

NOVEN PHARMACEUTICALS INC

Form 10-Q

November 09, 2006

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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, 2006**

**Commission file number 0-17254**

**NOVEN PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

STATE OF DELAWARE

59-2767632

(State or other jurisdiction of  
incorporation or organization)

(I.R.S. Employer  
Identification Number)

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

(Address of principal executive offices) (Zip Code)

(305) 253-5099

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer" and "large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐

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

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

Class	Outstanding at October 31, 2006
Common stock \$.0001 par value	24,361,178

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Cautionary Factors: Statements in this report that are not descriptions of historical facts are forward-looking statements provided under the safe harbor protection of the Private Securities Litigation Reform Act of 1995. 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 discussed in Item 1A of Part I of our Annual Report on Form 10-K for the year ended December 31, 2005 and in Item 1A of Part II of any quarterly reports on Form 10-Q we have filed with the Securities and Exchange Commission since the filing of our Form 10-K, as well as other reports filed from time to time with the Securities and Exchange Commission.

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

Limited.

**Table of Contents****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	
	2006	2005	2006	2005
Revenues:				
Product revenues Novogyne:				
Product sales	\$ 5,273	\$ 4,740	\$ 13,990	\$ 14,432
Royalties	1,791	1,790	5,138	4,617
Total product revenues Novogyne	7,064	6,530	19,128	19,049
Product revenues third parties	5,761	3,917	15,648	11,888
Total product revenues	12,825	10,447	34,776	30,937
Contract and license revenues:				
Contract	44	769	1,112	1,793
License	2,839	1,024	7,559	3,017
Contract and license revenues	2,883	1,793	8,671	4,810
Net revenues	15,708	12,240	43,447	35,747
Expenses:				
Cost of products sold Novogyne	3,702	3,521	10,304	9,219
Cost of products sold third parties	5,339	11,895	16,764	17,307
Total cost of products sold	9,041	15,416	27,068	26,526
Research and development	2,527	3,826	8,899	9,752
Marketing, general and administrative	6,010	4,237	16,386	12,481
Total expenses	17,578	23,479	52,353	48,759
Loss from operations	(1,870)	(11,239)	(8,906)	(13,012)
Equity in earnings of Novogyne	8,234	8,081	19,323	17,094
Interest income, net	1,168	512	2,890	1,608

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Income (loss) before income taxes	7,532	(2,646)	13,307	5,690
Provision (benefit) for income taxes	2,501	(1,224)	4,439	1,780
Net income (loss)	\$ 5,031	\$ (1,422)	\$ 8,868	\$ 3,910
Basic earnings (loss) per share	\$ 0.21	\$ (0.06)	\$ 0.37	\$ 0.17
Diluted earnings (loss) per share	\$ 0.20	\$ (0.06)	\$ 0.37	\$ 0.16
Weighted average number of common shares outstanding:				
Basic	23,954	23,586	23,768	23,554
Diluted	24,574	23,586	24,142	24,021

*The accompanying notes are an integral part of these statements.*

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

	September 30, 2006	December 31, 2005
Assets		
Current Assets:		
Cash and cash equivalents	\$ 8,676	\$ 66,964
Short-term investments available-for-sale, at fair value	130,510	17,900
Accounts receivable trade (less allowance for doubtful accounts of \$47 in 2006 and \$53 in 2005)	6,091	2,919
Accounts receivable Novogyne, net	7,783	8,912
Inventories	8,134	7,861
Net deferred income tax asset, current portion	4,200	6,000
Prepaid income taxes	6,007	7,697
Prepaid and other current assets	2,481	1,357
	173,882	119,610
Property, plant and equipment, net	37,414	34,455
Other Assets:		
Investment in Novogyne	22,710	23,243
Net deferred income tax asset	8,225	6,373
Patent development costs, net	2,371	2,211
Deposits and other assets	221	18
	33,527	31,845
	\$ 244,823	\$ 185,910
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 4,824	\$ 5,812
Capital lease obligation current portion	34	121
Accrued liability Shire	419	5,488
Accrued compensation and related liabilities	4,729	5,771
Other accrued liabilities	2,679	2,124
Deferred rent credit	89	89
Deferred contract revenues	1,758	1,481
Deferred license revenues current portion	11,174	7,602
	25,706	28,488
Long-Term Liabilities:		
Capital lease obligation	38	

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Deferred rent credit	681	748
Deferred license revenues	55,936	16,053
Deferred compensation liability	134	
	82,495	45,289
Commitments and Contingencies (Note 14)		
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 24,294,309 at September 30, 2006 and 23,617,221 at December 31, 2005	2	2
Additional paid-in capital	102,685	89,846
Retained earnings	59,641	50,773
	162,328	140,621
	\$ 244,823	\$ 185,910

*The accompanying notes are an integral part of these statements.*



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## Condensed Statements of Cash Flows

Nine Months Ended September 30,

(in thousands)

(unaudited)

	2006	2005
Cash flows from operating activities:		
Net income	\$ 8,868	\$ 3,910
Adjustments to reconcile net income to net cash flows provided by operating activities:		
Depreciation and amortization	2,864	1,892
Write-off of fentanyl inventories deemed non-saleable		9,475
Stock-based compensation expense	2,358	
Amortization of patent costs	379	334
Increase in cash surrender value of company-owned life insurance	(3)	
Amortization of deferred rent credit	(67)	(53)
Income tax benefits on exercise of stock options	687	228
Deferred income tax benefit	(52)	(689)
Recognition of deferred license revenues	(7,559)	(3,017)
Equity in earnings of Novogyne	(19,323)	(17,094)
Distributions from Novogyne	17,644	18,092
Changes in operating assets and liabilities:		
(Increase) decrease in accounts receivable trade, net	(3,172)	2,430
Decrease in accounts receivable Novogyne, net	1,129	3,319
Increase in accounts receivable Endo		(4,467)
(Increase) decrease in inventories	(273)	93
Decrease in prepaid income taxes	3,902	3,987
Increase in prepaid and other current assets	(1,124)	(1,130)
(Increase) decrease in deposits and other assets	(15)	3
Decrease in accounts payable	(988)	(5,346)
Decrease in accrued liability Shire	(5,069)	(5,608)
Decrease in accrued compensation and related liabilities	(1,042)	(1,595)
Increase in other accrued liabilities	555	111
Increase (decrease) in deferred contract revenue, net	277	(741)
Increase in deferred license revenue	51,000	
Increase in deferred compensation liability	134	
Amounts recoverable from (reimbursable to) Shire and offset against deferred license revenue related to Daytrana approval	14	(5,170)
Cash flows provided by (used in) operating activities	51,124	(1,036)
Cash flows from investing activities:		
Purchases of property, plant and equipment, net	(5,823)	(10,462)
Payments for patent development costs, net	(539)	(410)
Purchase of company-owned life insurance	(185)	
Purchases of short-term investments	(1,012,385)	(340,590)
Proceeds from sale of short-term investments	899,775	289,765
Cash flows used in investing activities	(119,157)	(61,697)

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Cash flows from financing activities:

Issuance of common stock from exercise of stock options	8,080	1,201
Payments under capital leases	(49)	(86)
Excess tax deduction from exercise of stock options	1,714	
Cash flows provided by financing activities	9,745	1,115
Net decrease in cash and cash equivalents	(58,288)	(61,618)
Cash and cash equivalents, beginning of period	66,964	93,958
Cash and cash equivalents, end of period	\$ 8,676	\$ 32,340

*The accompanying notes are an integral part of these statements.*

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**NOVEN PHARMACEUTICALS, INC.**

**Notes to Unaudited Condensed Financial Statements**

**1. DESCRIPTION OF BUSINESS:**

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

Noven and Novartis Pharmaceuticals Corporation ( Novartis ) entered into a joint venture, Vivelle Ventures LLC (d/b/a Novogyne Pharmaceuticals) ( Novogyne ), effective May 1, 1998, to market and sell women s prescription healthcare products in the United States and Canada. These products include Noven s transdermal estrogen delivery systems marketed under the brand names Vivelle®, 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, 2006, and the results of its operations and its cash flows for the three and nine months ended September 30, 2006 and 2005. Noven s business is subject to numerous risks and uncertainties including, but not limited to, those set forth in Part I Item 1A of Noven s Annual Report on Form 10-K for the year ended December 31, 2005 ( Form 10-K ) and in Part II Item 1A - Risk Factors of any quarterly reports on Form 10-Q filed by Noven with the Securities and Exchange Commission ( SEC ) since the filing of Noven s Form 10-K, as well as in other reports filed from time to time with the SEC. Accordingly, the results of operations and cash flows for the three and nine months ended September 30, 2006 and 2005 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 2006 or for periods thereafter.

The accompanying unaudited condensed financial statements have been prepared pursuant to the rules and regulations of the SEC 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, as updated and supplemented by the following:

**VENDOR DISCOUNTS:**

Noven receives purchase-volume-related discounts and rebates from vendors in the normal course of business. Management uses projected purchase volumes to estimate accrual rates, validates those projections based on actual purchase trends and applies those rates to actual purchase volumes to determine the amount of funds accrued by Noven and receivable

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from the vendor. Amounts accrued could be impacted if actual purchase volumes differ from projected purchase volumes. Purchase-volume-related discounts or rebates are treated as a reduction of inventory cost or cost of products sold, depending on whether the related inventory is on-hand or has been previously sold.

**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, 2006, and December 31, 2005, consisted primarily of overnight money market accounts, time deposits, commercial paper and money market funds with original maturities of three months or less at the date of purchase. Noven has invested a majority 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 . 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, 2006 and December 31, 2005, the cost of all short-term investments approximated fair value. No unrealized gains and losses have been recognized for the quarters ended September 30, 2006 and 2005, respectively. Realized gains and losses, interest, and dividends are included in interest income or interest expense, as appropriate.

**4. RECLASSIFICATIONS AND REVISIONS:**

Certain reclassifications have been made to prior period financial statements to conform to the current period s presentation. Cost of products sold has been revised for the prior period to include certain amounts previously included in research and development expenses.

**5. CASH FLOW INFORMATION:**

Cash payments for income taxes were \$0.8 million and \$0.1 million for the nine months ended September 30, 2006 and 2005, respectively. Under Noven s stock-based compensation arrangements, there can be increases in the value of equity instruments issued under those arrangements that are not recognizable as an expense for accounting purposes but are deductible in determining taxable income. Noven would have paid an additional \$1.7 million in income taxes for the nine months ended September 30, 2006 had these increases not been deductible from taxable income. Cash payments for interest were not material for the nine months ended September 30, 2006 and 2005.

*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 2006 and 2005, Novogyne paid \$2.2 million and \$1.5 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 as the landlord paid for the applicable leasehold improvements.

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In July 2006, the Financial Accounting Standards Board ( FASB ) issued Interpretation No. 48 Accounting for Uncertainty in Income Taxes ( FIN 48 ) to clarify the accounting for uncertainties related to income taxes that are recognized in an enterprise's financial statements in accordance with SFAS 109, Accounting for Income Taxes. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The evaluation of a tax position in accordance with FIN 48 is a two-step process. The first step is recognition, which requires an enterprise to determine whether it is more likely than not that a tax position will be sustained upon examination based on the technical merits of the position. The second step is measurement, which requires a company to recognize a tax position that meets the more likely than not recognition threshold at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. FIN 48 is effective as of the beginning of the first annual reporting period that begins after December 15, 2006. Noven is currently assessing FIN 48 and is unable to estimate the impact it will have on its results of operations and financial condition.

In September 2006, the SEC issued Staff Accounting Bulletin No. 108 ( SAB 108 ), which added Section N to Topic 1, Financial Statements, of the Staff Accounting Bulletin Series. Section N provides guidance on the consideration of the effects of prior year misstatements when quantifying current year financial statement misstatements for the purpose of materiality assessment. The SEC concluded in SAB 108 that a registrant's materiality evaluation of an identified unadjusted error should quantify the impact of correcting all misstatements, including both the carryover and reversing effects of prior year misstatements, on the current year financial statements. If either the carryover or reversing effects of prior year misstatements is material, the misstatements should be corrected in the current year. If correcting an error in the current year for prior year misstatements causes the current year to be materially misstated, the prior year financial statements should be corrected, even though such revision previously was and continues to be immaterial to the prior year financial statements. Correcting prior year financial statements for immaterial errors would not require previously filed reports to be amended. Such correction may be made the next time the registrant files the prior year financial statements. The guidance of SAB 108 should be applied in the annual financial statements covering the fiscal year ending after November 15, 2006.

**7. INVENTORIES:**

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

	September 30, 2006			December 31, 2005		
	Commercial	Pre-launch	Total	Commercial	Pre-launch	Total
Finished goods	\$ 1,362	\$	\$ 1,362	\$ 760	\$	\$ 760
Work in progress	2,735		2,735	1,278	1,004	2,282
Raw materials	4,037		4,037	3,422	1,397	4,819
	\$ 8,134	\$	\$ 8,134	\$ 5,460	\$ 2,401	\$ 7,861

Pre-launch inventories as of December 31, 2005 consisted of Noven's Daytran product, which received final approval from the United States Food and Drug Administration ( FDA ) in April 2006 and was commercially launched in June 2006. Provisions have been made to reduce inventories to net realizable value.

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Certain materials and compounds are available from limited sources and, in some cases, a single supplier. While Noven has not, to date, experienced any difficulty acquiring from its suppliers materials necessary to manufacture its products, no assurance can be given that Noven will not experience such difficulty in the future. In addition, the Drug Enforcement Administration ( DEA ) controls access to controlled substances, including methylphenidate, the active ingredient in Daytrana. Manufacturers of products containing controlled substances must annually apply to the DEA for procurement quota in order to obtain these substances for manufacturing. In 2006, Noven received an initial grant of methylphenidate quota and has submitted supplemental applications for additional quota in order to fulfill the 2006 product orders received from Shire plc ( Shire ). The DEA, which grants quota based primarily on historical product sales and prescription data, has not, to date, granted Noven's requests for additional 2006 quota. While Noven and Shire continue to work with the DEA to obtain additional methylphenidate quota for the remainder of 2006, Noven cannot assure that it will be successful in convincing the DEA that additional quota is necessary to meet patient demand. Because Noven has not received additional quota for 2006, Noven expects to complete the year with approximately \$8.0 million in full-year Daytrana product sales to Shire and approximately \$2.0 million in Daytrana product backorders that Noven would expect to fulfill following the receipt of its expected 2007 quota supply in the first quarter of 2007.

Other than products produced for commercial sale, Noven's policy is to immediately recognize as expense all inventory purchased for research and development purposes.

Shire retains title to the active methylphenidate ingredient ( AMI ) in Daytrana. AMI is not included in Daytrana product revenues or in Noven's cost of products sold. Noven records AMI maintained at its manufacturing facility as consignment inventory and bears certain manufacturing risks of loss related to the AMI. These risks include the contractual obligation of Noven to reimburse Shire for the cost of AMI if Noven does not meet certain minimum yields of the finished product. During the nine months ended September 30, 2006, Noven used \$2.7 million of AMI in the finished product and reimbursed Shire approximately \$0.1 million and \$0.5 million for the three and nine months ended September 30, 2006, respectively, for excess AMI used in production, which amount is included in cost of products sold. Noven had \$1.2 million of consignment AMI inventory on hand at September 30, 2006, which is not reflected in the table above.

### **8. EMPLOYEE STOCK PLANS:**

Prior to January 1, 2006, all awards granted to employees under the 1999 Long-Term Incentive Plan (the 1999 Plan ) were stock options. In 2006, Noven began granting stock-settled stock appreciation rights ( SSARs ) to employees and nonvested shares ( restricted stock ) to non-employee directors in lieu of stock options.

At September 30, 2006, there were 3,257,091 stock options and 28,726 SSARs issued and outstanding under the 1999 Plan. Since November 21, 2004, stock options and SSARs granted under the 1999 Plan have had a vesting period of four years, beginning one year after date of grant, and expire seven years after date of grant.

In May 2006, Noven issued a total of 34,344 shares of restricted stock to its non-employee directors. The grants fall under the definition of nonvested shares under SFAS No. 123 (revised 2004), Share-Based Payment ( SFAS 123(R) ). The shares vest over each director's one-year service period at the end of each calendar quarter beginning with the quarter ended June 30, 2006.

During the first quarter of 2006, Noven adopted the provisions of, and began accounting for stock-based compensation in accordance with, SFAS 123(R). Under the fair value

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recognition provisions of this statement, stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period. Noven elected the modified-prospective method, under which prior periods are not revised for comparative purposes. The valuation provisions of SFAS 123(R) apply to new grants and to grants that were outstanding as of the effective date and are subsequently modified. Estimated compensation for grants that were outstanding as of the effective date will be recognized over the remaining service period using the grant date fair value previously calculated for the SFAS No. 123, Accounting for Stock-Based Compensation (SFAS 123) pro forma disclosures requisite.

Noven currently uses the Black-Scholes option pricing model to determine the fair value of stock options and SSARs. The grant date fair value of stock-based payment awards using an option-pricing model is affected by Noven's stock price as well as assumptions regarding a number of complex and subjective variables. These variables include Noven's expected stock price volatility over the term of the awards, actual and projected employee equity award exercise behaviors, risk-free interest rate, estimated forfeitures of awards and expected dividends.

Noven estimates the expected term of options granted by taking the average of the vesting term and the contractual term of the option, as described in the SEC's Staff Accounting Bulletin Topic 14: Share-Based Payment (SAB 107) (SAB 107). Noven estimates the volatility of common stock by using a combination of both historical and implied volatility based on an equal weighting of each as management believes it is the expected volatility that marketplace participants would likely use in determining an exchange price for an option. Noven bases the risk-free interest rate that Noven uses in the option valuation model on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term on the options. Noven does not anticipate paying any cash dividends in the foreseeable future and therefore uses an expected dividend yield of zero in the option valuation model. Noven is required to estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. Noven uses historical data to estimate pre-vesting option forfeitures and records stock-based compensation expense only for those awards that are expected to vest. All stock-based payment awards are amortized on a straight-line basis over the requisite service periods of the awards, which are generally the vesting periods. The assumptions used to value option grants for the quarters ended September 30, 2006 and September 30, 2005 are as follows:

	2006	2005
Volatility	52.8%	69.0%
Risk free interest rate	5.17%	3.88%
Expected life (years)	5	5

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Total stock-based compensation recognized in Noven's statements of operations for the three and nine months ended September 30, 2006 was as follows (in thousands):

	Three Months	Nine Months
Marketing, general and administrative	\$ 649	\$ 1,791
Research and development	109	333
Cost of products sold	71	234
	\$ 829	\$ 2,358
Tax benefit recognized related to compensation expense	\$ 198	\$ 556

There were no stock-based compensation costs capitalized as part of inventory or fixed assets for the period ended September 30, 2006.

Prior to the adoption of SFAS 123(R), Noven presented all tax benefits for deductions resulting from the exercise of non-qualified stock options and disqualifying dispositions of incentive stock options as operating cash flows on its statement of cash flows. SFAS 123(R) requires the benefits of tax deductions in excess of recognized compensation expense, determined on an individual award basis, to be reported as a financing cash flow, rather than as an operating cash flow. This requirement has the effect of reducing net operating cash flows and increasing net financing cash flows in periods after adoption. However, under this requirement, total cash flow remains unchanged from what would have been reported under prior accounting rules. Cash received from options exercised under all share-based payment arrangements for the nine months ended September 30, 2006 and 2005 was \$8.1 million and \$1.2 million, respectively. The tax benefit realized on the tax deductions from option exercises under stock-based compensation arrangements totaled \$2.4 million and \$0.2 million for the nine months ended September 30, 2006 and 2005, respectively, of which \$1.7 million was reported as a financing cash flow for the nine months ended September 30, 2006. There were no amounts reported as financing cash flow for the nine months ended September 30, 2005.

Stock option transactions related to the plans are summarized as follows for the nine months ended September 30, 2006 (options / SSARs and aggregate intrinsic value in thousands):

	2006			Weighted Average Remaining Contractual Term
	Options/ SSARs	Weighted Average Exercise Price	Aggregate Intrinsic Value	
Outstanding at beginning of the period	4,004	\$ 17.23		
Granted	29	17.62		
Exercised	(682)	11.99	\$ 6,748	
Canceled and expired	(65)	12.37		
Outstanding at end of the period	3,286	\$ 18.32	\$ 23,087	4.05
Outstanding and exercisable at end of period	2,274	\$ 20.91	\$ 11,313	3.64





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The following table summarizes information concerning Noven's restricted stock at September 30, 2006 (shares in thousands):

	Shares	2006 Weighted Average Grant-Date Fair Value \$
Nonvested at December 31, 2005		
Granted	34	17.47
Vested	(17)	17.47
Forfeited		
Nonvested at September 30, 2006	17	\$ 17.47

As of September 30, 2006, the unamortized compensation expense that Noven expects to record in future periods related to currently outstanding unvested stock options, SSARs and restricted stock, as determined in accordance with SFAS 123(R), is approximately \$5.4 million before the effect of income taxes, of which \$0.8 million, \$2.5 million, \$1.5 million and \$0.6 million is expected to be incurred in the remainder of 2006 and in 2007, 2008 and 2009, respectively. The weighted-average period over which this compensation cost is expected to be recognized is 2 years.

Prior to 2006, in accordance with the provisions of SFAS 123, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure* (SFAS 148), Noven elected 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. Therefore no stock-based employee compensation cost is reflected in net income for the three months ended September 30, 2005, as all options granted under those plans had an exercise price equal to the market value of the underlying common stock on the date of grant.

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The following table illustrates the pro forma effect on net income and earnings per share for the three and nine months ended September 30, 2005 if Noven had applied the fair value recognition provisions of SFAS 123, as amended by SFAS 148 (in thousands, except per share amounts):

	Three Months 2005	Nine Months 2005
Net income:		
As reported	\$ (1,422)	\$ 3,910
Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(149)	(12,119)
Pro forma	\$ (1,571)	\$ (8,209)
Basic earnings per share:		
As reported	\$ (0.06)	\$ 0.17
Pro forma	\$ (0.07)	\$ (0.35)
Diluted earnings per share:		
As reported	\$ (0.06)	\$ 0.16
Pro forma	\$ (0.07)	\$ (0.35)

In order to eliminate some of the future compensation expense that Noven would otherwise have recognized in its statements of operations under SFAS 123(R), during 2005 Noven accelerated the vesting of certain stock options under the 1999 Plan. As a result of this action, options to purchase approximately 1.1 million shares of Noven's common stock became immediately exercisable, including options held by Noven's executive officers to purchase approximately 455,000 shares. Noven recorded an immaterial charge to compensation expense during the fourth quarter of 2005 due to the acceleration of a nominal amount of in-the-money options. As a result of the acceleration, during 2005, approximately \$10.1 million of compensation expense, net of applicable income taxes, was eliminated from Noven's future statements of operations and included in the pro forma footnote disclosure for the year ended December 31, 2005.

**9. DEFERRED COMPENSATION PLAN:**

Effective January 1, 2006, Noven established a deferred compensation plan (the Plan) available to Noven's officers and members of its Board of Directors. The Plan permits participants to defer receipt of part of their current compensation to a later date as part of their personal retirement or financial planning. Participants may elect to defer, as applicable, portions of their director fees, base salary, bonus, long-term incentive plan awards, and/or restricted stock grants. Benefit security for the Plan is provided by a funded rabbi trust.

The compensation withheld from Plan participants, together with investment income on the Plan, is reflected as a deferred compensation obligation to participants and is classified as a long-term liability in the accompanying condensed balance sheets. The related assets, which are held in the rabbi trust in the form of a company-owned life insurance policy that names Noven as the beneficiary, are classified within other assets in the accompanying condensed balance sheets and are reported at cash surrender value, which was approximately \$0.2 million as of September 30, 2006. At September 30, 2006, the balance of the deferred compensation liability totaled \$0.1 million.

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**10. CONTRACT AND LICENSE AGREEMENTS:**

*Shire*

On April 6, 2006, Noven's amended New Drug Application ( NDA ) for Daytrana was approved for marketing by the FDA. In April 2006, Noven received a \$50 million milestone payment from Shire (the global licensee of the product) as a result of the approval, and Noven may also earn additional milestone payments of up to \$75 million depending on the level of Shire's commercial sales of the product. The product was commercially launched by Shire in June 2006. Noven expects to defer and recognize approval and sales milestones as license revenues on a straight-line basis through the first quarter of 2013, which is Noven's current best estimate of the useful economic life of the product. Noven began recognizing the \$50 million milestone payment as well as the balance of the Shire deferred license revenues (\$4.8 million at March 31, 2006) in the second quarter of 2006. Noven also manufactures and supplies finished product for Shire.

In July 2006, Noven and Shire amended their agreement related to the development of a transdermal amphetamine patch for Attention Deficit Hyperactivity Disorder ( ADHD ). Under the original agreement, Noven was entitled to payments of up to \$5.0 million if certain development milestones were achieved. At the time of the signing of the amended agreement, Noven had received \$0.5 million in such milestone payments. Under the amendment, Shire paid Noven an additional \$1.0 million in August 2006, which is included in deferred contract revenues as of September 30, 2006, and Noven will perform certain early-stage development activities which were previously to be performed by Shire. Upon completion of such development activities by Noven, Shire may elect to retain exclusive rights to the product under development in exchange for payment of a total of \$5.9 million.

*P&G Pharmaceuticals*

In April 2003, Noven established a collaboration with Procter & Gamble Pharmaceuticals, Inc. ( P&G Pharmaceuticals ) for the development of new prescription patches for Hypoactive Sexual Desire Disorder ( HSDD ). The product under development explores follow-on product opportunities for Intrinsa, P&G Pharmaceuticals in-licensed investigational transdermal testosterone patch designed to help restore sexual desire in menopausal women diagnosed with HSDD. In the U.S., P&G Pharmaceuticals withdrew its NDA for Intrinsa in December 2004 based on safety concerns expressed by an FDA Advisory Committee and other factors. P&G Pharmaceuticals has indicated that work on Intrinsa for the U.S. market has been placed on hold while they evaluate alternatives for the project. If P&G Pharmaceuticals is unable to identify a practical strategy to complete development and commercialize the product in the U.S., or if their evaluation of alternatives significantly delays the project, the prospects for Noven's collaboration with P&G Pharmaceuticals will be adversely affected.

*Other*

During the nine months ended September 30, 2006, Noven recognized a \$1.0 million one-time payment from a third party for a license to certain Noven patents due to Noven having no continuing involvement nor Noven having any future economic benefit related to the license.

**11. 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 2006 and 2005 to meet Novartis' annual

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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, 2006 and 2005, Noven had the following transactions with Novogyne (in thousands):

	Three Months		Nine Months	
	2006	2005	2006	2005
Revenues:				
Product sales	\$ 5,273	\$ 4,740	\$ 13,990	\$ 14,432
Royalties	1,791	1,790	5,138	4,617
	\$ 7,064	\$ 6,530	\$ 19,128	\$ 19,049
Reimbursed expenses	\$ 7,125	\$ 6,576	\$ 21,043	\$ 20,196

As of September 30, 2006 and December 31, 2005, Noven had amounts due from Novogyne of \$7.8 million and \$8.9 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, 2006 and 2005 are as follows (in thousands):

	Three Months		Nine Months	
	2006	2005	2006	2005
Gross revenues	\$ 39,204	\$ 37,974	\$ 112,138	\$ 100,519
Sales allowances	4,283	4,007	11,622	11,078
Sales return allowances	1,193	192	4,576	1,057
Sales allowances and returns	5,476	4,199	16,198	12,135
Net revenues	33,728	33,775	95,940	88,384
Cost of sales <sup>1</sup>	7,529	7,940	22,212	21,347
Selling, general and administrative expenses	9,419	9,187	28,172	25,627
Income from operations	16,780	16,648	45,556	41,410
Interest income	250	201	564	336
Net income	\$ 17,030	\$ 16,849	\$ 46,120	\$ 41,746
Noven's equity in earnings of Novogyne	\$ 8,234	\$ 8,081	\$ 19,323	\$ 17,094

<sup>1</sup> Novogyne's costs of sales for all periods presented include the amortization of the marketing rights Novogyne

acquired for  
CombiPatch® of  
\$1.5 million and  
\$4.6 million for  
each of the three  
and nine months  
ended  
September 30,  
2006 and 2005,  
respectively.  
This  
amortization  
was previously  
reported as a  
separate  
operating  
expense in  
Novogyne's  
statement of  
operations.

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The activity in the Investment in Novogyne account for the nine months ended September 30, 2006 is as follows (in thousands):

Investment in Novogyne, beginning of period	\$ 23,243
Equity in earnings of Novogyne	19,323
Cash distributions from Novogyne	(17,644)
Non-cash distribution from Novogyne (Note 5)	(2,212)
Investment in Novogyne, end of period	\$ 22,710

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, 2006, Noven received cash distributions representing return on investment of \$7.4 million and \$17.6 million from Novogyne, respectively. For the three and nine months ended September 30, 2005, Noven received cash distributions representing return on investment of \$9.2 million and \$18.1 million from Novogyne, respectively. In addition, as discussed in Note 5, tax payments of \$2.2 million and \$1.5 million were made by Novogyne on Noven's behalf to the New Jersey Department of Revenue in April 2006 and 2005, respectively. These payments were deemed distributions from Novogyne to Noven and were recorded as reductions in Noven's investment in Novogyne when deemed received.

#### 12. 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, 2006 or 2005.

#### 13. COST REDUCTION PROGRAM:

Over the past two years, Noven expanded its facilities and increased staffing for the production of fentanyl, Daytrana and other developmental products. In September 2005, the FDA ceased review of Noven's Abbreviated New Drug Application (ANDA) for its fentanyl product after informing Noven that it did not expect to approve the ANDA. In the third quarter of 2006, Noven implemented a program to reduce overhead associated with this expansion. This program included the elimination of certain employee positions. A pre-tax one-time termination charge of \$0.6 million associated with the elimination of these positions was included in marketing, general and administrative expenses for the three months ended September 30, 2006. In addition, Noven may incur an additional \$0.1 million in pre-tax outplacement costs, which will be recognized as incurred in marketing, general and administrative expenses. Noven does not expect any further workforce reductions in connection with this program. There were no payments made as of September 30, 2006 related to this workforce reduction.

#### 14. COMMITMENTS AND CONTINGENCIES:

##### *HT Studies*

As a result of the findings from the Women's Health Initiative (WHI) study and other studies previously disclosed in Noven's Form 10-K, the FDA has required that "black box" labeling be included on all menopausal hormone therapy (HT) products marketed in the United States to warn, among other things, that these products have been associated with increased risks

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for heart disease, heart attacks, strokes, and breast cancer and that they are not approved for heart disease prevention.

Researchers continue to analyze data from both arms of the WHI study and other studies. Other studies evaluating HT are currently underway or in the planning stages. The market for Noven's products could be adversely affected if these studies find that a transdermal estrogen patch is less beneficial than other dosage forms, and Noven could be subject to increased product liability risk if HT patch products are found to increase the risk of adverse health consequences. Noven is currently named as a defendant in six product liability lawsuits involving its HT products and Noven may have liability with respect to other actions in which it has not, to date, been made a party. See *Litigation, Claims and Assessments* below for a further discussion on related product liability lawsuits.

Since the July 2002 publication of the WHI and other study data, total United States prescriptions have declined for substantially all HT products, including Noven's products in the aggregate. 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 Novogyne 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.

In 2003, Noven's product stability testing program revealed that certain lots of CombiPatch® and Vivelle-Dot patches did not maintain required specifications throughout the products' shelf lives, resulting in product recalls of certain lots. As a result, Noven initiated a series of special stability protocols to monitor commercial lots in distribution as well as future production. 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 specification or were associated with lots that did not meet specification. 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 remained in distribution. A joint Noven and Novartis task force is working to identify the definitive root cause of the Vivelle-Dot stability failures. Based on testing and analysis to date, Noven believes that the probable cause of the Vivelle-Dot stability failures relates to certain patch backing material that Noven obtained from a raw material supplier. If the root cause determination or additional testing indicates that the production issue affects more product than Noven's current testing and analysis suggests, additional recalls may be required. Noven continues to manufacture and ship Vivelle-Dot to Novogyne.

In the fourth quarter of 2005, Novartis Pharma AG (Novartis Pharma), an affiliate of Novartis, recalled three commercial lots of Estalis® (the form of CombiPatch® manufactured for sale outside the United States) after special stability protocols put in place after an October 2004 CombiPatch® stability failure indicated that certain lots did not maintain required specifications.



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throughout the product's shelf-life due to the formation of crystals. The recall of these lots did not have a material impact on Noven's financial statements for the year ended December 31, 2005. During 2006, additional lots of Estalis® have been found to have developed crystals as well. Any recall of these lots by Novartis Pharma is not expected to have a material impact on Noven's results of operations because an immaterial number of patches from these lots remain in distribution. Noven continues to manufacture and ship Estalis® to Novartis Pharma.

Noven continues to maintain stability testing related to the foregoing production issues. If Noven's testing indicates that additional lots of CombiPatch®, Estalis® or Vivelle-Dot or other products do not meet specifications, there could be additional recalls. Although Noven and Novartis work together in assessing production issues related to these products, the decision to recall product resides with Novartis and its affiliates as the holders of the regulatory approvals for these products and is not within Noven's control. If Noven's estimate concerning product returns associated with a recall are incorrect, or if Noven's continued testing indicates that additional lots are affected, or if Novartis should initiate additional recalls for any reason, then Noven's and Novogyne's business and results of operations could be materially and adversely impacted. 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 recent recalls 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 under the agreement's commercial terms could have a material adverse effect on Noven's financial position and results of operations. 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. Noven does not expect any activity in this case in the near future, as the court has entered an order to stay proceedings in all its pending and future HT cases except for cases where Wyeth Pharmaceuticals and its affiliates and Pfizer, Inc. are the defendants.

In April 2006, an individual plaintiff and her husband filed a complaint in the United States District Court, District of Minnesota against Noven, Novogyne, Novartis, Wyeth Inc. and Wyeth Pharmaceuticals, Inc. alleging liability in connection with personal injury claims allegedly arising from the use of HT products, including Noven's CombiPatch® product. The plaintiffs claim compensatory and other damages in an unspecified amount.

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In July 2006, four complaints were filed in the United States District Court, District of Minnesota against Noven and other pharmaceutical companies by four separate individual plaintiffs, each filing alone or with her husband. Three of the complaints also name Novartis as a defendant, and of these, two name Novogyne as a defendant as well. Each complaint alleges liability in connection with personal injury claims allegedly arising from the use of HT products, including Vivelle® in one case and CombiPatch® in two of the cases. The plaintiffs in each case claim compensatory and other damages in an unspecified amount. Noven has established an accrual for the expected legal fees related to the cases referenced above, although the amount is not material.

Novartis has advised Noven that Novartis has been named as a defendant in at least 28 pending additional lawsuits that include approximately 35 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-DotVivelle®, and CombiPatch® products. In addition, Novartis has been named as a defendant in over 80 additional lawsuits in which the plaintiffs' complaints do not identify the HT products used by the plaintiffs and therefore these cases may also involve Noven HT products. Novogyne has been named as a defendant in one lawsuit in addition to the four lawsuits referenced above. Novartis has indicated that it will seek indemnification from Noven and Novogyne to the extent permitted by the agreements between and among Novartis, Novogyne and Noven. Novogyne has established an accrual for the expected legal fees and settlements of these lawsuits for \$8.5 million with an offsetting insurance recovery of \$6.1 million. This accrual represents Novartis management's best estimate as of September 30, 2006. Although Novogyne believes that recovery of the insurance receivable is probable, no assurance can be given that Novogyne will in fact recover such amount, including as a result of any decision by Novogyne's product liability insurance carrier to contest a claim.

Noven intends to defend all of the foregoing lawsuits vigorously, but the outcome of these product liability lawsuits cannot ultimately be predicted.

Noven is a party to other pending legal proceedings arising in the normal course of business, none of which Noven believes is material to its financial position, results of operations or cash flows.

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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 our financial condition at September 30, 2006, and our results of operations for the three and nine months ended September 30, 2006 and 2005. The contents of this section include:

An executive summary of our results of operations for the three months ended September 30, 2006;

An overview of Noven and our Novogyne joint venture;

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

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

An outlook that includes our current financial guidance;

A discussion of how we apply our critical accounting estimates; and

A discussion of recently-issued accounting standards.

This discussion should be read in conjunction with Noven's financial statements for the three and nine months ended September 30, 2006 and 2005 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 Form 10-K.

**Executive Summary**

*The following Executive Summary is qualified in its entirety by the more detailed discussion and analysis of our financial condition and results of operations appearing in this Item 2 as well as in our financial statements and related notes included in this Form 10-Q.*

The three months ended September 30, 2006 included a strong performance by our Novogyne joint venture, the first full quarter of commercial sales of Daytrana, and significant improvement in our overall gross margin compared to the second quarter of 2006.

Daytrana was approved by the FDA on April 6, 2006, triggering payment of a \$50 million approval milestone payment from Shire. The three months ended September 30, 2006 included the recognition of \$2.0 million in license revenues associated with that milestone and \$2.0 million in Daytrana product sales to Shire. Primarily due to Daytrana product and license revenues, our net revenues for the three months ended September 30, 2006 increased 28% to \$15.7 million.

Due in part to our efforts undertaken in the three months ended September 30, 2006 to improve efficiencies and reduce costs associated with Daytrana production, our overall gross margin improved from 11% in the three months ended June 30, 2006 to 30% in the three months ended September 30, 2006.

Research and development expenses for the three months ended September 30, 2006 decreased \$1.3 million or 34% to \$2.5 million compared to the same period in the prior year, primarily as a result of higher 2005 expenses associated with development of Daytrana. Marketing, general and administrative expenses increased \$1.8 million or 42% to \$6.0 million, primarily as a result of the recognition of \$0.6 million in stock-based compensation expenses in 2006 pursuant to accounting guidance that we adopted in January 2006, and a \$0.6 million charge in the three months ended September 30, 2006 resulting from the elimination of certain employee positions as part of a program intended to reduce costs and improve efficiencies within Noven.

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We recognized \$8.2 million in earnings from Novogyne for the three months ended September 30, 2006 compared to \$8.1 million for the same period in the prior year. For the three months ended September 30, 2006, we reported net income of \$5.0 million (\$0.20 diluted earnings per share), compared to a net loss of \$1.4 million (\$0.06 diluted loss per share) reported in the 2005 quarter.

Novogyne's net revenues for the three months ended September 30, 2006 were \$33.7 million, largely unchanged from the 2005 quarter, reflecting increased sales of Vivelle-Dot, offset by increased sales and returns allowances. Novogyne's gross margin for the three months ended September 30, 2006 increased slightly to 78% due to increased sales of Vivelle-Dot. Novogyne's selling, general and administrative expenses for the third quarter of 2006 increased 3% to \$9.4 million compared to the same period in the prior year, primarily reflecting increased promotional spending in support of Vivelle-Dot. Novogyne's net income for the three months ended September 30, 2006 was \$17.0 million compared to \$16.8 million for the same period in 2005.

Total prescriptions for Vivelle-Dot increased 4% in the third quarter of 2006 compared to the third quarter of 2005, and total prescriptions for Novogyne's products, taken as a whole, increased 1% period-over-period. By comparison, the overall U.S. HT market declined 4% for the third quarter of 2006 compared to the same period of 2005. Total prescriptions for Daytrana (launched in June 2006) increased 17% in September 2006 (the most recent month for which data are available) compared to August 2006, while prescriptions for ADHD stimulant therapies as a class were largely unchanged for the same period.

### **Overview of Noven and Our Novogyne Joint Venture**

We develop and manufacture advanced transdermal patches and presently derive the majority of our revenues from sales of transdermal patches for use in menopausal HT. 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 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 of operations 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, 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 \$19.3 million and \$17.1 million for the nine months ended September 30, 2006 and 2005, respectively. The income we 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

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recognize from Novogyne for that period. For the nine months ended September 30, 2006 and 2005, we received \$17.6 million and \$18.1 million, respectively, in distributions from Novogyne, which, not including the \$50 million received from Shire, accounted for a substantial portion of our net cash flows generated by 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, as well as any additional milestone payments we may receive from Shire. Any failure by Novogyne to remain profitable or to continue to make distributions would 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 2006, total prescriptions dispensed in the HT market in the United States decreased by 53.8%. For the same period, aggregate prescriptions for Noven's United States HT products decreased 6.5%. The estrogen segment of the HT market in the United States declined 49.4%, while our Vivelle® line of products increased 7.6%. Vivelle-Dot, which represented approximately 87.0% of our total United States prescriptions in the third quarter of 2006, increased 36.6% from the second quarter of 2002 to the third quarter of 2006. 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 9.7% of our total United States prescriptions in the third quarter of 2006) declined 57.9% from the second quarter of 2002 to the third quarter of 2006, while prescriptions for the total United States market for fixed combination hormone therapy products decreased 71.8%. Further decreases in net sales of our CombiPatch® product (whether as a result of the WHI studies, the production issues discussed below, higher rates of sales returns or otherwise) could require Novogyne (which holds the CombiPatch® marketing rights) to record an impairment loss related to this intangible asset (\$27.8 million at September 30, 2006), which would adversely affect the results of operations of both Noven and Novogyne.

**Certain Items that May Affect Historical or Future Comparability**

For a discussion of certain items that may affect the historical or future comparability of our results of operations and financial condition, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations of our Form 10-K as well as the following updated and/or supplemented items. Such disclosure is not intended to address every item that may affect the historical or future comparability of our results of operations or financial condition and such disclosure should be read in conjunction with the discussion and analysis of our results of operations, liquidity and capital resources and outlook appearing elsewhere in this Item 2.

***Cost Reduction Program***

Over the past two years, we expanded our facilities and increased staffing for the production of fentanyl, Daytrana and other developmental products. In September 2005, the FDA ceased review of our ANDA for our fentanyl product after informing us that it did not expect to approve the ANDA. In the third quarter of 2006, we implemented a program to reduce overhead associated with this expansion. This program included the elimination of certain employee positions, which we believe will result in annual pre-tax savings of up to \$1.8 million. A pre-tax one-time termination charge of \$0.6 million associated with the elimination of these positions was included in marketing, general and administrative expenses for the three months ended September 30, 2006. In addition, we may incur an additional \$0.1 million in pre-tax outplacement costs, which will be recognized as incurred in marketing, general and administrative expenses. We do not expect any further workforce reductions in connection with this program.

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### *DEA Quota*

The DEA controls access to controlled substances, including methylphenidate, the active ingredient in Daytrana. Manufacturers of products containing controlled substances must annually apply to the DEA for procurement quota in order to obtain these substances for manufacturing. In 2006, we received an initial grant of methylphenidate quota and have submitted supplemental applications for additional quota in order to fulfill the 2006 product orders received from Shire. The DEA, which grants quota based primarily on historical product sales and prescription data, has not, to date, granted our requests for additional 2006 quota. While Noven and Shire continue to work with the DEA to obtain additional methylphenidate quota for the remainder of 2006, we cannot assure that we will be successful in convincing the DEA that additional quota is necessary to meet patient demand. Because we have not received additional quota for 2006, we expect to complete the year with approximately \$8.0 million in full-year Daytrana product sales to Shire and approximately \$2.0 million in Daytrana product backorders that we would expect to fulfill following receipt of our expected 2007 quota supply in the first quarter of 2007. As discussed under *Outlook* below, the reduction in Daytrana revenues will negatively affect our gross margin in the fourth quarter of 2006 but, to the extent that these backorders are filled as expected in the first quarter of 2007, the related revenues should benefit our gross margin in 2007. If the DEA declines to grant us additional 2006 quota, it is possible (subject to a number of factors including ongoing demand for the product) that product supply for certain dosage strengths may be interrupted and, as a result, Daytrana sales as well as our results of operations could be adversely affected.

### *P&G Pharmaceuticals*

In April 2003, we established a collaboration with P&G Pharmaceuticals for the development of new prescription patches for HSDD. The product under development explores follow-on product opportunities for Intrinsa, P&G Pharmaceuticals' in-licensed investigational transdermal testosterone patch designed to help restore sexual desire in menopausal women diagnosed with HSDD. In the U.S., P&G Pharmaceuticals withdrew its New Drug Application for Intrinsa in December 2004 based on safety concerns expressed by an FDA Advisory Committee and other factors. P&G Pharmaceuticals has indicated that work on Intrinsa for the U.S. market has been placed on hold while they evaluate alternatives for the project. If P&G Pharmaceuticals is unable to identify a practical strategy to complete development and commercialize the product in the U.S., or if their evaluation of alternatives significantly delays the project, the prospects for our collaboration with P&G Pharmaceuticals will be adversely affected.

### *Stock-Based Compensation*

Currently, our outstanding stock-based compensation consists of: (i) stock options; (ii) SSARs; and (iii) for our non-employee directors, restricted stock awards. Prior to January 1, 2006, all awards granted to employees under the 1999 Plan were stock options. In 2006, Noven began granting SSARs to employees and restricted stock to non-employee directors in lieu of stock options, and from time to time we may consider or grant other forms of stock-based compensation.

On January 1, 2006, we adopted the provisions of, and for the three and nine months ended September 30, 2006, we accounted for stock-based compensation in accordance with, SFAS 123(R). We elected the modified-prospective method, under which prior periods are not revised for comparative purposes. Under the fair value recognition provisions of this statement, stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense on a straight-line basis over the requisite service period, which is typically the vesting period. The determination of the fair value of stock-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. See *Critical Accounting Estimates*.

Total stock-based compensation recognized in our statements of operations for the nine months ended September 30, 2006 was \$2.4 million, of which \$1.8 million was recognized in

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marketing, general and administrative and \$0.3 million was recognized in each of research and development and cost of products sold, respectively. There were no stock-based compensation costs capitalized as part of inventory or fixed assets for the nine months ended September 30, 2006.

At September 30, 2006, the unamortized compensation expense that we expect to record in future periods related to currently outstanding unvested stock options, SSARs and restricted stock, as determined in accordance with SFAS 123(R), is approximately \$5.4 million before the effect of income taxes, of which \$0.8 million, \$2.5 million, \$1.5 million and \$0.6 million is expected to be incurred in the remainder of 2006 and in 2007, 2008 and 2009, respectively. We will also incur additional expense in future years related to new equity awards that may be granted in the future that cannot yet be quantified.

In order to eliminate some of the future compensation expense that we would otherwise have recognized in our statements of operations under SFAS 123(R), during 2005 we accelerated the vesting of certain stock options under the 1999 Plan. As a result of this action, options to purchase approximately 1.1 million shares of our common stock became immediately exercisable, including options held by our executive officers to purchase approximately 455,000 shares. We recorded an immaterial charge to compensation expense during the fourth quarter of 2005 due to the acceleration of a nominal amount of in-the-money options. As a result of the acceleration, during 2005, we eliminated approximately \$10.1 million of compensation expense, net of applicable income taxes, from our future statements of operations and this expense is included in the pro forma footnote disclosure for the year ended December 31, 2005.

**Table of Contents****Results of Operations****Three and nine months ended September 30, 2006 compared to the three and nine months ended September 30, 2005*****Revenues***

Total revenues for the three and nine months ended September 30, 2006 and 2005 are summarized as follows (dollar amounts in thousands):

	Three Months			Nine Months		
	2006	2005	% Change	2006	2005	% Change
Product revenues						
Novogyne:						
Product sales	\$ 5,273	\$ 4,740	11%	\$ 13,990	\$ 14,432	(3%)
Royalties	1,791	1,790	0%	5,138	4,617	11%
	7,064	6,530	8%	19,128	19,049	0%
Product revenues third parties:						
Product sales	5,671	3,823	48%	15,402	11,646	32%
Royalties	90	94	(4%)	246	242	2%
	5,761	3,917	47%	15,648	11,888	32%
Total product revenues	12,825	10,447	23%	34,776	30,937	12%
Contract and license revenues:						
Contract	44	769	(94%)	1,112	1,793	(38%)
License	2,839	1,024	177%	7,559	3,017	151%
	2,883	1,793	61%	8,671	4,810	80%
Net revenues	\$ 15,708	\$ 12,240	28%	\$ 43,447	\$ 35,747	22%

**Net Revenues**

As described in more detail below, the 28% increase in net revenues for the three months ended September 30, 2006 as compared to the same period in 2005 was primarily attributable to the launch of Daytrana and an increase in license revenue associated with that product. In addition, aggregate sales to Novogyne increased due to timing of shipments. These increases were offset by an aggregate decline in international product sales, which we believe was due to the timing of orders.

As described in more detail below, the 22% increase in net revenues for the nine months ended September 30, 2006 as compared to the same period in 2005 was primarily attributable to the product launch of Daytrana, an increase in license revenue associated with that product and an increase in royalties. These increases were offset by an



aggregate decline in product sales to Novogyne and international product sales, which we believe was due primarily to the timing of orders.

Product Revenues - Novogyne

Product revenues - Novogyne consists of our sales of Vivelle-DōEstradot®, CombiPatch® and Vivelle® 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-Dō and Vivelle®.

The \$0.5 million increase in product revenues from Novogyne for the three months ended September 30, 2006 as compared to the same period in the prior year primarily related to a \$0.8

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million increase in unit sales of Vivelle-Dot, partially offset by a \$0.2 million and \$0.1 million decline in unit sales of Estradot® and Vivelle®, respectively. The increase in Vivelle-Dot and the decrease in Estradot® and Vivelle® are primarily related to the timing of trade product orders from Novogyne.

The \$0.1 million increase in product revenues from Novogyne for the nine months ended September 30, 2006 as compared to the same period in the prior year primarily related to a \$0.3 million increase in unit sales of Vivelle-Dot and a \$0.5 million increase in royalties, partially offset by a \$0.4 million, \$0.2 million and \$0.1 million decline in unit sales of CombiPatch®, Estradot® and Vivelle®, respectively. The increase in Vivelle-Dot was primarily attributable to a \$0.8 million increase in product samples, partially offset by a \$0.4 million decline in unit sales of trade product. The increase in product samples related to the timing of shipments to Novogyne. The decline in trade product sales was attributable to the timing of orders placed by Novogyne and not a decline in market demand. The increase in royalties was attributable to higher sales by Novogyne for the nine months ended September 30, 2006. The decline in CombiPatch® was primarily related to declining prescription trends which we believe are attributable to the ongoing effects of WHI and other studies on combination therapy products as well as the impact of a competitive product. The decline in unit sales of Estradot® were attributable to the timing of trade product orders. The decline in unit sales of Vivelle® to Novogyne primarily reflected the planned discontinuation of the production of this mature product by the end of 2006.

### **Product Revenues – Third Parties**

Product revenues – third parties consists of sales of Estradot®, Estalis® and Menorest 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. Beginning in the second quarter of 2006, product revenues – third parties also includes sales of Daytrana® to Shire for commercial resale in the United States.

The \$1.8 million increase in product revenues from third parties for the three months ended September 30, 2006 as compared to the same period in the prior year primarily related to a \$2.0 million, \$0.2 million and \$0.1 million increase in unit sales of Daytrana®, Estradot® and Estalis®, respectively, partially offset by a \$0.5 million decline related to pricing. The increase in Daytrana was due to the initial product launch that occurred during the period while the increase in Estradot® and Estalis® was attributable to the timing of orders. The decline related to pricing was due to a decline in price reconciliation payments from Novartis Pharma.

The \$3.8 million increase in product revenues from third parties for the nine months ended September 30, 2006 as compared to the same period in the prior year primarily related to a \$5.7 million increase in unit sales of Daytrana partially offset by a decline in unit sales of \$0.7 million and \$0.4 million of Estalis® and Menorest, respectively. In addition, the nine month period included a decline of \$0.9 million related to pricing as we recognized less of a price reconciliation payment in the current nine month period for all products sold to Novartis Pharma. The increase in Daytrana and the decline related to pricing are attributable to the same factors as discussed above for the three-month comparable periods. The decline in Estalis® was attributable to the timing of orders while the decline in Menorest was attributable to the continued transition from Menorest to Estradot®.

### **Contract and License Revenues**

Contract revenues consist of the recognition of payments received as work is performed on research and development projects. The payments received may take the form of non-refundable up- front payments, payments received upon the completion of certain phases of work and success

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milestone payments. License revenues consist of the recognition of non-refundable up-front, milestone and similar payments under license agreements.

Contract revenues declined \$0.7 million for both the three and nine months ended September 30, 2006 as compared to the same periods in the prior year due to a decline in contract work performed. License revenues increased \$1.8 million and \$4.5 million for the three and nine months ended September 30, 2006, respectively, due primarily to the recognition in the nine months ended September 30, 2006 of \$3.9 million in deferred license revenues related to Daytrana and the recognition of a \$1.0 million one-time non-refundable payment from a third party for a license to certain of our patents.

***Gross Margin***

The following section presents Noven's gross margin on (i) total product revenues, (ii) product revenues derived from sales to Novogyne, which for accounting purposes is considered to be a related party; and (iii) product revenues derived from sales to third parties (i.e., excluding sales to Novogyne).

The allocation of overhead costs impacts our determination of gross margins, including our gross margins for product revenues derived from sales to Novogyne compared to gross margins for product revenues derived from sales to third parties. Overhead costs consist of salaries and benefits, supplies and tools, equipment costs, depreciation and insurance costs and represent a substantial portion of our production costs. The allocation of overhead between and among our various products requires us to make significant estimates that involve subjective and often complex judgments. Using different estimates would likely result in materially different gross margins for product revenues derived from sales to Novogyne compared to gross margins for product revenues derived from sales to third parties.

**Table of Contents****Gross Margin Total**

Noven's overall gross margin for the three and nine months ended September 30, 2006 and 2005 is summarized as follows (dollar amounts in thousands):

	Three Months		Nine Months	
	2006	2005	2006	2005
<b>Gross Margin Total:</b>				
Product revenues	\$ 12,825	\$ 10,447	\$ 34,776	\$ 30,937
Cost of products sold	9,041	15,416	27,068	26,526
Gross profit (product revenues less cost of products sold)	3,784	(4,969)	7,708	4,411
Gross margin (gross profit as a percentage of product revenues)	30%	-48%	22%	14%
Pre-launch inventory write-off		9,475		9,475
Gross profit excluding pre-launch inventory write-off of fentanyl	3,784	4,506	7,708	13,886
Gross margin excluding pre-launch inventory write-off of fentanyl	30%	43%	22%	45%

Our overall gross margin for the three and nine months ended September 30, 2005 was adversely affected by a \$9.5 million charge incurred in the third quarter of 2005 related to the write-off of fentanyl pre-launch inventories. In light of the significance of this charge, we have provided gross margin information that excludes its effect. We believe such non-GAAP information is useful to investors in order to meaningfully evaluate our ongoing, underlying business and to compare our financial results for the periods presented in 2006 and 2005. For the same reasons, management uses these non-GAAP financial measures to evaluate Noven's ongoing, underlying business. These measures should not be considered alternatives to measures computed in accordance with GAAP, nor should they be considered indicators of our overall financial performance.

Excluding the effect of our write-off of pre-launch fentanyl inventory in the third quarter of 2005, the decline in our overall gross margin for the three and nine months periods ended September 30, 2006 compared to the same periods in the prior year was primarily due to costs and inefficiencies associated with the start-up of commercial production of Daytrana, which was launched in June 2006. The cost reduction program commenced in the three months ended September 30, 2006 to reduce costs and improve efficiencies and yields contributed to significant improvement in overall gross margin for the three months ended September 30, 2006 compared to the overall gross margin that we recognized for the three months ended June 30, 2006. Our expectations for overall gross margin in future periods are addressed under "Outlook" below.

Increased personnel and other resources dedicated to quality control in our HT operations also contributed to a decline in gross margin for the three and nine month periods ended September 30, 2006 compared to the same periods in the prior year. The cost of these resources increased approximately \$0.2 million and \$0.8 million for the three and nine months ended September 30, 2006, respectively, compared to the same periods in 2005.

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Over the past two years, we expanded our facilities and increased staffing for the production of fentanyl, Daytrana and other developmental products. In September 2005, the FDA ceased review of our ANDA for our fentanyl product after informing us that it did not expect to approve the ANDA. In the third quarter of 2006, we implemented a program intended to reduce overhead associated with this expansion. Our results of operations and gross margins for future periods are expected to continue to be adversely affected by our prior expansion activities and related continuing overhead expenses unless and until we are able to improve the utilization of these resources through the commercialization of additional products. No assurance can be given that we will be able to improve the utilization of these resources.

As described in our Form 10-K, Noven's cost of products sold may be affected in a given period by changes in deferred profit on Noven's sale of product to Novogyne. For the three and nine months ended September 30, 2006, however, changes in deferred profit on Noven's sale of product to Novogyne did not materially affect our overall gross margin or the gross margin from our sales to Novogyne and therefore such information has not been included in this Form 10-Q.

**Gross Margin Sales to Novogyne**

	Three Months		Nine Months	
	2006	2005	2006	2005
<b>Gross Margin Novogyne:</b>				
Product revenues	\$ 7,064	\$ 6,530	\$ 19,128	\$ 19,049
Cost of products sold	3,702	3,521	10,304	9,219
Gross profit (product revenues less cost of products sold)	3,362	3,009	8,824	9,830
Gross margin (gross profit as a percentage of product revenues)	48%	46%	46%	52%

Gross margin on product sales to Novogyne for the three months ended September 30, 2006 increased, primarily due to a shift in the product mix as there was an increase in product sales of Vivelle-Dot and a decline in sales of Estradot® and Vivelle® and overall samples sold to Novogyne. Vivelle-Dot has a higher gross margin than Estradot® and Vivelle® and product sales have a higher gross margin than sample sales. These increases are partially offset by increased overhead costs associated with the facilities expansion and increased staffing discussed above.

Gross margin on product sales to Novogyne for the nine months ended September 30, 2006 declined due to the product mix, as there was a higher percentage of sample sales to Novogyne (which have a lower margin than sales of trade product). Sample product sales to Novogyne were 15% of total product sales to Novogyne, not including royalties, for the nine months ended September 30, 2006 as compared to 8% for the comparable period in 2005. In addition, the facilities expansion and increased staffing discussed above contributed to the decline in gross margin in this period.

**Table of Contents****Gross Margin Sales to third parties**

	<b>Three Months</b>		<b>Nine Months</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
<b>Gross Margin Third Parties:</b>				
Product revenues	\$ 5,761	\$ 3,917	\$ 15,648	\$ 11,888
Cost of products sold	5,339	11,895	16,764	17,307
 Gross profit (loss) (product revenues less cost of products sold)	 422	 (7,978)	 (1,116)	 (5,419)
 Gross margin (gross profit (loss) as a percentage of product revenues)	 7%	 (204%)	 (7%)	 (46%)
 Pre-launch inventory write-off of fentanyl		9,475		9,475
 Gross profit (loss) excluding pre-launch inventory write-off of fentanyl	 422	 1,497	 (1,116)	 4,056
 Gross margin excluding pre-launch inventory write-off of fentanyl	 7%	 38%	 (7%)	 34%

Excluding the charge taken in the third quarter of 2005 from the write-off of pre-launch fentanyl inventory, the decline in gross margin related to third parties for the three and nine months ended September 30, 2006, primarily related to on-going inefficiencies associated with manufacturing Daytrana, the facilities expansion and increased staffing discussed above, and to a lesser extent smaller production orders in our third party HT business.

For the three month period ended September 30, 2006, Daytrana product revenues were \$2.0 million and cost of products sold related to Daytrana was \$2.7 million. This represents a significant improvement from the second quarter of 2006. The increase in gross margin was attributable to the implementation of a program in the three months ended September 30, 2006 intended to improve Daytrana production efficiencies and reduce manufacturing costs. Only a portion of the expected benefits of this program was recognized in the three month period ended September 30, 2006. The quarter ended September 30, 2006 also included \$2.0 million in non-cash license revenues related to Daytrana that are not included in the calculation of gross margin.

The active methylphenidate ingredient is not included in our Daytrana product revenues or in our cost of products sold. Shire is responsible for supplying us with the AMI used in the production of Daytrana and Shire retains title to the AMI. We maintain AMI on hand at our manufacturing facility as consignment inventory and bear certain risks of manufacturing loss related to the AMI. These risks include the contractual obligation to reimburse Shire for the cost of AMI if we do not meet certain minimum contractual yields of the finished product. During the three and nine months ended September 30, 2006, we reimbursed Shire approximately \$0.1 million and \$0.5 million, respectively, for excess AMI used in production, which amounts are included in costs of products sold for such periods.

Our expectations for overall gross margin in future periods are addressed under **Outlook** below.

**Table of Contents*****Operating Expenses***

Operating expenses for the three and nine months ended September 30, 2006 and 2005 are summarized as follows (dollar amounts in thousands):

	Three Months			Nine Months		
	2006	2005	% Change	2006	2005	% Change
Research and development	\$2,527	\$3,826	(34%)	\$ 8,899	\$ 9,752	(9%)
Marketing, general and administrative	6,010	4,237	42%	16,386	12,481	31%

**Research and Development**

Research and development expenses include costs associated with, among other things, product formulation, pre-clinical testing, clinical studies, regulatory and medical affairs, production for clinical and regulatory purposes, production related development engineering for developmental products, and the personnel associated with each of these functions.

The decline in research and development expenses for the three months ended September 30, 2006 was primarily attributable to a \$1.3 million decline in production of clinical and regulatory supplies related to Daytrana and other products and a \$0.3 million decline in clinical trial costs. This decline was partially offset by a \$0.1 million increase in consulting costs, a \$0.1 million in stock-based compensation and a \$0.1 million increase in personnel costs.

The decline in research and development expenses for the nine months ended September 30, 2006 compared to the same period of 2005 was primarily attributable to the absence of development engineering expenses related to our fentanyl transdermal system in the 2006 period, compared to \$2.3 million of such expenses in the 2005 period, as well as a \$0.3 million decline in pre-clinical costs, partially offset by a \$0.4 million increase in development engineering and production of clinical and regulatory supplies related to Daytrana, \$0.4 million in personnel costs, \$0.3 million in stock-based compensation expense, a \$0.2 million increase in the purchase of testing supplies and a \$0.1 million increase in clinical costs related to other products under development.

**Marketing, General and Administrative**

The increase in marketing, general and administrative expenses for the three months ended September 30, 2006 was primarily attributable to a \$0.7 million increase in salary and related benefits, \$0.6 million in stock-based compensation expenses that were not required to be recognized in the 2005 quarter, and the \$0.6 million charge associated with the elimination of employee positions discussed above. These increases were partially offset by a \$0.2 million decline in professional fees due to the timing of services performed.

The increase in marketing, general and administrative expenses for the nine months ended September 30, 2006 was primarily attributable to \$1.8 million in stock-based compensation expenses that were not required to be recognized in the 2005 period, a \$1.3 million increase in salary and related benefits, the \$0.6 million charge associated with the elimination of employee positions discussed above, and a \$0.1 million increase in costs associated with compliance with the Sarbanes-Oxley Act of 2002, the latter of which was due to the timing of services performed. In addition, 2005 benefited from a \$0.2 million reduction in product recall related expenses. These increases were offset by a \$0.2 million reduction in professional fees primarily in the areas of legal and human resources.

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### **Other Income and Expenses**

#### *Interest Income*

Interest income for the three and nine months ended September 30, 2006 increased \$0.7 million and \$1.3 million, respectively, due to an increase in the average cash balance, which was primarily attributable to the \$50 million milestone payment received from Shire in April 2006 in connection with the approval of our Daytrana product by the FDA. In addition to higher average cash balances, we invested a higher portion of our cash in short-term investments that yielded higher interest income.

#### *Income Taxes*

Our effective tax rate was approximately 33% and 31% for the nine months ended September 30, 2006 and 2005, respectively. The increase in our effective tax rate is primarily related to higher taxable income for the nine months ended September 30, 2006 compared to the comparable period in the prior year due to the fentanyl write-offs in the prior year, as well as certain credits and reductions for reserves for pending Internal Revenue Service audits that occurred in the prior period that did not recur in the current period. These increases are partially offset by higher non-taxable interest as a percentage of taxable income. The provision for income taxes is based on the Federal statutory and state income tax rates. Net deferred income tax assets are measured using the average graduated tax rate for the estimated amount of annual taxable income in the years that the liability is expected to be settled or the asset recovered. The effect of adjusting the expected tax rate related to the net deferred income tax assets is included in the provision for income taxes. As of September 30, 2006, we had a net deferred tax asset of \$12.4 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 (a non-cash item) increases as Novogyne's product sales increase, subject to a cap of 49%. Novogyne produced sufficient income in the first quarters of 2006 and 2005 to meet Novartis' annual preferred return for those periods 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 in our unaudited statements of operations.



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The financial results of Novogyne for the three and nine months ended September 30, 2006 and 2005 are summarized as follows (dollar amounts in thousands):

	Three Months			Nine Months		
	2006	2005	% Change	2006	2005	% Change
Gross revenues <sup>1</sup>	\$ 39,204	\$ 37,974	3%	\$ 112,138	\$ 100,519	12%
Sales allowances	4,283	4,007	7%	11,622	11,078	5%
Sales returns allowances	1,193	192	N/M	4,576	1,057	N/M
 Sales and returns allowances	 5,476	 4,199	 30%	 16,198	 12,135	 33%
 Net revenues	 33,728	 33,775	 0%	 95,940	 88,384	 9%
Cost of sales <sup>2</sup>	7,529	7,940	(5%)	22,212	21,347	4%
 Gross profit	 26,199	 25,835	 1%	 73,728	 67,037	 10%
Gross margin percentage	78%	76%		77%	76%	
Selling, general and administrative expenses	9,419	9,187	3%	28,172	25,627	10%
 Income from operations	 16,780	 16,648	 1%	 45,556	 41,410	 10%
Interest income	250	201	24%	564	336	68%
 Net income	 \$ 17,030	 \$ 16,849	 1%	 \$ 46,120	 \$ 41,746	 10%
 Noven's equity in earnings of Novogyne	 \$ 8,234	 \$ 8,081	 2%	 \$ 19,323	 \$ 17,094	 13%

N/M Not  
Meaningful

<sup>1</sup> 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.

- 2 Novogyne's costs of sales for all periods presented include the amortization of the marketing rights Novogyne acquired for CombiPatch® of \$1.5 million and \$4.6 million for each of the three and nine months ended September 30, 2006 and 2005, respectively. This amortization was previously reported as a separate operating expense in Novogyne's statement of operations.

#### Novogyne Net Revenues

Novogyne sells its products to trade customers, including wholesalers, distributors and chain pharmacies. As has historically been the case, the timing of purchases by trade customers is driven by the inventory needs of each customer and other factors, and does not necessarily track underlying prescription trends in any given period or

coincide with Novogyne's quarterly financial reporting periods. As a result, the timing of orders by trade customers is difficult to predict and can lead to significant variability in Novogyne's quarterly results.

Novogyne's gross revenues increased \$1.2 million for the three months ended September 30, 2006 compared to the same period in the prior year. Novogyne's gross revenues for the three months ended September 30, 2006 benefited from the release of a \$0.6 million reserve that Novogyne had established since October 2004 in response to certain pricing claims made by the Veterans Administration, which claims were rejected by a federal court during the three months ended September 30, 2006. By product, the increase in Novogyne's gross revenues reflects a \$2.6 million increase in sales of Vivelle-Dot partially offset by a \$0.6 million and \$0.4 million decline in sales

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of Estradot® to Canada and CombiPatch®, respectively. In addition, Vivelle®, our first generation estrogen patch declined \$0.3 million in unit sales. We expect to complete our planned discontinuation of Vivelle® production by the end of 2006. The higher Vivelle-Dot sales were primarily attributable to a \$3.3 million increase related to pricing, offset by a \$0.7 million decrease in unit sales attributable to the timing of orders. The \$0.6 million decline in sales of Estradot® was attributable to timing of orders as sales are expected to be in line with 2005 results.

The decrease in Novogyne's CombiPatch® sales was due primarily to a \$0.8 million decline in unit sales, which we believe is a result of the continuing decline in the market for combination therapies and the impact of a competitive product, partially offset by a \$0.4 million increase related to price increases.

Novogyne's gross revenues increased \$11.6 million for the nine months ended September 30, 2006 compared to the same period in the prior year, primarily due to a \$13.6 million increase in sales of Vivelle-Dot, partially offset by a \$0.9 million and \$0.7 million decline in sales of Vivelle® and CombiPatch®, respectively. In addition, sales of Estradot® to Canada declined \$0.4 million in unit sales. The higher Vivelle-Dot sales were primarily attributable to a \$7.6 million increase in unit sales and a \$6.0 million increase related to pricing. The increase in unit sales is a result of higher prescription trends as compared to the same period in the prior year. The decline in Vivelle® sales were primarily attributable to a \$1.1 million decline in unit sales, partially offset by a \$0.2 million increase related to pricing. The decline in CombiPatch® is primarily attributable to a \$1.3 million decline in unit sales, partially offset by a \$0.6 million increase related to pricing. The decline in unit sales of Estradot®, Vivelle® and CombiPatch® were attributable to the same factors as discussed above for the three month comparable periods.

Sales allowances consist of chargebacks, Medicaid rebates, managed healthcare rebates, cash discounts and other allowances, which tend to fluctuate based on changes in gross revenues. These sales allowances were 11% of gross revenues for each of the three months ended September 30, 2006 and 2005, and 10% and 11% of gross revenues for the nine months ended September 30, 2006 and 2005, respectively.

Sales returns allowances primarily consist of allowances for returns of expiring product. Allowances for returns for product recalls were not material for the three and nine months ended September 30, 2006 and 2005. The activity for sales returns allowances for the three and nine months ended September 30, 2006 and 2005 was as follows:

	Three Months		Nine Months	
	2006	2005	2006	2005
Changes in allowances for returns primarily of expiring product	\$ 1,193	\$ 192	\$ 4,576	\$ 1,057
Actual returns primarily for expiring product	\$ (862)	\$ (1,174)	\$ (3,135)	\$ (2,909)

The increase in allowances for returns of expiring product for the three months ended September 30, 2006 was primarily due to increased sales of Vivelle-Dot, partially offset by lower actual returns of CombiPatch®. The increase in allowances for returns of expiring product for the nine months ended September 30, 2006 was primarily related to higher expected returns as a result of increased sales of Vivelle-Dot as well as higher actual returns of CombiPatch®. In addition, the three and nine months ended September 30, 2005 benefited from a reduction in allowances of expiring product due to lower expected returns as a result of a decline in actual returns of Vivelle® at the time. The current three and nine month period did not benefit from such a reduction.

**Table of Contents****Novogyne Gross Margin**

Novogyne's gross margin was consistent for the three and nine months ended September 30, 2006 compared to the same periods of the prior year.

**Novogyne Selling, General and Administrative Expenses**

Novogyne's selling, general and administrative expenses for the three months ended September 30, 2006 increased \$0.2 million compared to the same period in 2005, due primarily to a \$0.7 million increase in administrative, advertising and promotional expenses, partially offset by a \$0.4 million decline in litigation expenses related to HT litigation.

Novogyne's selling, general and administrative expenses for the nine months ended September 30, 2006 increased \$2.5 million compared to the same period in 2005, due primarily to a \$1.0 million increase in sample expense due to timing of shipments, a \$1.3 million increase in administrative, advertising and promotional expenses and a \$0.4 million increase in litigation expenses related to HT litigation, partially offset by a \$0.4 million decline in sales force expenses.

**Liquidity and Capital Resources**

As of September 30, 2006 and December 31, 2005, we had the following (amounts in thousands):

	September 30, 2006	December 31, 2005
Cash and cash equivalents	\$ 8,676	\$ 66,964
Short-term investments	130,510	17,900
Working capital	148,176	91,122

Cash provided by (used in) operating, investing and financing activities for the nine months ended September 30, 2006 and 2005 is summarized as follows (amounts in thousands):

	Nine Months	
	2006	2005
Cash flows:		
Operating activities	\$ 51,124	\$ (1,036)
Investing activities	(119,157)	(61,697)
Financing activities	9,745	1,115

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### ***Operating Activities***

Net cash provided by operating activities for the nine months ended September 30, 2006 primarily resulted from the receipt of \$50.0 million related to the Daytrana approval and \$17.6 million in cash distributions from Novogyne. These receipts were offset by changes in working capital due to the timing of certain payments, including those related to insurance, compensation and related liabilities and payments to Shire for clinical trial costs incurred in connection with obtaining Daytrana regulatory approval.

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 Daytrana 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.

### ***Investing Activities***

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 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, 2006 was primarily attributable to \$112.6 million in net purchases of short-term investments, as well as the purchase of \$5.8 million in fixed assets to expand production capacity for future products.

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.

### ***Financing Activities***

Net cash provided by financing activities for the nine months ended September 30, 2006 and September 30, 2005 was primarily attributable to \$8.1 million and \$1.2 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, 2006, 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 short-term liquidity. 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 distributions from Novogyne and sales, royalties and license fees associated with our transdermal products. Any decrease in sales of those products by us or our licensees or any increase in returns of products to Novogyne (including any such changes resulting from the 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 cash flow and require us to rely on our existing cash balances or on borrowings to support our operations and business.

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In April 2006, Noven received a \$50 million milestone payment from Shire as a result of the approval of Daytrana, and Noven may also earn up to three additional \$25 million milestone payments upon Shire's achievement of \$25 million, \$50 million and \$75 million in annual net sales of Daytrana, respectively. Shire commercially launched the product in June 2006. The majority of the income taxes related to the \$50 million milestone is expected to be paid in late 2007 or early 2008.

Capital expenditures were \$5.8 million for the nine months ended September 30, 2006. We expect to fund any 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.

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 own products. We expect that our cash requirements will generally continue to increase, primarily to fund plant and equipment purchases to expand production capacity for new products. If our products under development with collaborative partners are successful, these expenditures, which may include the cost of building an additional manufacturing plant, 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 in Part I Item 1A of our Form 10-K and in Part II Item 1A of any quarterly reports on Form 10-Q we have filed with the SEC since the filing of the Form 10-K, as well as in other reports filed from time to time with the SEC.

From time to time we may explore the acquisition of one or more technologies, products or businesses that we believe may be complementary to our existing business. We may draw upon our cash and short-term investments to fund such potential strategic acquisitions. We may also consider issuing equity securities to fund potential acquisitions. To the extent our existing cash and short-term investments are insufficient to fund any large-scale acquisitions we may be required to seek debt financing or to issue equity or debt securities. If a material acquisition is completed, our results of operations and financial condition could change materially in future periods. If we finance all or any portion of an acquisition through debt financing or debt securities we could be required to devote a portion of our cash to the prepayment of such debt and could be subject to financial or operational covenants that could limit or hinder our ability to conduct our business.

In addition, although we have not repurchased any of our common stock since 2003, it is possible that a portion of our cash and short-term investments could be used to repurchase Noven common stock under our previously-announced stock repurchase program. Stock repurchases, if any, may be made in the open market, including pursuant to a trading program under Rule 10b5-1 promulgated under the Securities Exchange Act of 1934.

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

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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.

### **Aggregate Contractual Obligations**

There have been no material changes outside of the ordinary course of our business since December 31, 2005 to our aggregate contractual obligations previously disclosed in our Form 10-K.

### **Critical Accounting Estimates**

For a discussion of our critical accounting policies, see Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Estimates, which is included in our Form 10-K, as updated and supplemented by the following:

#### *Revenue Recognition License Revenues*

License revenues consist of up-front, milestone and similar payments under license agreements and are not recognized until earned under the terms of the applicable agreements. In most cases, license revenues are deferred and recognized over the estimated product life cycle, which is management's best estimate of the earning period. Estimates of product life cycles are inherently uncertain as a result of regulatory, competitive or medical developments. We estimate product life cycles based on our assessment of various factors, including the expected launch date of the licensed product, the strength of the intellectual property protection of the product, the contractual terms, and various other competitive, developmental and regulatory issues. Any change to the actual or estimated product life could require us to change the recognition period. Management's best estimate of the end of the product life cycle for Daytrana extends through the first quarter of 2013, which results in the annual recognition of approximately \$8.0 million in license revenues for the \$50 million approval milestone payment we received from Shire in April 2006. If our estimate of the Daytrana product life cycle should change, we will be required to change the license revenue recognition period, which may materially change the license revenues that we recognize in any given period. For example, Daytrana license revenues would be \$5.0 million and \$3.8 million on an annual basis had we determined that the product life cycle ended in the first quarter of 2016 and 2019, respectively, for the \$50 million approval milestone.

#### *Stock-Based Compensation*

We currently use the Black-Scholes option pricing model to determine the fair value of stock options and SSARs. The determination of the fair value of stock-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include our expected stock price volatility over the term of the awards, actual and projected employee equity award exercise behaviors, risk-free interest rate, expected forfeiture rates and expected dividends.

We estimate the expected term of options granted by taking the average of the vesting term and the contractual term of the option, as described in SAB 107. We estimate the volatility of common stock by using a combination of both historical and implied volatility based on an equal weighting of each as management believes it is the expected volatility that marketplace participants would likely use in determining an exchange price for an option. We base the risk-free interest rate that we use in the option pricing model on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term on the options. We do not anticipate paying any cash dividends in the foreseeable future and therefore use an expected dividend yield of zero in the option pricing model. We are required to estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. We use historical data to estimate pre-vesting



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option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. All share-based payment awards are amortized on a straight-line basis over the requisite service periods of the awards, which are generally the vesting periods. If factors change and we employ different assumptions for estimating stock-based compensation expense in future periods or if we decide to use a different valuation model, the future periods may differ significantly from what we have recorded in the current period and could materially affect our operating income, net income and net income per share. The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable, characteristics not present in our option grants. Existing valuation models, including the Black-Scholes and lattice binomial models, may not provide reliable measures of the fair values of our stock-based compensation. Consequently, there is a risk that our estimates of the fair values of our stock-based compensation awards on the grant dates may bear little resemblance to the actual values realized upon the exercise, expiration, early termination or forfeiture of those stock-based payments in the future. Stock options or SSARs may expire worthless or otherwise result in zero intrinsic value as compared to the fair values originally estimated on the grant date and reported in our financial statements. Alternatively, value may be realized from these instruments that are significantly higher than the fair values originally estimated on the grant date and reported in our financial statements. There currently is no market-based mechanism or other practical application to verify the reliability and accuracy of the estimates stemming from these valuation models, nor is there a means to compare and adjust the estimates to actual values.

The guidance in SFAS 123(R) and SAB 107 is relatively new. The application of these principles may be subject to further interpretation and refinement over time. There are significant differences among valuation models, and there is a possibility that we will adopt different valuation models in the future. This may result in a lack of consistency in future periods and materially affect the fair value estimate of stock-based payments. It may also result in a lack of comparability with other companies that use different models, methods and assumptions.

**Recent Accounting Pronouncements**

In July 2006, the FASB issued FIN 48 to clarify the accounting for uncertainties related to income taxes that are recognized in an enterprise's financial statements in accordance with SFAS 109. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The evaluation of a tax position in accordance with FIN 48 is a two-step process. The first step is recognition, which requires an enterprise to determine whether it is more likely than not that a tax position will be sustained upon examination based on the technical merits of the position. The second step is measurement, which requires a company to recognize a tax position that meets the more likely than not recognition threshold at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. FIN 48 is effective as of the beginning of the first annual reporting period that begins after December 15, 2006. We are currently assessing FIN 48 and are unable to estimate the impact it will have on our results of operations and financial condition.

In September 2006, the SEC issued SAB 108, which added Section N to Topic 1, Financial Statements, of the Staff Accounting Bulletin Series. Section N provides guidance on the consideration of the effects of prior year misstatements when quantifying current year financial statement misstatements for the purpose of materiality assessment. The SEC concluded in SAB 108 that a registrant's materiality evaluation of an identified unadjusted error should quantify the impact of correcting all misstatements, including both the carryover and reversing effects of prior year misstatements, on the current year financial statements. If either the carryover or reversing effects of prior year misstatements is material, the misstatements should be corrected in the current year. If correcting an error in the current year for prior year misstatements causes the current year to be materially misstated, the prior year financial statements should be corrected, even though such revision previously was and continues to be immaterial to the prior year financial statements.

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Correcting prior year financial statements for immaterial errors would not require previously filed reports to be amended. Such correction may be made the next time the registrant files the prior year financial statements. The guidance of SAB 108 should be applied in the annual financial statements covering the fiscal year ending after November 15, 2006.

### **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 2006 there will not be any material:

transactions;

changes in Noven's or Novogyne's accounting or accounting principles (except as indicated below with respect to Noven's method of accounting for equity compensation) or any of the estimates or judgments underlying our critical accounting policies;

regulatory, technological or clinical study developments;

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

unexpected actions with respect to our applications for methylphenidate quota;

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, and 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 in Part I Item 1A of our Form 10-K and in Part II Item 1A of any quarterly reports on Form 10-Q we have filed with the SEC since the filing of the Form 10-K, as well as in other reports filed from time to time with the SEC.

*Stock-Based Compensation Expenses.* Effective as of the first quarter of 2006, we adopted SFAS 123(R), Accounting for Stock Based Compensation. As a result, our Statements of Operations in 2006 and subsequent periods will include significant expenses associated with stock-based compensation that were not included in 2005 and prior periods. Based on the expense associated with stock-based compensation previously awarded, and our estimate of the expense associated with such compensation that may be awarded in the course of 2006, we estimate that our total stock-based compensation expenses for full-year 2006 will be approximately \$3.5 million, including approximately \$2.4 million of such expenses recorded in the first nine months of 2006. The specific financial guidance provided below includes expected increases resulting from the expensing of stock-based compensation.

*Daytrana.* On April 6, 2006, our amended NDA for Daytrana was approved for marketing by the FDA. On April 7, 2006, we received a \$50 million milestone payment from Shire (the global licensee of the product) as a result of the approval, and we may also earn up to three additional \$25 million milestone payments depending on the level of Shire's commercial sales of the product. We expect to defer and recognize approval and sales milestones as license revenues on a straight-line basis through the first quarter of 2013, which is our current best estimate of the useful economic life of the product. Using this method, we began recognizing the \$50 million milestone payment, as well as the balance of the Shire deferred license revenues (\$4.8 million at March 31, 2006), in the second quarter of 2006.

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In 2006, we received an initial grant of methylphenidate quota and have submitted supplemental applications for additional quota in order to fulfill the 2006 product orders received from Shire. The DEA, which grants quota based primarily on historical product sales and prescription data, has not, to date, granted our requests for additional 2006 quota. While Noven and Shire continue to work with the DEA to obtain additional methylphenidate quota for the remainder of 2006, we cannot assure that we will be successful in convincing the DEA that additional quota is necessary to meet patient demand. Because we have not received additional quota for 2006, we expect to complete the year with approximately \$8.0 million in full-year Daytrana product sales to Shire and approximately \$2.0 million in Daytrana product backorders that we would expect to fulfill following receipt of our expected 2007 quota supply in the first quarter of 2007. As discussed below, the reduction in Daytrana revenues will negatively affect our gross margin in the fourth quarter of 2006 but, to the extent that these backorders are filled as expected in the first quarter of 2007, the related revenues should benefit our gross margin in 2007. If the DEA declines to grant us additional 2006 quota, it is possible (subject to a number of factors including ongoing demand for the product) that product supply for certain dosage strengths may be interrupted and, as a result, Daytrana sales as well as our results of operations could be adversely affected.

*HT Product Revenues.* Given customer orders, prescription trends and other factors, we expect Noven's HT product revenues for full-year 2006 to approximate 2005 levels, with growth in our U.S. HT product revenues expected to be offset by a decline in our international HT revenues.

*Gross Margin.* We are working to reduce costs and improve yields, and we reported significant improvement in gross margin for the 2006 third quarter compared to 2006 second quarter levels. Due in part to the DEA quota issue discussed above, we are targeting an overall gross margin of 30% for the fourth quarter of 2006. For 2007, we believe improvement in gross margin is possible compared to 2006 third quarter levels, subject to a variety of factors (some of which are not within our control), including the availability and timing of methylphenidate quota, our ability to effectively coordinate production between Daytrana and our HT products to improve facility utilization, our ability to improve yields, and our ability to develop and commercialize new products that would be manufactured in our facilities.

*Research and Development.* We expect our research and development expense in 2006 to decrease in the 10% range from full-year 2005 levels, reflecting in part the absence in 2006 of expenses associated with the development of our fentanyl and Daytrana products.

*Marketing, General and Administrative Expense.* We expect Noven's marketing, general and administrative expense to increase in the 30% range over 2005 levels, primarily reflecting stock-based compensation expenses that commenced in 2006, and a \$0.6 million one-time termination charge taken in the 2006 third quarter.

*Novogyne.* Based on current prescription trends and other factors, we expect Novogyne's full year 2006 net revenues to increase nearly 10% compared to 2005 levels, and we expect Novogyne's net income and profit contribution to Noven for 2006 to increase in the 12% range compared to 2005 levels.

*Effective Tax Rate.* We estimate that our effective tax rate for full-year 2006 will be in the 33% to 35% range.

*Capital Expenditures.* We expect our capital expenditures for full-year 2006 to decrease significantly compared to 2005 levels.

**Item 3. Quantitative and Qualitative Disclosure About Market Risk**

Not Applicable.

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**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 not been any changes in our internal controls or in other factors that are reasonably likely to affect those controls subsequent to the date of the last evaluation. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective in alerting them to material information relating to us to allow timely decisions regarding disclosure of information required to be included in our periodic SEC 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 SEC's implementing regulations. This Item 4 of this quarterly report is the information concerning the evaluation referred to in those certifications, and you should read this information in conjunction with those certifications for a more complete understanding of the topics presented.

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**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

Certain lawsuits and legal proceedings in which we are involved are described in Part I, Item 3 Legal Proceedings of our Form 10-K as well as in Part II, Item 1 Legal Proceedings of our quarterly reports on Form 10-Q for the periods ended March 31, 2006 and June 30, 2006. The following is a description of material developments related to our legal proceedings during the period covered by this Form 10-Q, and through the filing of this Form 10-Q, and should be read in conjunction with the reports referenced above. Unless otherwise indicated, all proceedings discussed in the reports referenced above remain outstanding.

In addition to the HT cases previously disclosed in prior reports, Novartis has advised us that Novartis has been named as a defendant in at least 28 lawsuits that include approximately 35 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 our Vivelle-Dot, Vivelle®, and CombiPatch® products. In addition, Novartis has been named as a defendant in over 80 additional lawsuits in which the plaintiffs' complaints do not identify the HT products used by the plaintiffs and therefore these cases may also involve our HT products. Novartis has indicated that it will seek indemnification from Noven and Novogyne to the extent permitted by the agreements between and among Novartis, Novogyne and Noven.

We intend to defend all of the foregoing lawsuits vigorously, but the outcome of these product liability lawsuits cannot ultimately be predicted.

We are a party to other pending legal proceedings arising in the normal course of business, none of which we believe is material to our financial position or results of operations.

**Item 1A. Risk Factors**

There have been no material changes to the risk factors previously disclosed in our Form 10-K and in our quarterly reports on Form 10-Q we have filed with the SEC since the filing of the Form 10-K, as well as in other reports filed from time to time with the SEC. Readers are urged to carefully review our risk factors since they may cause our results to differ from the forward-looking statements made in this report or otherwise made by or on our behalf. The risk factors are not listed in order of priority and are not the only ones we face. If any of these risks actually occurs, our business, financial condition and results of operations would suffer. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operation. 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.

**Table of Contents****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 2006:

	Total Number of Shares Purchased as Part of	Average Price Paid Per Share	Publicly Announced Program	Approximate Dollar Value That May Yet be Purchased under the Program <sup>(1)</sup>
July 1, 2006 to July 31, 2006				\$23,711,040
August 1, 2006 to August 31, 2006				\$23,711,040
September 1, 2006 to September 30, 2006				\$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.

**Item 5. Other Information**

The following executive officers have currently effective trading plans intended to comply with the guidelines specified in Rule 10b5-1 under the Securities Exchange Act of 1934: Eduardo A. Abrao, Diane M. Barrett, Jeffrey F. Eisenberg, W. Neil Jones, and Robert C. Strauss. Other Noven executive officers (as well as Noven employees) may adopt Rule 10b5-1 trading plans from time to time. These plans generally provide for the exercise of stock options and the subsequent sale of the acquired shares on the open market, subject to specified limitations and minimum price thresholds. Under these plans, the executive officers do not control the specific timing of any option exercise or sale. Rule 10b5-1 permits corporate officers and directors to adopt written, pre-arranged stock trading plans when they are not in possession of material, non-public information. Public disclosure of the transactions under these plans is required to be made by the executive officers through Form 144 and Form 4 filings with the SEC.

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**Item 6. Exhibits**

- 10.1 Noven Pharmaceuticals, Inc. Nonqualified Deferred Compensation Plan, as amended and restated September 15, 2006.
- 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 9, 2006

By: /s/ Diane M. Barrett

Diane M. Barrett  
Vice President and  
Chief Financial Officer  
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