enforceable with respect to post-expiration occurrences. A decision to discontinue operating in accordance with the agreement s commercial terms could have a material adverse effect on Noven s financial position, results of operations, and cash flows. Novogyne s designation of a new supplier and approval of a new supply agreement would require the affirmative vote of four of the five members of Novogyne s Management Committee. Accordingly, both Novartis and Noven must agree on Novogyne s supplier.

Litigation, Claims and Assessments

In September 2005, Noven, Novogyne and Novartis were served with a summons and complaint from an individual plaintiff in Superior Court of New Jersey Law Division, Atlantic County in which the plaintiff claims personal injury allegedly arising from the use of HT products, including Vivelle®. The plaintiff claims compensatory, punitive and other damages in an unspecified amount.

Novartis has advised Noven that Novartis has been named as a defendant in at least 17 additional lawsuits that include approximately 28 plaintiffs that allege liability in connection with personal injury claims allegedly arising from the use of HT patches distributed and sold by Novartis and Novogyne, including Noven s Vivelle®, Vivelle-Dot and CombiPatch® products.

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Novogyne has been named as a defendant in one lawsuit in addition to the one referenced above. Novartis has indicated that it will seek indemnification from Noven and Novogyne to the extent permitted by law and by the agreements between and among Novartis, Novogyne and Noven. Novogyne s accrual for expected legal fees and settlements of these lawsuits was $4.9 million as of September 30, 2005, for which there was a related insurance receivable of $3.5 million. This accrual represents Novartis management s best estimate as of September 30, 2005. The ultimate outcome of these product liability lawsuits cannot be predicted.

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

Contract and License Agreements

Noven is obligated to perform under its contract and license agreements. In certain circumstances, Noven is required to indemnify its licensees from damages caused by the products Noven manufactures as well as claims or losses related to patent infringement.

Internal Revenue Service Audit

Noven is periodically audited by federal and state taxing authorities. The outcome of these audits may result in Noven being assessed taxes in addition to amounts previously paid. Accordingly, Noven maintains tax contingency accruals for such potential assessments. The accruals are determined based upon Noven s best estimate of possible assessments by the Internal Revenue Service (IRS) or other taxing authorities and are adjusted, from time to time, based upon changing facts and circumstances. In the third quarter of 2005, the IRS completed its fieldwork related to the audits of Noven s federal income tax returns for the years 2001 through 2003. The IRS-proposed audit adjustments were primarily in the areas of research and development credits and to a lesser extent capitalization of software development costs and timing of depreciation and amortization. As a result of the IRS issuing its proposed audit adjustments related to the periods under examination, Noven reassessed its income tax contingency accruals to reflect the IRS findings. Based upon this reassessment, Noven recorded a $0.2 million reduction in these accruals in the third quarter of 2005, primarily related to interest charges on potential assessments. In addition, during the third quarter, Noven paid the IRS $0.2 million related to assessed taxes in addition to amounts previously paid, including interest, related to Noven s federal income tax returns for the 2001 year. As of September 30, 2005, Noven had $0.7 million in tax contingency accruals, related to the proposed IRS adjustments for Noven s federal income tax returns for the years 2002 through 2003.

Facility Lease

In February 2005, Noven entered into an Industrial Long-Term Lease (the Lease) for approximately 73,000 square feet of newly constructed space located in close proximity to its manufacturing facility in Miami, Florida. Noven intends to use the leased space for the storage and, as needed, the manufacture of new product. The lease term is 10 years, which may be extended for up to an additional 21 years pursuant to four renewal options of five years each and a one-time option to renew for one year. The annual base rent is $6.40 per square foot. Noven will also pay a monthly management fee equal to 1.5% of the base rent. The rent for the first year is discounted to $3.20 per square foot. The base rent is subject to annual increases of 3% during the initial 10-year term. After the initial term, the rent will be 95% of the fair market rate of the leased space as determined under the Lease. Noven is in the process of improving the leased space in order to prepare it for its intended use. The landlord was responsible for up to approximately $0.9 million of leasehold improvements, which were fully paid as of June 30, 2005. Any amounts paid to the general contractor in excess of this amount and any other

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leasehold improvements will be the responsibility of Noven. For accounting purposes, Noven is amortizing the total expected rental payments on a straight-line basis over the initial 10-year term of the Lease. The renewal terms have not been included for amortization purposes because Noven cannot reasonably estimate the rental payments after the initial term and Noven cannot assure that it will renew the Lease after the initial term. Any leasehold improvements will be recorded at cost and will be amortized on a straight-line basis over the shorter of the estimated useful life of the improvements or the remaining initial 10-year lease term. Leasehold improvements to the leased space paid by the landlord will be recorded by Noven as a deferred rent credit and will be amortized on a straight-line basis when incurred over the remaining initial 10-year lease term as a reduction of rent expense. Rent expense related to this lease was $0.3 million for the nine months ended September 30, 2005.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following section addresses material aspects of Noven s financial condition at September 30, 2005, and the results of operations for the three and nine months ended September 30, 2005 and 2004. The contents of this section include:

An overview of Noven and our Novogyne joint venture;

A review of certain items that affect the historical or future comparability of our results of operations;

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

A discussion of recently issued accounting standards and the application of our critical accounting policies;

An outlook that includes our current financial guidance for 2005; and

A review of cautionary factors that could have a material adverse effect on our business, financial condition and results of operations.

This discussion should be read in conjunction with Noven s financial statements for the three and nine months ended September 30, 2005 and 2004 and the related notes included elsewhere in this Form 10-Q, as well as the section Management s Discussion and Analysis of Financial Condition and Results of Operations from our Annual Report on Form 10-K for the year ended December 31, 2004.

Overview

We develop and manufacture advanced transdermal patches and presently derive substantially all of our revenues from sales of transdermal patches for use in menopausal hormone therapy. In the United States, our HT products are marketed and sold by Novogyne Pharmaceuticals, the joint venture that we formed with Novartis in 1998. Our business, financial position and results of operations currently depend largely on Novogyne and its marketing of our three principal HT products Vivelle®, Vivelle-Dot and CombiPatch® in the United States. A discussion of Novogyne s results and their impact on our results can be found under the caption Results of Operations Equity in Earnings of Novogyne.

In all countries other than the United States, Canada and Japan, we have licensed the marketing rights to these products to Novartis Pharma AG (Novartis Pharma), which is an affiliate of Novartis. In most of these markets, Vivelle® is marketed under the brand name Menorest, Vivelle-Dot is marketed under the brand name Estradot and CombiPatch® is marketed under the brand name Estalis®.

We hold a 49% equity interest in Novogyne, and Novartis holds the remaining 51% equity interest. Under the terms of the joint venture agreements, we manufacture and supply Vivelle®, Vivelle-Dot and CombiPatch® to Novogyne, perform marketing, sales and promotional activities, and receive royalties from Novogyne based on Novogyne s sales of the estrogen therapy (ET) products. Novartis distributes Vivelle®, Vivelle-Dot and CombiPatch® and provides certain other services to Novogyne, including financial and accounting functions.

Novartis is entitled to an annual $6.1 million preferred return from Novogyne, which has the effect of reducing our share of Novogyne s income in the first quarter of each year. After the annual preferred return to Novartis, our share of Novogyne s income increases as product sales increase, subject to a maximum of 49%. Our share of Novogyne s income was $17.1 million and $15.1 million for the nine months ended September 30, 2005 and 2004, respectively. The income we

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recognize from Novogyne is a non-cash item. Any cash we receive from Novogyne is in the form of cash distributions declared by Novogyne s Management Committee. Accordingly, the amount of cash that we receive from Novogyne in any period may not be the same as the amount of income we recognize from Novogyne for that period. For the nine months ended September 30, 2005 and 2004, we received $18.1 million and $12.3 million, respectively, in distributions from Novogyne, which accounted for a substantial portion of our cash flows from operating activities for these periods. We expect that a significant portion of our earnings and cash flow for the next several years will be generated through our interest in Novogyne, but we cannot assure that Novogyne will continue to be profitable or make cash distributions. Any failure by Novogyne to remain profitable or to continue to make distributions could have a material adverse effect on our results of operations and financial condition.

The market for HT products, including our transdermal HT products, has contracted since the July 2002 publication of the WHI study that found adverse health risks associated with HT products. Comparing the second quarter of 2002 (the quarter immediately preceding the publication of initial data from the WHI study) to the third quarter of 2005, total prescriptions dispensed in the HT market in the United States declined by 52%. For the same period, aggregate prescriptions for Noven s United States HT products declined by 7.9%. The estrogen segment of the HT market in the United States declined 47.3%, while our Vivelle® line of products increased 4% over the second quarter 2002. Vivelle-Dot, which represented 84% of our total United States prescriptions in the third quarter of 2005, increased 30.5% from the second quarter of 2002 to the third quarter of 2005. We believe Vivelle-Dot patch prescriptions have benefited from both increased demand and patient conversions from the original Vivelle® product.

United States prescriptions for our CombiPatch® product (which represented approximately 11.3% of our total United States prescriptions in the third quarter of 2005) declined 51.5% from the second quarter of 2002 to the third quarter of 2005, while prescriptions for the total United States market for fixed combination hormone therapy products declined 70.1%. The combination therapy arm of WHI involved an oral combination estrogen/progestin product and, accordingly, the combination therapy segment of the HT market has experienced the most significant decline. Further declines for our CombiPatch® product (whether as a result of the WHI studies, the production issues discussed below or otherwise) could require Novogyne (which holds the CombiPatch® marketing rights) to record an impairment loss related to these marketing rights, which would adversely affect the results of operations of both Noven and Novogyne.

Certain Items That Affect or Could Affect Historical or Future Comparability

Endo

In July 2003, we submitted an ANDA to the FDA seeking approval to market a generic fentanyl transdermal system and we entered into an exclusive agreement with Endo in the first quarter of 2004 pursuant to which we granted Endo the right to market our fentanyl patch in the United States and Canada. We received an up-front payment of $8.0 million from Endo, of which $6.5 million was allocated to license revenue for the fentanyl patch and the remaining $1.5 million was allocated based on fair value to fund feasibility studies that seek to determine whether certain compounds identified by the parties can be delivered through our transdermal patch technology. In April 2005, Endo returned the Canadian marketing rights to us for no consideration.

On July 14, 2005, the FDA issued a public advisory that it is investigating reports of death and other serious side effects from overdoses involving both the branded and generic fentanyl patches. On September 27, 2005 the FDA advised us that it did not expect to approve our ANDA and was consequently ceasing its review of our ANDA, based on the FDA s assessment of potential safety concerns related to the higher drug content in our generic product versus the branded product.

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We are currently evaluating available avenues from which we may continue to pursue approval of a generic fentanyl patch.

We agreed with Endo that we would manufacture initial launch quantities of our fentanyl patch prior to receipt of final regulatory approval from the FDA and that the parties would share the cost of any non-saleable fentanyl inventories in accordance with an agreed-upon formula. As a result of the FDA s decision to cease review of our ANDA, we deemed the entire $14.0 million of fentanyl patch inventories to be non-saleable and recorded a $9.5 million charge to our cost of products sold for the three and nine months ended September 30, 2005. This charge represents the portion of the cost of the existing fentanyl inventories and purchasing commitments for raw materials allocable to us under the contractual formula. Endo is responsible for the remaining $4.5 million of the fentanyl patch production costs, and we recorded a receivable of $4.5 million from Endo. At September 30, 2005, we owed Endo $2.6 million related to fentanyl raw materials. In addition, we expect to incur up to approximately $0.7 million in costs associated with disposal and destruction of our fentanyl inventories, substantially all of which is expected to be incurred and charged to costs of products sold in the fourth quarter of 2005.

We are evaluating avenues to pursue approval of a generic fentanyl patch with Endo. If we determine that we have no further performance obligations or any continuing involvement relating to the Endo fentanyl patch license agreement, we expect to recognize the full balance of deferred license revenue, which was $5.7 million as of September 30, 2005, in the period the determination is made.

Shire

We are developing a transdermal methylphenidate patch for ADHD. In the first quarter of 2003, we licensed the global rights to the developmental product to Shire for payments up to $150.0 million, including $25.0 million paid at closing of the license transaction. In April 2005, Noven and Shire announced preliminary results from additional clinical trials conducted in 2004 and 2005 that were intended to address clinical issues raised in the not approvable letter that we received from the FDA in April 2003. In June 2005, Noven submitted an amendment to the NDA that included these new trial results, and the FDA accepted the amendment for filing in July 2005. The FDA review period for the amended NDA under PDUFA is scheduled to conclude on December 28, 2005. No assurance can be given that the data obtained from the additional studies will in fact address the FDA s issues or that the FDA may not raise additional issues. The FDA has scheduled a December 2, 2005 meeting of its Psychopharmacologic Advisory Committee to consider our pending methylphenidate patch NDA.

Noven s direct costs incurred in pursuit of approval are being deferred and offset against a portion of the $25.0 million deferred revenue previously received from Shire. Such expenses did not impact Noven s research and development expenses in 2004 or in the three and nine months ended September 30, 2005, although the direct expenses incurred in pursuit of FDA approval reduce our 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, 2005, the amount of available deferred revenues was $0.5 million (which excludes the $5.0 million of deferred revenues related to Shire s repurchase right) and Noven does not expect its prospective cost in pursuit of approval to exceed this amount.

The DEA controls access to controlled substances, including methylphenidate. Manufacturers of products containing controlled substances must annually apply to the DEA for procurement quota in order to obtain these substances for manufacturing. Pursuant to recent legislation, the DEA may not establish procurement quota for a product containing controlled substance until after the DEA reviews and provides public comment on the labeling, promotion, risk management plan and other documents associated with such product. In connection with our 2005

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request for methylphenidate procurement quota, we have submitted certain documents to the DEA for review pursuant to this recent legislation. The DEA has indicated that it must review and comment on final versions of all required documents in order to complete its review. Accordingly, we may not receive procurement quota to manufacture launch supplies of our methylphenidate patch until after the DEA has reviewed and commented on final versions of the necessary documentation, which may not be available until after the FDA renders a decision on the NDA for our methylphenidate patch, which could delay our ability to manufacture launch supplies of the product and consequently effectively delay the product launch. The DEA s review and comment procedures are part of a new regulatory process that is still in the implementation stage, and no assurance can be given that this process will not result in delays in obtaining procurement quota for methylphenidate, a reduction in the quota awarded to us, or the denial of our pending procurement quota request.

Stock Options

In April 2005, the Compensation and Stock Option Committee of our Board of Directors approved the acceleration of vesting of unvested out-of-the-money stock options under the Noven 1999 Long-Term Incentive Plan. The affected options were those with exercise prices greater than $17.28 per share, which was the closing price of our common stock on April 7, 2005 (the effective date of the modification to accelerate vesting of the out-of-the-money stock options). As a result of this action, options to purchase approximately 932,000 shares of our common stock became immediately exercisable, including options held by our executive officers to purchase approximately 401,000 shares. The accelerated options represented approximately 26% of our total outstanding options on the date of the transaction. The exercise prices of the accelerated options ranged from $17.88 to $41.81 per share.

The purpose of the accelerated vesting was to eliminate the future compensation expense that we would otherwise recognize in our Statement of Operations with respect to these accelerated options upon the adoption of Financial Accounting Standards Board Statement of Financial Accounting Standards No. 123 (Revised 2004), Share-Based Payment. SFAS 123(R) is effective from the first annual reporting period that begins after June 15, 2005, and will require that we recognize the compensation expense associated with stock options in our Statement of Operations, rather than as historically presented as a footnote disclosure in our financial statements. Unless the effective date is further delayed, we will begin expressing stock-based employee compensation in accordance with SFAS 123(R), in the first quarter of 2006. Our total stock-based employee compensation expense determined under the fair value based method net of applicable income taxes (Compensation Expense) was $0.1 million and $12.1 million for the three and nine months ended September 30, 2005, respectively, of which, approximately $8.8 million resulted from the acceleration of vesting of unvested out-of-the-money stock options in April 2005. At September 30, 2005, unamortized Compensation Expense related to outstanding unvested options, as determined in accordance with SFAS 123(R) was $7.3 million, of which we expect to record during 2006 approximately $3.3 million before the effect of income taxes. We will incur additional Compensation Expense during 2006 and in future years related to new awards granted after September 30, 2005.

Production Issues

We maintain in-house product stability testing for our commercialized products. This process includes, among other things, testing samples from commercial lots under a variety of conditions to confirm that the samples remain within required specifications for the shelf-life of the product.

As a result of the 2003 recall of certain Vivelle-Dot patches, Noven initiated a series of special stability protocols to monitor commercial lots in distribution as well as future production of

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Vivelle-Dot. In the first quarter of 2005, a total of ten lots of Vivelle-Dot manufactured in 2003 were identified for recall when one of our stability protocols revealed that these lots did not meet required specifications or were associated with lots that did not meet specifications. The recall of these lots in the first quarter of 2005 did not have a material impact on Noven s or Novogyne s results of operations because an immaterial number of patches from these lots (manufactured in 2003) remained in distribution. Based on testing and analysis to date, Noven believes that the probable cause of the Vivelle-Dot stability failures remains related to certain patch backing material that Noven obtained from a raw material supplier. Noven and Novartis have established a joint task force to identify the definitive root cause of the Vivelle-Dot stability failures. If the root cause determination or additional testing (including Noven s routine stability testing) indicates that the production issue affects more product than Noven s current testing and analysis suggests, additional recalls may be required. We cannot predict what action, if any, the FDA may take with respect to the recalls of Vivelle-Dot. Although Noven and Novartis are working together in assessing the Vivelle-Dot production issues, the decision to recall product resides with Novartis as the holder of the Vivelle-Dot NDA and is not within our control. Among other risks, the 2005 recall, or any additional recalls, of Vivelle-Dot could result in a decision to: recall all or a significant portion of the product in distribution until a definitive root cause has been identified and any required corrective action has been completed; cease production or shipment of new product until a definitive root cause has been identified and any required corrective action has been completed; or reduce the shelf-life of Vivelle-Dot. Vivelle-Dot represented over 84% of Noven s United States prescriptions in the third quarter of 2005 and Noven s and Novogyne s results of operations and prospects would be materially and adversely affected in the event these or similar actions were to occur.

As previously disclosed, we continue to maintain special stability protocols involving our combination-therapy products related to the October 2004 stability failure. In October 2005, one of these protocols indicated that one commercial lot of Estalis® (a product substantially similar to CombiPatch® and manufactured for sale outside the United States) did not maintain required specifications throughout the product s shelf-life due to the formation of crystals. This special stability protocol also indicates that two additional lots of Estalis®, while within specifications, are trending adversely. We are investigating the cause of the stability failure. While we plan to work together with Novartis regarding these issues, the decision to recall product and/or suspend shipment of new product resides with Novartis as the holder of the various regulatory authorizations to market Estalis® outside the United States and CombiPatch® in the United States and is not within our control. Noven s and Novogyne s business and results of operations could be materially and adversely impacted if these stability failures lead to the recall of a significant amount of Estalis®/CombiPatch® or the suspension of shipments of the product. Among other things, any CombiPatch® recalls could have a material adverse impact on the ability of Novogyne to recover its investment in its CombiPatch® marketing rights.

The recalls and stability failures may result in more frequent and stringent inspections and monitoring by the FDA, and we cannot assure that the FDA will be satisfied with our operations and procedures. If the FDA were to conclude that our manufacturing controls and procedures are not sufficient, we could be required to suspend production until we demonstrate to the FDA that our controls and procedures are sufficient.

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Results of Operations

Three and nine months ended September 30, 2005 compared to the three and nine months ended September 30, 2004

Revenues

Total revenues for the three and nine months ended September 30, 2005 and 2004 are summarized as follows (dollar amounts in thousands):

	Three Months			Nine Months		
	2005	2004	% Change	2005	2004	% Change
Product revenues						
Novogyne:						
Product sales	$ 4,740	$ 4,364	9%	$ 14,432	$ 15,058	(4%)
Royalties	1,790	1,411	27%	4,617	3,909	18%
	6,530	5,775	13%	19,049	18,967	0%
Product revenues third parties:						
Product sales	3,823	3,287	16%	11,646	9,614	21%
Royalties	94		N/M	242	214	13%
	3,917	3,287	19%	11,888	9,828	21%
Total product revenues	10,447	9,062	15%	30,937	28,795	7%
Contract and license revenues:						
Contract	769	43	N/M	1,793	1,415	27%
License	1,024	996	3%	3,017	2,976	1%
	1,793	1,039	73%	4,810	4,391	10%
Net revenues	$ 12,240	$ 10,101	21%	$ 35,747	$ 33,186	8%

N/M not meaningful

Net Revenues

As described in more detail below, the 21% increase in net revenues for the three months ended September 30, 2005 as compared to the same period in 2004 was primarily attributable to an aggregate increase in sales for our U.S. and international products, as well as an increase in contract revenues.

As described in more detail below, the 8% increase in net revenues for the nine months ended September 30, 2005 as compared to the same period in 2004 reflected an aggregate increase in sales of our international products and contract revenue, partially offset by declines in sales of product to Novogyne. In addition, royalties increased for the

nine months ended September 30, 2005 as compared to the same period in 2004 as a result of Novogyne s higher sales of Vivelle® and Vivelle-Dot.

Product Revenues Novogyne

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

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The $0.8 million increase in product revenues from Novogyne for the three months ended September 30, 2005 as compared to the same period in the prior year primarily related to a $0.6 million and $0.4 million increase in unit sales of CombiPatch® and Estradot, respectively. In addition, royalties increased $0.4 million. These increases were partially offset by a $0.6 million decline in unit sales of Vivelle-Dot. We believe these fluctuations in unit sales were due to the timing of orders by Novogyne, as total prescriptions for Vivelle-Dot increased in the third quarter of 2005 compared to the third quarter of 2004. The increase in royalties is a result of Novogyne s higher sales of Vivelle® and Vivelle-Dot.

The $0.1 million increase in product revenues from Novogyne for the nine months ended September 30, 2005 as compared to the same period in the prior year primarily relates to a $0.7 million increase in royalties, partially offset by a $0.6 million decline in unit sales of Estradot. The increase in royalties was a result of Novogyne s higher sales of Vivelle® and Vivelle-Dot. The decline in unit sales of Estradot was primarily attributable to Estradot sales in 2004 benefiting from stocking orders related to a planned transition from Vivelle® to Estradot in Canada.

Product Revenues Third Parties

Product revenues third parties consists primarily of sales of Menorest, Estradot and Estalis® to Novartis Pharma at a price based on a percentage of Novartis Pharma s net selling price (subject to certain minima) for resale primarily outside the United States and Japan, together with royalties generated from Novartis Pharma s sales of Vivelle® and Estradot in Canada.

The $0.6 million increase in product revenues from third parties for the three months ended September 30, 2005 as compared to the same period in the prior year primarily related to $0.5 million of higher unit sales of Estradot and a $0.4 million increase in revenue related to pricing. This increase was offset by a $0.5 million decline in unit sales of Estalis®. We believe the increase in unit sales of Estradot was mostly attributable to the timing of orders by trade customers. The decline in Estalis® sales related to the continuing decline in the combination therapy market as a result of WHI and other studies. The $0.4 million increase in revenue related to pricing was primarily due to the recognition of a higher price adjustment payment received from Novartis Pharma in the current quarter as compared to the same period in the prior year. Noven records such price adjustment payments from time to time upon Novartis Pharma s determination that its actual sales price of our product entitles us to receive amounts in excess of the minimum transfer price at which we initially sell the product to Novartis Pharma.

The $2.1 million increase in product revenues from third parties for the nine months ended September 30, 2005 as compared to the same period in the prior year primarily related to a $1.4 million increase in unit sales and a $0.7 million increase in revenue related to pricing. The increase in unit sales was mostly attributable to $0.6 million in higher sales of Estalis® and $0.6 million in higher sales of Estradot. We believe the increase in Estalis® sales in comparison to the same period in the prior year was attributable to the timing of orders due to re-stocking of inventory in launched countries and not to an increase in underlying demand for this combination therapy product. We believe the increase in Estradot was due to the same factors as above. The $0.7 million price increase was primarily related to the recognition of a higher price adjustment payment from Novartis Pharma during 2005, as discussed above.

Contract and License Revenues

The increase in contract revenues of $0.7 million and $0.4 million for the three and nine months ended September 30, 2005, respectively, compared to the same periods in prior year was primarily attributable to work performed during the three and nine months ended September 30, 2005 on contracts related to our development collaborations. The increase for the nine months ended September 30, 2005 was partially offset by our recognition of $1.2 million in contract revenues recognized for the nine months ended September 30, 2004

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related to the attainment of certain product development milestones under our collaboration with P&G Pharmaceuticals that were not repeated in 2005. License revenues were consistent for the three and nine months ended September 30, 2005 as compared to the same periods in 2004.

Gross Margin

Gross margin for the three and nine months ended September 30, 2005 and 2004 are summarized as follows (dollar amounts in thousands):

	Three Months			Nine Months		
	2005	2004	% Change	2005	2004	% Change
Total product revenues	$ 10,447	$ 9,062	15%	$ 30,937	$ 28,795	7%
Cost of products sold	15,289	4,984	207%	26,170	15,477	69%
Gross profit (loss) (product revenues less cost of products sold)	(4,842)	4,078	(219%)	4,767	13,318	(64%)
Gross margin (gross profit (loss) as a percentage of product revenues)	-46%	45%		15%	46%	

Our gross margins for the three and nine months ended September 30, 2005 were significantly and adversely affected by increased cost of products sold resulting from the $9.5 million charge we recorded in connection with the FDA s decision to cease review of our fentanyl ANDA.

Operating Expenses

Operating expenses for the three and nine months ended September 30, 2005 and 2004 are summarized as follows (dollar amounts in thousands):

	Three Months			Nine Months		
	2005	2004	% Change	2005	2004	% Change
Research and development	$ 3,953	$ 2,741	44%	$ 10,108	$ 7,730	31%
Marketing, general and administrative	4,237	4,358	(3%)	12,481	12,024	4%

Research and Development

The $1.2 million and $2.4 million increases in research and development expenses for the three and nine months ended September 30, 2005, respectively, as compared to the same period in 2004, were primarily attributable to increases in non-clinical development expenses, including expenses related to production and launch preparations for our developmental methylphenidate and fentanyl patches.

Marketing, General and Administrative

The $0.1 million decline in marketing, general and administrative expenses for the three months ended September 30, 2005 as compared to the same period in 2004 was primarily attributable to a $0.4 million decline in incentive compensation costs and a $0.1 million decline in recruiting agency fees, partially offset by a $0.2 million increase in consulting and professional fees and a $0.2 million increase in costs associated with expansion for anticipated new product launches.

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The $0.5 million increase in marketing, general and administrative expenses for the nine months ended September 30, 2005 as compared to the same period in 2004 was primarily attributable to a $0.7 million increase in costs associated with expansion for anticipated new product launches and a $0.5 million increase in consulting and professional fees, partially offset by a $0.3 million decline in incentive compensation costs and a $0.2 million decline in recall related expenses.

Other Income and Expenses

Income Taxes

Our effective tax rate was approximately 31% and 38% for each of the nine months ended September 30, 2005 and 2004. The reduction in our tax rate was primarily caused by the substantially lower income before income taxes, mostly due to the write-off of fentanyl inventories deemed non-saleable. Due to this reduction in income before taxes, our non-taxable income exclusions, which are primarily non-taxable interest income on short term investments and extraterritorial income exclusion on revenues outside of the United States, represented a higher proportion of our income before taxes thereby creating a lower effective tax rate. The provision for income taxes is based on the Federal statutory and state income tax rates.

We are periodically audited by federal and state taxing authorities. The outcome of these audits may result in Noven being assessed taxes in addition to amounts previously paid. Accordingly, we maintain tax contingency accruals for such potential assessments. The accruals are determined based upon our best estimate of possible assessments by the IRS or other taxing authorities and are adjusted, from time to time, based upon changing facts and circumstances. In the third quarter of 2005, the IRS completed its fieldwork related to the audits of our federal income tax returns for the years 2001 through 2003. The IRS-proposed audit adjustments were primarily in the areas of research and development credits and to a lesser extent capitalization of software development costs and timing of depreciation and amortization. As a result of the IRS issuing its proposed audit adjustments related to the periods under examination, we reassessed our income tax contingency accruals to reflect the IRS findings. Based upon this reassessment, we recorded a $0.2 million reduction in these accruals in the third quarter of 2005, primarily related to interest charges on potential assessments. In addition, during the third quarter, we paid the IRS $0.2 million related to assessed taxes in addition to amounts previously paid, including interest, related to our federal income tax returns for the 2001 year. As of September 30, 2005, we had $0.7 million in tax contingency accruals, related to the proposed IRS adjustments for our federal income tax returns for the years 2002 through 2003.

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 September 30, 2005, we had a net deferred tax asset of $15.6 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 according to an established formula after satisfaction of an annual preferred return of $6.1 million to Novartis. Our share of Novogyne s earnings increases as Novogyne s product sales increase, subject to a maximum of 49%. Novogyne produced sufficient income in the first quarters of 2005 and 2004 to meet Novartis annual preferred return for those years and for us to recognize earnings from Novogyne under the formula. We report our share of Novogyne s earnings as Equity in earnings of Novogyne on our unaudited Condensed Statements of Operations.

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The financial results of Novogyne for the three and nine months ended September 30, 2005 and 2004 are summarized as follows (dollar amounts in thousands):

	Three Months			Nine Months		
	2005	2004	% Change	2005	2004	% Change
Gross revenues[1]	$ 37,974	$ 34,314	11%	$ 100,519	$ 94,463	6%
Sales allowances	4,007	3,123	28%	11,078	9,412	18%
Sales returns allowances	192	3,676	(95%)	1,057	3,968	(73%)
Sales and returns allowances	4,199	6,799	(38%)	12,135	13,380	(9%)
Net revenues	33,775	27,515	23%	88,384	81,083	9%
Cost of sales	6,395	5,394	19%	16,712	16,926	(1%)
Gross profit	27,380	22,121	24%	71,672	64,157	12%
Gross margin percentage	81%	80%		81%	79%	
Selling, general and administrative expenses	9,187	7,957	15%	25,627	22,519	14%
Amortization of intangible asset	1,545	1,545		4,635	4,635	
Income from operations	16,648	12,619	32%	41,410	37,003	12%
Interest income	201	50	302%	336	103	226%
Net income	$ 16,849	$ 12,669	33%	$ 41,746	$ 37,106	13%
Noven s equity in earnings of Novogyne	$ 8,081	$ 6,232	30%	$ 17,094	$ 15,097	13%

(1) Novogyne s gross revenues, which are calculated by adding sales allowances and sales returns allowances to net revenues, are discussed in this section because Noven s management

believes it is a useful measure to evaluate and compare Novogyne s sales period to period in light of the significant historic fluctuations in Novogyne s sales allowances and returns.

Novogyne Net Revenues

Novogyne s gross revenues increased $3.7 million for the three months ended September 30, 2005 compared to the same period in the prior year, primarily due to a $2.8 million increase in sales of Vivelle-Dot and $1.1 million increase in sales of Estradot to Novartis in Canada. These increases were offset by a $0.4 million decline in unit sales of Vivelle®, our first generation estrogen patch. Approximately $1.0 million of the Vivelle-Dot increase was due to increased unit sales based on increased trade demand, while the remaining $1.8 million increase related to price increases. The increase in sales of Estradot to Novartis in Canada is primarily attributable to the timing of orders. In the prior year, sales increased during the first six months of the year due to the planned transition from Vivelle® to Estradot in 2004, which resulted in no sales of Estradot in the third quarter of 2004. The decline in unit sales of Vivelle® is primarily attributable to product maturity.

Novogyne s gross revenues increased $6.1 million for the nine months ended September 30, 2005 compared to the same period in the prior year, primarily due to a $10.3 million increase in sales of Vivelle-Dot, partially offset by a $1.4 million decline in sales of Estradot to Novartis in Canada and a $1.5 million decline in sales of CombiPatch®. In addition, Vivelle®, our first generation estrogen patch, declined $1.4 million in unit sales. Approximately $5.8 million of the Vivelle-Dot increase was due to increased unit sales based on increased trade demand, while the remaining $4.5 million increase related to price increases. Sales to Canada by Novogyne in 2004 benefited from stocking orders of Estradot related to a planned transition from Vivelle® to Estradot in Canada. The lower sales of CombiPatch® were due to a continuing decline in the market for combination therapies

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after the publication of the combination arm of the WHI study. The decline in unit sales of Vivelle® is attributable to product maturity.

Sales allowances consist of chargebacks, Medicaid rebates, managed healthcare rebates, cash discounts and other allowances, and tend to fluctuate based on changes in gross revenues. These sales allowances were 11% and 9% of gross revenues for the three months ended September 30, 2005 and 2004 and 11% and 10% of gross revenues for the nine months ended September 30, 2005 and 2004, respectively.

Sales returns allowances consist of: (i) allowances for returns of expiring product, and (ii) allowances for returns for product recalls. The activity for sales returns allowances for the three and nine months ended September 30, 2005 and 2004 was as follows:

	Three Months		Nine Months	
	2005	2004	2005	2004
Changes in allowances for returns of expiring product	$ 192	$ 3,676	$ 1,120	$ 7,068
Changes in allowances for returns for product recalls			(63)	(3,100)
Net change in sales returns allowances	$ 192	$ 3,676	$ 1,057	$ 3,968
Actual returns for expiring product	$ (1,174)	$ (1,615)	$ (2,869)	$ (6,074)
Actual returns for product recalls		(91)	(40)	(2,620)
Actual returns for the period	$ (1,174)	$ (1,706)	$ (2,909)	$ (8,694)

The decline in allowances for returns of expiring product for the three and nine months ended September 30, 2005 as compared to the same period in 2004, respectively, is primarily related to lower expected returns as a result of a decline in actual returns of Vivelle® and Vivelle-Dot in the current period as compared to the same period in the prior year. The decline in allowances for returns for product recalls for the nine months ended September 30, 2004 was based on a review of relevant information available at the time, including actual product returns and future expected returns for the 2003 recalls.

Novogyne Gross Margin

Gross margin increased for the three months ended September 30, 2005 as compared to the same period in 2004 due an increase in sales of Vivelle-Dot, which has a higher gross margin than the other products sold by Novogyne, and significantly lower sales returns allowances.

Gross margin increased for the nine months ended September 30, 2005 as compared to the same period in 2004 due to increased sales of Vivelle-Dot, which has a higher gross margin than the other products sold by Novogyne, coupled with decreased sales of Estradot to Novartis in Canada, which typically have a lower gross margin. In addition, gross margin for the nine months ended September 30, 2005 benefited from significantly lower sales returns allowances.

Novogyne Selling, General and Administrative Expenses

The $1.2 million increase in selling, general and administrative expenses for the three months ended September 30, 2005 as compared to the same period in 2004, was primarily attributable to a $0.4 million increase in litigation costs, $0.4 million increase in sample expenses, and $0.3 million increase in insurance and other costs.

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The $3.1 million increase in selling, general and administrative expenses for the nine months ended September 30, 2005 as compared to the same period in 2004, was primarily attributable to a $0.9 million increase in sales force expenses, $0.8 million increase in insurance and other costs, and $0.5 million increase in litigation costs. In addition, the nine months ended September 30, 2004 benefited from a $0.6 million decline in expenses associated with the co-promotion of Novartis Famvir product.

Novogyne Amortization of Intangible Asset

Novogyne amortized $1.5 million related to the acquisition cost for the CombiPatch® product for each of the three month periods ended September 30, 2005 and 2004, and $4.6 million for each of the nine month periods ended September 30, 2005 and 2004. Our CombiPatch® product was licensed by Novogyne in March 2001.

Liquidity and Capital Resources

As of September 30, 2005 and December 31, 2004, we had the following (amounts in thousands):

	September 30, 2005	December 31, 2004
Cash and cash equivalents	$ 32,340	$ 93,958
Short-term investments	50,825	
Working capital	90,563	97,349

Cash provided by (used in) operating, investing and financing activities for the nine months ended September 30, 2005 and 2004 is summarized as follows (amounts in thousands):

	Nine Months	
	2005	2004
Cash flows:		
Operating activities	$ (1,036)	$ 16,914
Investing activities	(61,697)	(5,426)
Financing activities	1,115	5,478

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2005 primarily resulted from the timing of certain payments, including payments of: $10.0 million to Shire related to expenses incurred in pursuit of methylphenidate regulatory approval, $3.1 million made for the purchases of fentanyl, $3.3 million for compensation and related liabilities, and $2.3 million related to insurance, partially offset by $18.1 million in distributions received from Novogyne.

Net cash provided by operating activities for the nine months ended September 30, 2004 primarily resulted from the receipt of an $8.0 million license payment upon the closing of the Endo transaction in February 2004 and $12.3 million in distributions from Novogyne, partially offset by $6.7 million in expenses incurred in pursuit of regulatory approval for our methylphenidate product.

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Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2005 was primarily attributable to $50.8 million in net purchases of short-term investments, as well as the purchase of $10.5 million in fixed assets to expand production capacity for future products. Beginning in the first quarter of 2005, Noven invested a portion of its cash in short-term investments, which primarily consist of investment grade, asset backed, variable rate debt obligations and municipal auction rate securities, which are categorized as available-for-sale under the provisions of Statement of Financial Accounting Standards (SFAS) No. 115 Accounting for Certain Investments in Debt and Equity Securities .

Net cash used in investing activities for the nine months ended September 30, 2004 was primarily attributable to the purchase of fixed assets to expand production capacity for future products and payment of patent development costs.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2005 and September 30, 2004 was primarily attributable to $1.2 million and $5.6 million, respectively, received in connection with the issuance of common stock from the exercise of stock options.

Short-Term and Long-Term Liquidity

Our principal sources of short-term liquidity are existing cash, cash generated from product sales, fees and royalties under development and license agreements and distributions from Novogyne. For the nine months ended September 30, 2005, substantially all of our income before income taxes was comprised of equity in earnings of Novogyne, a non-cash item. Accordingly, our net income may not be reflective of our cash from operations. 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.

Our short-term cash flow is dependent on sales, royalties and license fees associated with transdermal HT products. Any decline 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 HT studies), the further decline of the HT market, or the inability or failure of Novogyne to pay distributions would have a material adverse effect on our short-term liquidity and require us to rely on our existing cash balances or on borrowings to support our operations and business.

For the nine months ended September 30, 2005, $5.2 million in deferred license revenues were used to offset development expenses related to our methylphenidate patch. As of September 30, 2005, $5.0 million remained payable to Shire, which amount is expected to be paid in the remainder of 2005. Under our agreement with Shire, we will receive $50.0 million upon receipt of final marketing approval for our methylphenidate patch by the FDA and three installments of $25.0 million each upon Shire s achievement of $25.0 million, $50.0 million and $75.0 million in annual net sales of our methylphenidate patch, respectively. Prior to any FDA approval of our methylphenidate patch, Shire has the right to require Noven to repurchase the product rights to our methylphenidate patch for $5.0 million under certain circumstances. We cannot assure that our methylphenidate patch will be approved by the FDA, and there is no assurance that the recently submitted amendment to our methylphenidate NDA will address the issues raised in the not approvable letter we received from the FDA in 2003 or that the FDA may not raise additional issues in the review of the amended NDA. Additionally, even if the FDA approves our methylphenidate

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patch, we cannot assure that Shire will generate sales at levels that would trigger our milestone payments; therefore, we cannot assure that we will receive any further payments from Shire with respect to our methylphenidate patch or that we will be able to recover our development expenses through sales of the product.

We agreed with Endo that we would manufacture initial launch quantities of our fentanyl patch prior to receipt of final regulatory approval from the FDA and that the parties would share the cost of any non-saleable fentanyl inventories in accordance with an agreed-upon formula. As a result of the FDA s decision to cease review of our ANDA, we deemed the entire $14.0 million of fentanyl patch inventories to be non-saleable and recorded a $9.5 million charge to our cost of products sold for the three and nine months ended September 30, 2005. This charge represents the portion of the cost of the existing fentanyl inventories and purchasing commitments for raw materials allocable to us under the contractual formula. Endo is responsible for the remaining $4.5 million of the fentanyl patch production costs, and we recorded a receivable of $4.5 million from Endo. At September 30, 2005, we owed Endo $2.6 million related to fentanyl raw materials. In addition, we expect to incur up to approximately $0.7 million in costs associated with disposal and destruction of our fentanyl inventories, substantially all of which is expected to be incurred and charged to costs of products sold in the fourth quarter of 2005.

Capital expenditures were $11.4 million for the nine months ended September 30, 2005, of which $0.9 million represented landlord-funded leasehold improvements to a leased facility. We expect that our capital expenditures will continue at this rate for the remainder of 2005 and into 2006 as we continue to expand our manufacturing and storage facilities for products under development. We expect to fund these capital expenditures from our existing cash balances. As a general matter, we believe that we have sufficient liquidity available to meet our operating needs and anticipated short-term capital requirements.

In February 2005, we entered into an Industrial Long-Term Lease (the Lease) for approximately 73,000 square feet of newly constructed space located in close proximity to our manufacturing facility in Miami, Florida. We intend to use the leased space for the storage and, as needed, the manufacture of new product. The lease term is 10 years, which may be extended for up to an additional 21 years pursuant to four renewal options of five years each and a one-time option to renew for one year. The annual base rent is $6.40 per square foot. We also pay a monthly management fee equal to 1.5% of the base rent. The rent for the first year is discounted to $3.20 per square foot. The base rent is subject to annual increases of 3% during the initial 10-year term. After the initial term, the rent will be 95 percent of the fair market rate of the leased space as determined under the Lease. We are in the process of improving the leased space in order to prepare it for its intended use. The landlord was responsible for up to approximately $0.9 million of leasehold improvements, which were fully paid as of June 30, 2005. Any amounts paid to the general contractor in excess of this amount and any other leasehold improvements will be our responsibility. For accounting purposes, we are amortizing the expected rental payments on a straight-line basis over the initial 10-year term of the Lease. The renewal terms have not been included for amortization purposes because we cannot reasonably estimate the rental payments after the initial term and we cannot assure that we will renew the Lease after the initial term. Any leasehold improvements will be recorded at cost and will be amortized on a straight-line basis over the shorter of the estimated useful life of the improvements or the remaining initial 10-year lease term. Leasehold improvements to the leased space paid by the landlord will be recorded by us as a deferred rent credit and will be amortized on a straight-line basis when incurred over the remaining initial 10-year lease term as a reduction of rent expense.

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 possible direct sales of our

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own products. We expect that our cash requirements will continue to increase, primarily to fund plant and equipment purchases to expand production capacity for new products. If our products under development are successful, these expenditures, which may include the cost of building additional manufacturing facilities, are expected to be significant.

We cannot assure that we will successfully complete the development of such products, that we will obtain regulatory approval for any such products, that any approved product may be produced in commercial quantities, at reasonable costs, and be successfully marketed, or that we will successfully negotiate future licensing or product acquisition arrangements. Because much of the cost associated with product development and expansion of manufacturing facilities is incurred prior to product launch, if we are unsuccessful in out-licensing, or if we are unable to launch additional commercially-viable products that we develop or that we license or acquire from others, we will have incurred the up-front costs associated with product development or acquisition without the benefit of the liquidity generated by sales of those products, which could adversely affect our long-term liquidity needs. Factors that could impact our ability to develop or acquire and launch additional commercially-viable products are discussed under Cautionary Factors that May Impact Future Results as well as in our Annual Report on Form 10-K for the year ended December 31, 2004.

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

New Accounting Standards

In November 2004, the FASB issued Statement of Financial Accounting Standard No. 151 Inventory Costs an amendment of ARB No. 43, Chapter 4 (SFAS 151), to clarify the accounting for abnormal amounts of idle facility expense, freight, or wasted material (spoilage). SFAS 151 requires that those items be recognized as current-period charges regardless of whether they meet the so abnormal criterion outlined in Accounting Research Bulletin 43, Chapter 4, Inventory Pricing . SFAS 151 also introduces the concept of normal capacity and requires the allocation of fixed production overheads to inventory based on the normal capacity of the production facilities. Unallocated overheads must be recognized as an expense in the period in which they are incurred. This statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. We currently account for abnormal amounts of idle facility expense, freight or wasted material (spoilage) as current-period charges and allocate fixed production overheads to inventory based on the normal capacity of the production facilities and recognize unallocated overheads as an expense in the period in which they are incurred. For the foregoing reasons, we do not anticipate that implementation of this statement will have a material impact on our results of operations and financial condition.

In December 2004, the FASB issued SFAS No. 123(R) Share-Based Payment (Revised 2004) that will require compensation costs related to share-based payment transactions to be recognized in the financial statements. With limited exceptions, the amount of compensation cost will be measured based on the grant-date fair value of the equity or liability instruments issued. Compensation cost will be recognized over the period that an employee provides service in exchange for the award, which is generally over the vesting period. SFAS 123(R) also requires the benefits of tax deductions in excess of recognized compensation costs to be reported as financial cash flows, rather than as operating cash flows as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. While we cannot estimate what those amounts will be in the future, the amount of such income tax benefits on exercise of stock options was $0.2 million and $3.0 million for the nine months ended September 30,

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2005 and 2004, respectively. SFAS 123(R) replaces SFAS 123, Accounting for Stock-Based Compensation , and supersedes APB 25, Accounting for Stock Issued to Employees . For public companies such as Noven, the statement is effective as of the beginning of the first annual reporting period that begins after June 15, 2005 and accordingly, we anticipate adopting this statement in the first quarter of 2006.

In December 2004, the FASB issued SFAS No. 153 Exchanges of Nonmonetary Assets, An Amendment of APB Opinion No. 29 (SFAS 153). SFAS 153 eliminates the exception for exchange of similar productive assets and replaces it with a general exception for exchanges of non-monetary assets that do not have commercial substance. SFAS 153 is effective for non-monetary assets and exchanges occurring in the first quarterly period beginning after June 15, 2005. As we have not and have no present intention to engage in exchanges of non-monetary assets, we do not anticipate that implementation of this statement will have a material impact on our results of operations and financial condition.

In June 2005, the FASB issued SFAS No. 154, Accounting Changes and Error Corrections (SFAS 154). SFAS 154 replaces APB Opinion No. 20, Accounting Changes and FAS No. 3, Reporting Accounting Changes in Interim Financial Statements . SFAS 154 requires that a voluntary change in accounting principle be applied retrospectively with all prior period financial statements presented on the new accounting principle. SFAS 154 also requires that a change in method of depreciating or amortizing a long-lived non-financial asset be accounted for prospectively as a change in estimate, and correction of errors in previously issued financial statements should be termed a restatement. SFAS 154 is effective for accounting changes and correction of errors made in the first annual reporting period beginning after December 15, 2005. The implementation of SFAS 154 is not presently expected to have a material impact on our results of operations and financial condition.

Outlook

A summary of our current financial guidance is provided below. This forward-looking information is based on our current assumptions and expectations, many of which are beyond our control to achieve. In particular, for purposes of this guidance we have assumed, among other things, that during the remainder of 2005 (except as otherwise indicated below) there will not be any material:

transactions;

changes in Noven s or Novogyne s accounting or accounting principles or any of the estimates or judgments underlying its critical accounting policies;

regulatory, technological or clinical study developments;

changes in the supply of, demand for, or distribution of our HT products (including any changes resulting from product recalls, competitive HT products, or new HT study results);

changes in our business relationships/collaborations; or

changes in the economy or the health care sector generally.

Financial guidance is inherently uncertain. Accordingly, we cannot assure that we will achieve results consistent with this guidance. If our assumptions or expectations concerning any of these matters prove to be incorrect, our actual financial results could differ materially from the expected results discussed below. For a discussion of certain factors that may impact our actual financial results for the periods referenced, readers should carefully consider the risks, uncertainties and cautionary factors discussed below under the caption Factors Affecting Our Business and Prospects and in our Annual Report on Form 10-K for the year ended December 31, 2004.

Novogyne. Based on current prescription trends, our estimates of trade inventory levels and other factors, we believe that Novogyne s net revenues should increase in the 10% range, and

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Novogyne s net income should increase in the 25% range for full-year 2005 compared to 2004 levels.

HT Product Revenues. Given customer orders in hand for our HT products and other factors, we expect product revenues from our hormone therapy products for full-year 2005 to increase in the 5% to 10% range compared to 2004 levels.

Contract and License Revenues. We expect contract revenues for 2005 to decline compared to 2004, primarily due to the receipt in 2004 of $4.4 million in payments from P&G Pharmaceuticals which are not expected to recur in 2005.

Research and Development. We expect our research and development expense in 2005 to increase substantially over 2004 levels, with anticipated increases in non-clinical development, new product development and clinical trial expenses.

Marketing, General and Administrative Expense. We expect Noven s marketing, general and administrative expense in 2005 to increase modestly over 2004 levels, with anticipated increases in costs associated with facility expansion, product liability insurance, professional services fees and other areas.

Capital Expenditures. We expect that our capital expenditures will continue for 2005 and into 2006 at a rate comparable to the nine-month period ended September 30, 2005, primarily due to the expansion of our manufacturing and storage facilities in connection with products under development with our industry partners.

Fentanyl. On September 27, 2005, the FDA advised us that it did not expect to approve our ANDA for a generic fentanyl transdermal system and had ceased its review of our ANDA. Our results of operations for future periods are expected to be adversely affected by increased overhead expenses associated with fentanyl production unless and until we are able to successfully redeploy the personnel and other assets previously associated with fentanyl production.

Effective Tax Rate. Noven estimates that its effective tax rate for full-year 2005 will be approximately 31%.

Novogyne Sales Force. Effective January 1, 2006, members of the Novogyne sales force (which is currently a contract sales force) are expected to become direct employees of Noven. As is the case with other costs incurred by Noven on behalf of Novogyne, Noven will be reimbursed by Novogyne for costs associated with these sales force employees.

Cautionary Factors that May Impact Future Results

Except for historical information contained herein, the matters discussed in this report are forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements about our and our licensees respective plans, objectives, expectations, estimates, strategies, prospects, product approvals and development plans, and anticipated financial results. These statements are typically identified by the use of terms such as anticipates, believes, estimates, hopes, expects, intends, may, plans, could, should, will, would and similar words. These statements current expectations and beliefs concerning future events and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed herein. We do not undertake to update any of these forward-looking statements or to announce the results of any revisions to these forward-looking statements except as required by law. In addition to the factors described elsewhere in this report and in our Form 10-K for the year ended December 31, 2004 the risks and uncertainties in the following categories, among others, as well as our success at managing those risks, could cause our actual results to differ materially from those expressed in any forward-looking statements:

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HT Market, risks associated with increased competition in the HT market; any further impact on our HT business due to the announcement of additional negative clinical results or otherwise, which could reduce or eliminate any profit contribution by Novogyne to us and/or sales of HT products from us to Novartis Pharma; uncertainties regarding any future regulatory developments resulting from those studies; the risk that Novogyne may not be able to realize the full value of the marketing rights for our CombiPatch® product; the European HT market may be limited due to pricing pressures and delayed Estradot launches in certain countries due to labeling issues; and the risk of product liability claims resulting from the use of HT products such as the lawsuits presently pending against Noven, Novogyne and Novartis with respect to our products, as well as any indemnification or contribution obligations that we may have to Novartis or Novogyne related to product liability claims.

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

Production Matters, risks related to our reliance on suppliers for the availability and quality of raw materials used in our products; risks related to our reliance on a single supplier for certain raw materials and compounds used in our products; risks related to obtaining procurement quota for controlled substances (including methylphenidate) from the DEA, including possible delays or failure to obtain such quota resulting from recent legislation that requires the DEA to review and provide public comment on the labeling, promotion, risk management plan and other documents associated with such product prior to establishing procurement quota for controlled substances; uncertainties regarding the timing and magnitude of any product recalls; the impact of the recalls or related issues on Novartis or other partners strategy for the commercialization of our products; the possibility that our estimates of the impact of future returns and charges may prove inaccurate, incomplete or otherwise incorrect; the impact of detected or undetected product stability failures or other product defects on our ability to estimate our reserves for sales returns and other associated accounting consequences.

Our Partners, the risk that our development partners may have different or conflicting priorities than ours which may adversely impact their ability or willingness to assist in the development and commercialization of our products or to continue the development programs in which they and we have partnered; uncertainties regarding our ability to attract additional development partners; the possibility that our technologies may not be approvable or suitable for use in additional therapeutic categories, including those categories addressed through products developed with our development partners; the possibility that we may be unsuccessful in achieving milestone objectives under our development programs and may not receive any further payments; the possibility that our development programs may not proceed on schedule or as expected, which could, among other things, prevent us from achieving milestone objectives under our development programs and/or cause delays or cancellations of programs; the possibility that our current development priorities could render us unable to advance our other development projects or increase the cost of advancing those projects; risks related to our dependence on Novartis to perform Novogyne s financial, accounting, inventory, distribution, revenues and sales deductions functions (including any asset impairment decisions for Novogyne), including the risk that Novartis may perform these functions differently than we would have, inadequately or incorrectly; risks and uncertainties related to the fact that Vivelle-Dot comprises a substantial majority of Novogyne s aggregate total prescriptions; risks and uncertainties relating to the integration of Novogyne s contract sales force into our employee force, including the risk that such integration may be unsuccessful or prove more costly than expected; and the possibility that our financial results could fluctuate from period to period or

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otherwise be affected by Novartis monitoring of trade inventory levels for Novogyne and its decisions related thereto.

Methylphenidate Patch, the possibility that the FDA and/or the advisory committee will determine that our amended NDA for our methylphenidate patch does not support approval or that our methylphenidate patch may not ultimately be approved or commercialized; the possibility that safety concerns by the FDA and/or the advisory committee regarding the use of controlled substances in patches may delay or prevent approval of our amended NDA for our methylphenidate patch; risks and uncertainties related to the fact that our methylphenidate transdermal system is a novel delivery system for this controlled substance, which may result in new and additional concerns for the advisory committee and/or the FDA; the timing of the FDA s review of any amended NDA for our methylphenidate patch as well as any product approval and the timing of any DEA approval of a methylphenidate procurement quota for Noven, which are outside Noven s control and which may impact the success of product launch and market penetration; risks and uncertainties related to the 2005 study by researchers at the M.D. Anderson Cancer Center that found adverse chromosomal effects on 12 children treated with oral methylphenidate, including risks related to the timing of any FDA approval of our methylphenidate patch, the impact on the market for methylphenidate products (including our patch, if approved) and any follow-on or related study finding adverse effects from methylphenidate use; any exercise of Shire s right to terminate the agreement, including the risk that, in such event, our right to receive a $50.0 million approval milestone would terminate, and that we may be unable or unwilling to proceed with the project or may be unable to license our methylphenidate patch to a third party or to a party with the resources of Shire on commercially reasonable terms; the possibility that our method of accounting for the $25.0 million received from Shire could change under certain circumstances, including if the parties product strategy changes or if our methylphenidate patch development is discontinued; and the likelihood that our development strategy would change if Shire were to terminate the agreement under certain circumstances, or if our methylphenidate patch were not ultimately approved or were abandoned.

Fentanyl Patch, the risk that Endo may exercise its contractual right to terminate the license agreement; that we may not receive any milestone payments under the license agreement; the risk that we and Endo may not agree on a strategy to continue to seek approval of a generic fentanyl patch or that any strategy on which we agree may be unsuccessful; the possibility that our generic fentanyl patch might never be approved by the FDA; the risk that our results of operations may be adversely affected by increased overhead expenses associated with fentanyl production unless and until we successfully redeploy the personnel and other assets previously associated with fentanyl production; the risk that our estimates of the disposal costs of our fentanyl inventory could be incorrect; and the risk that Endo may suspend or terminate its other collaborations with us.

Other Matters, expected fluctuations in quarterly revenues and research and development expenses; uncertainties associated with our beliefs regarding the timing of trade customer orders; and uncertainties regarding the outcome of IRS audits of prior periods. We caution that the foregoing list of factors is not exhaustive.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Not Applicable.

Item 4. Controls and Procedures

Pursuant to Exchange Act Rule 13a-15, as of the end of the quarterly period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures. In addition, we reviewed our internal controls, and there have been no significant changes in our internal controls or in other factors that could significantly affect those controls subsequent to the date of the last evaluation. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and

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procedures are effective in timely alerting them to material information relating to Noven required to be included in our periodic Securities and Exchange Commission filings. However, that conclusion should be considered in light of the various limitations described below on the effectiveness of those controls and procedures, some of which pertain to most if not all business enterprises, and some of which arise as a result of the nature of our business. Our management, including the Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures will prevent all error and all improper conduct. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of improper conduct, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Further, the design of any system of controls also is based in part upon assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. Furthermore, our level of historical and current equity participation in Novogyne may substantially impact the effectiveness of our disclosure controls and procedures. Because we do not control Novogyne, and all of Novogyne s financial, accounting, inventory, distribution, revenues and sales deductions functions are performed by Novartis, our disclosure controls and procedures with respect to Novogyne are necessarily more limited than those we maintain with respect to ourselves. No significant changes were made in our internal controls or in other factors that could significantly affect these controls subsequent to the date of the Chief Executive Officer s and Chief Financial Officer s evaluation.

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

We do not control Novogyne and Novartis performs all of Novogyne s financial, accounting, inventory, sales and sales deductions functions. As previously disclosed, in the course of its audit of Novogyne s financial statements for the year ended December 31, 2004, Novogyne s independent registered public accounting firm identified what it believes is a significant deficiency in Novogyne s internal controls which related to oversights by Novartis in connection with Novogyne s accounting for certain rebate accruals. These oversights resulted in an immaterial adjustment at Novogyne in the fourth quarter of 2004. As previously disclosed, the Audit and Compliance Committee of Novartis AG engaged outside counsel to conduct an internal investigation of this matter. We have been advised that outside counsel completed its investigation in August 2005 and has concluded that Novartis personnel engaged in no intentional misconduct or intentional violations of generally accepted accounting principles.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

In September 2005, Noven, Novogyne and Novartis were served with a summons and complaint from an individual plantiff in Superior Court of New Jersey Law Division, Atlantic County in which the plaintiff claims personal injury allegedly arising from the use of HT products, including Vivelle®. The plaintiff claims compensatory, punitive and other damages in an unspecified amount.

Novartis has advised Noven that Novartis has been named as a defendant in at least 17 additional lawsuits that include approximately 28 plaintiffs that allege liability in connection with personal injury claims allegedly arising from the use of HT patches distributed and sold by Novartis and Novogyne, including Noven s Vivelle®, Vivelle-Dot and CombiPatch® products. Novogyne has been named as a defendant in one lawsuit in addition to the one referenced above. Novartis has indicated that it will seek indemnification from Noven and Novogyne to the extent permitted by law and by the agreements between and among Novartis, Novogyne and Noven. Novogyne s accrual for expected legal fees and settlements of these lawsuits was $4.9 million as of September 30, 2005, for which there was a related insurance receivable of $3.5 million. This accrual represents Novartis management s best estimate as of September 30, 2005. The ultimate outcome of these product liability lawsuits cannot be predicted.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

The following table provides information with respect to our stock repurchases during the third quarter of 2005:

	Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Program	Approximate Dollar Value That May Yet be Purchased under the Program[1]
July 1, 2005 to July 31, 2005				$ 23,711,040
August 1, 2005 to August 31, 2005				$ 23,711,040
September 1, 2005 to September 30, 2005				$ 23,711,040
Totals				$ 23,711,040

(1) In March 2003, we announced a stock repurchase program authorizing the repurchase of up to $25.0 million of our Common Stock. There is no expiration date specified for this program.

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Item 5. Other Information

Dr. John Clarkson, a member of Noven s Board of Directors, has indicated that commencing on January 1, 2006 he intends to accept compensation for his service on Noven s Board to the full extent provided to Noven s other directors. Currently, Dr. Clarkson does not accept any compensation for his service on the Board other than the annual stock option grants.

Item 6. Exhibits

31.1 Certification of Robert C. Strauss, President, Chief Executive Officer and Chairman of the Board, pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

31.2 Certification of Diane M. Barrett, Vice President and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

32.1 Certification of Robert C. Strauss, President, Chief Executive Officer and Chairman of the Board, pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

32.2 Certification of Diane M. Barrett, Vice President and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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Signatures

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

NOVEN
PHARMACEUTICALS,
INC.

Date: November 4, 2005

By: /s/ Diane M. Barrett

Diane M. Barrett
Vice President and
Chief Financial Officer