

NOVEN PHARMACEUTICALS INC

Form 10-Q

August 09, 2006

**Table of Contents**

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**  
**FORM 10-Q**  
**Quarterly Report Pursuant to Section 13 or 15 (d) of the**  
**Securities Exchange Act of 1934**  
**For the quarterly period ended June 30, 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 July 31, 2006
Common stock \$.0001 par value	23,783,587

**NOVEN PHARMACEUTICALS, INC.**  
**INDEX**

	Page No.
<b><u>PART I FINANCIAL INFORMATION</u></b>	
<b><u>Item 1 Unaudited Condensed Financial Statements</u></b>	
<u>Condensed Statements of Operations for the Three and Six Months Ended June 30, 2006 and 2005</u>	3
<u>Condensed Balance Sheets as of June 30, 2006 and December 31, 2005</u>	4
<u>Condensed Statements of Cash Flows for the Six Months Ended June 30, 2006 and 2005</u>	5
<u>Notes to Unaudited Condensed Financial Statements</u>	6
<b><u>Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	18
<b><u>Item 3 Quantitative and Qualitative Disclosures About Market Risk</u></b>	36
<b><u>Item 4 Controls and Procedures</u></b>	36
<b><u>PART II OTHER INFORMATION</u></b>	
<b><u>Item 1 Legal Proceedings</u></b>	38
<b><u>Item 1A Risk Factors</u></b>	38
<b><u>Item 2 Unregistered Sales of Equity Securities and Use of Proceeds</u></b>	40
<b><u>Item 4 Submission of Matters to a Vote of Security Holders</u></b>	40
<b><u>Item 6 Exhibits</u></b>	41
<b><u>SIGNATURES</u></b>	42
<u>EX-31.1 SECTION 302 CERTIFICATION OF CEO</u>	
<u>EX-31.2 SECTION 302 CERTIFICATION OF CFO</u>	
<u>EX-32.1 SECTION 906 CERTIFICATION OF CEO</u>	
<u>EX-32.2 SECTION 906 CERTIFICATION OF CFO</u>	

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 Item 1A of Part II of this report, as well as other reports filed from time to time with the Securities and Exchange Commission.

Trademark Information: Vivellev<sup>®</sup>, Vivellev-Dot, Estradot<sup>®</sup> and Menorest are trademarks of Novartis AG or its affiliated companies; CombiPatch<sup>®</sup> and Estalis<sup>®</sup> are registered trademarks of Vivellev Ventures LLC; 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 Six Months Ended June 30,  
 (in thousands, except per share amounts)  
 (unaudited)

	Three Months		Six Months	
	2006	2005	2006	2005
Revenues:				
Product revenues Novogyne:				
Product sales	\$ 5,630	\$ 4,714	\$ 8,717	\$ 9,692
Royalties	1,658	1,713	3,347	2,827
Total product revenues Novogyne	7,288	6,427	12,064	12,519
Product revenues third parties	6,016	3,933	9,887	7,971
Total product revenues	13,304	10,360	21,951	20,490
Contract and license revenues:				
Contract	404	429	1,068	1,024
License	3,839	982	4,720	1,993
Contract and license revenues	4,243	1,411	5,788	3,017
Net revenues	17,547	11,771	27,739	23,507
Expenses:				
Cost of products sold Novogyne	4,459	2,449	6,602	5,698
Cost of products sold third parties	7,428	2,787	11,425	5,412
Total cost of products sold	11,887	5,236	18,027	11,110
Research and development	2,890	3,033	6,372	5,926
Marketing, general and administrative	5,638	4,189	10,376	8,244
Total expenses	20,415	12,458	34,775	25,280
Loss from operations	(2,868)	(687)	(7,036)	(1,773)
Equity in earnings of Novogyne	6,762	8,101	11,089	9,013
Interest income, net	1,111	593	1,722	1,096

Edgar Filing: NOVEN PHARMACEUTICALS INC - Form 10-Q

Income before income taxes	5,005	8,007	5,775	8,336
Provision for income taxes	1,672	2,886	1,938	3,004
Net income	\$ 3,333	\$ 5,121	\$ 3,837	\$ 5,332
Basic earnings per share	\$ 0.14	\$ 0.22	\$ 0.16	\$ 0.23
Diluted earnings per share	\$ 0.14	\$ 0.21	\$ 0.16	\$ 0.22
Weighted average number of common shares outstanding:				
Basic	23,685	23,565	23,673	23,537
Diluted	24,071	24,068	23,925	24,017

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

**Table of Contents**

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

	June 30, 2006	December 31, 2005
<u>Assets</u>		
Current Assets:		
Cash and cash equivalents	\$ 11,570	\$ 66,964
Short-term investments available-for-sale, at fair value	114,660	17,900
Accounts receivable trade (less allowance for doubtful accounts of \$42 in 2006 and \$53 in 2005)	5,866	2,919
Accounts receivable Novogyne, net	7,067	8,912
Inventories	7,832	7,861
Net deferred income tax asset, current portion	5,200	6,000
Prepaid income taxes	6,245	7,697
Prepaid and other current assets	2,414	1,357
	160,854	119,610
Property, plant and equipment, net	37,010	34,455
Other Assets:		
Investment in Novogyne	21,910	23,243
Net deferred income tax asset	7,356	6,373
Patent development costs, net	2,377	2,211
Deposits and other assets	222	18
	31,865	31,845
	\$ 229,729	\$ 185,910
<u>Liabilities and Stockholders Equity</u>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 4,702	\$ 5,812
Capital lease obligation current portion	52	121
Accrued liability Shire	419	5,488
Accrued compensation and related liabilities	3,607	5,771
Other accrued liabilities	2,499	2,124
Deferred rent credit	89	89
Deferred contract revenues	551	1,481
Deferred license revenues current portion	11,279	7,602
	23,198	28,488
Long-Term Liabilities:		
Deferred rent credit	704	748

Edgar Filing: NOVEN PHARMACEUTICALS INC - Form 10-Q

Deferred license revenues	58,670	16,053
Deferred compensation liability	92	
	82,664	45,289

Commitments and Contingencies (Note 13)

Stockholders' Equity:

Preferred stock authorized 100,000 shares of \$.01 par value; no shares issued or outstanding		
Common stock authorized 80,000,000 shares, par value \$.0001 per share; issued and outstanding 23,719,753 at June 30, 2006 and 23,617,221 at December 31, 2005	2	2
Additional paid-in capital	92,453	89,846
Retained earnings	54,610	50,773
	147,065	140,621
	\$ 229,729	\$ 185,910

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



**Table of Contents**

**NOVEN PHARMACEUTICALS, INC.**  
Condensed Statements of Cash Flows  
Six Months Ended June 30,  
(in thousands)  
(unaudited)

	2006	2005
Cash flows from operating activities:		
Net income	\$ 3,837	\$ 5,332
Adjustments to reconcile net income to net cash flows provided by operating activities:		
Depreciation and amortization	1,850	1,134
Stock-based compensation expense	1,529	
Amortization of patent costs	250	218
Increase in cash surrender value of company-owned life insurance	(4)	
Amortization of deferred rent credit	(44)	(31)
Income tax benefits on exercise of stock options	256	154
Deferred income tax (benefit) expense	(183)	57
Recognition of deferred license revenues	(4,720)	(1,993)
Equity in earnings of Novogyne	(11,089)	(9,013)
Distributions from Novogyne	10,210	8,926
Changes in operating assets and liabilities:		
(Increase) decrease in accounts receivable trade, net	(2,947)	105
Decrease in accounts receivable Novogyne, net	1,845	2,720
Decrease (increase) in inventories	29	(3,790)
Decrease in prepaid income taxes	3,664	4,394
Increase in prepaid and other current assets	(1,057)	(1,450)
Increase in deposits and other assets	(15)	(1)
Decrease in accounts payable	(1,110)	(5,881)
Decrease in accrued liability Shire	(5,069)	(5,608)
Decrease in accrued compensation and related liabilities	(2,164)	(2,153)
Increase (decrease) in other accrued liabilities	375	(281)
Decrease in deferred contract revenue, net	(930)	(223)
Increase in deferred license revenue	51,000	
Increase in deferred compensation liability	92	
Amounts recoverable from (reimbursable to) Shire and offset against deferred license revenue related to Daytrana approval	14	(4,822)
Cash flows provided by (used in) operating activities	45,619	(12,206)
Cash flows from investing activities:		
Purchases of property, plant and equipment, net	(4,405)	(4,582)
Payments for patent development costs, net	(416)	(241)
Purchase of company-owned life insurance	(185)	
Purchases of short-term investments	(685,035)	(201,665)
Proceeds from sale of short-term investments	588,275	157,065
Cash flows used in investing activities	(101,766)	(49,423)

Edgar Filing: NOVEN PHARMACEUTICALS INC - Form 10-Q

Cash flows from financing activities:		
Issuance of common stock from exercise of stock options	822	1,060
Payments under capital leases	(69)	(56)
Cash flows provided by financing activities	753	1,004
Net decrease in cash and cash equivalents	(55,394)	(60,625)
Cash and cash equivalents, beginning of period	66,964	93,958
Cash and cash equivalents, end of period	\$ 11,570	\$ 33,333

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

**Table of Contents**

**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<sup>®</sup>, Vivelle-Dot and CombiPatch<sup>®</sup>. 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 June 30, 2006, and the results of its operations and its cash flows for the three and six months ended June 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 this quarterly report on Form 10-Q. Accordingly, the results of operations and cash flows for the three and six months ended June 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 Securities and Exchange Commission for reporting on Form 10-Q. Pursuant to such rules and regulations, certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted. The unaudited condensed financial statements should be read in conjunction with the financial statements and the notes to the financial statements included in Noven s Form 10-K. The accounting policies followed for interim financial reporting are the same as those disclosed in Note 2 of the notes to the financial statements included in Noven s Form 10-K, 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 from the vendor. Amounts accrued could be impacted if actual purchase volumes differ from projected purchase volumes. Noven treats purchase-volume-related discounts or rebates 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, which is consistent with Emerging Issues Task Force 02-16 Accounting by a Customer (Including a Reseller) for Certain Consideration Received from a Vendor .

**Table of Contents**

**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 June 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 June 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 June 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 \$0.2 million for each of the six months ended June 30, 2006 and 2005. Cash payments for interest were not material for the six months ended June 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 six months ended June 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.

**6. RECENT ACCOUNTING PRONOUNCEMENTS:**

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

**Table of Contents**

accordance with SFAS 109, Accounting for Income Taxes. This interpretation 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. As Noven believes it currently performs both the recognition and measurement process prescribed by FIN 48, it does not expect that the adoption of this interpretation will have a material impact on its results of operations, financial condition and cash flows.

**7. INVENTORIES:**

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

	June 30, 2006			December 31, 2005		
	Commercial	Pre-launch	Total	Commercial	Pre-launch	Total
Finished goods	\$ 399	\$	\$ 399	\$ 760	\$	\$ 760
Work in progress	2,118		2,118	1,278	1,004	2,282
Raw materials	5,315		5,315	3,422	1,397	4,819
	\$ 7,832	\$	\$ 7,832	\$ 5,460	\$ 2,401	\$ 7,861

Pre-launch inventories as of December 31, 2005 consisted of Noven's Daytrana 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.

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 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 Agency (DEA) must grant Noven quota for controlled substances such as methylphenidate, the active ingredient in Daytrana, and no assurance can be given that Noven will be granted sufficient DEA quota to meet production requirements for Daytrana.

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 plc (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 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 contractual yields of the finished product. During the three and six months ended June 30, 2006, Noven used \$2.1 million of AMI in the finished product and reimbursed Shire approximately \$0.4 million for excess AMI used in production which amount is included in cost of products sold. Noven had \$1.4 million of consignment AMI inventory on hand at June 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-

**Table of Contents**

settled stock appreciation rights ( SSARs ) to employees and nonvested shares ( restricted stock ) to non-employee directors in lieu of stock options.

At June 30, 2006, there were 3,859,351 stock options and 26,000 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 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 Securities and Exchange Commission'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.

**Table of Contents**

The assumptions used to value option grants for the quarters ended June 30, 2006 and June 30, 2005 are as follows:

	2006	2005
Volatility	55.1%	69.0%
Risk free interest rate	4.95%	3.83%
Expected life (years)	5	5

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

	Three Months	Six Months
Marketing, general and administrative	\$ 745	\$ 1,142
Research and development	133	224
Cost of products sold	102	163
	\$ 980	\$ 1,529
Tax benefit recognized related to compensation expense	\$ 239	\$ 358

There were no stock-based compensation costs capitalized as part of inventory or fixed assets for the period ended June 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 increase 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 six months ended June 30, 2006 and 2005 was \$0.8 million and \$1.1 million, respectively. The tax benefit realized for the tax deductions from option exercise of the share-based payment arrangements totaled \$0.3 million and \$0.2 million for the six months ended June 30, 2006 and 2005, respectively. There were no benefits of tax deductions in excess of recognized stock-based compensation expense to be reported as a financing cash flow for the six months ended June 30, 2006.

**Table of Contents**

Stock option transactions related to the plans are summarized as follows for the six months ended June 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	26	17.55		
Exercised	(103)	8.10	\$ 876	
Canceled and expired	(42)	19.61		
Outstanding at end of the period	3,885	\$ 17.45	\$ 12,307	4.1
Outstanding and exercisable at end of period	2,739	\$ 19.52	\$ 6,114	3.7

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

	2006	
	Shares	Weighted Average Grant-Date Fair Value \$
Nonvested at December 31, 2005		
Granted	34	17.47
Vested	(8)	17.47
Forfeited		
Nonvested at June 30, 2006	26	\$17.47

As of June 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 \$6.4 million before the effect of income taxes, of which \$1.7 million, \$2.6 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 2.5 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 June 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.





**Table of Contents**

The following table illustrates the effect on net income and earnings per share for the three and six months ended June 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	Six Months 2005
Net income:		
As reported	\$ 5,121	\$ 5,332
Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(10,223)	(11,970)
Pro forma	\$ (5,102)	\$ (6,638)
Basic earnings per share:		
As reported	\$ 0.22	\$ 0.23
Pro forma	\$ (0.22)	\$ (0.28)
Diluted earnings per share:		
As reported	\$ 0.21	\$ 0.22
Pro forma	\$ (0.22)	\$ (0.28)

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 June 30, 2006. At June 30, 2006, the balance of the deferred compensation liability totaled \$0.1 million.

**Table of Contents****10. CONTRACT AND LICENSE AGREEMENTS:***Shire*

On April 6, 2006, Noven's amended New Drug Application (NDA) for Daytrava 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 ADHD. Under the original agreement, Noven is entitled to payments of up to \$5.0 million if certain development milestones are achieved. As of June 30, 2006, Noven has received \$0.5 million in such milestone payments. Under the amendment, Shire paid Noven an additional \$1.0 million in August 2006 in exchange for which Noven will perform certain early-stage development activities which were previously to be performed by Shire and which amount Noven expects to recognize over time. 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.

*Other*

During the three months ended June 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 preferred return for those years and for Noven to recognize earnings from Novogyne under the formula.

During the three and six months ended June 30, 2006 and 2005, Noven had the following transactions with Novogyne (in thousands):

	Three Months		Six Months	
	2006	2005	2006	2005
Revenues:				
Product sales	\$ 5,630	\$ 4,714	\$ 8,717	\$ 9,692
Royalties	1,658	1,713	3,347	2,827
	\$ 7,288	\$ 6,427	\$ 12,064	\$ 12,519
Reimbursed expenses	\$ 6,648	\$ 6,378	\$ 13,918	\$ 13,620

**Table of Contents**

As of June 30, 2006 and December 31, 2005, Noven had amounts due from Novogyne of \$7.1 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 six months ended June 30, 2006 and 2005 are as follows (in thousands):

	Three Months		Six Months	
	2006	2005	2006	2005
Gross revenues	\$ 35,665	\$ 35,211	\$ 72,934	\$ 62,545
Sales allowances	3,546	3,676	7,339	7,071
Sales return allowances	1,487	(401)	3,383	865
Sales allowances and returns	5,033	3,275	10,722	7,936
Net revenues	30,632	31,936	62,212	54,609
Cost of sales <sup>1</sup>	7,162	7,307	14,683	13,407
Selling, general and administrative expenses	9,596	7,770	18,753	16,440
Income from operations	13,874	16,859	28,776	24,762
Interest income	162	42	314	135
Net income	\$ 14,036	\$ 16,901	\$ 29,090	\$ 24,897
Noven's equity in earnings of Novogyne	\$ 6,762	\$ 8,101	\$ 11,089	\$ 9,013

<sup>1</sup> Included in Novogyne's costs of sales for all periods presented in the table is the amortization of the marketing rights Novogyne acquired for CombiPatch®, which in prior reports was listed as a separate operating expense in Novogyne's statement of operations.

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

Edgar Filing: NOVEN PHARMACEUTICALS INC - Form 10-Q

Investment in Novogyne, beginning of period	\$ 23,243
Equity in earnings of Novogyne	11,089
Cash distributions from Novogyne	(10,210)
Non-cash distribution from Novogyne (Note 5)	(2,212)
Investment in Novogyne, end of period	\$ 21,910

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 six months ended June 30, 2006, Noven received cash distributions representing return on investment of \$2.9 million and \$10.2 million from Novogyne, respectively. For the three and six months ended June 30, 2005, Noven received cash distributions representing return on investment of \$1.5 million and \$8.9 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.

**Table of Contents**

**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 six months ended June 30, 2006 or 2005.

**13. 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 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 as disclosed in Noven's Form 10-K. 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<sup>®</sup>, 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<sup>®</sup> 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<sup>®</sup> intangible asset. Impairment of the CombiPatch<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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

**Table of Contents**

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 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.

**Table of Contents**

*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 indicated that it intends 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.

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 26 pending additional lawsuits that include approximately 33 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, in July 2006 Novartis was named as a defendant in at least 71 additional lawsuits (along with several other defendants) in which the plaintiff's 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 \$8.3 million with an offsetting insurance recovery of \$6.0 million. This accrual represents Novartis management's best estimate as of June 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.



**Table of Contents**

**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 June 30, 2006, and our results of operations for the three and six months ended June 30, 2006 and 2005. The contents of this section include:

An executive summary of our results of operations for the three months ended June 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 six months ended June 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 approval, production and launch of Daytrana, our methylphenidate patch for the treatment of ADHD, influenced our operational activities and significantly impacted our financial results for the three months ended June 30, 2006.

Daytrana was approved by the FDA on April 6, 2006, triggering payment of a \$50 million approval milestone from Shire, the global licensee of the product. The three months ended June 30, 2006 included recognition of \$2.0 million in license revenues associated with that milestone. We manufactured and shipped Daytrana launch quantities during the quarter, resulting in \$3.6 million in product sales to Shire for the quarter. Our timely product shipments permitted Shire to launch the product in June with sufficient time to begin promotion of the product in advance of the back-to-school season.

Primarily due to the product and license revenues associated with Daytrana referenced above, our net revenues for the three months ended June 30, 2006 increased 49% to \$17.5 million.

Our overall gross margin for the three months ended June 30, 2006 was materially and adversely affected by start-up expenses associated with commencing production of Daytrana, and production inefficiencies including lower than desired yields and costs incurred to meet launch timelines. As a result of these inefficiencies and expenses, our gross margin on product sales to Shire in the second quarter was negative. We are working to improve efficiencies in Daytrana production and reduce expenses, and we expect but cannot assure that we will realize gross margin improvement in the second half of 2006.

**Table of Contents**

Research and development expenses for the three months ended June 30, 2006 decreased 5% to \$2.9 million compared to the 2005 quarter, primarily as a result of higher 2005 expenses associated with development engineering for our fentanyl patch. Marketing, general and administrative expenses increased 35% to \$5.6 million, primarily reflecting increases in salary and related benefits, including stock-based compensation expenses that commenced in 2006.

We recognized \$6.8 million in earnings from Novogyne in the three months ended June 30, 2006, compared to \$8.1 million recognized in the three months ended June 30, 2005, reflecting higher sales returns allowances and higher HT litigation expenses at Novogyne.

Our net income for the three months ended June 30, 2006 was \$3.3 million (or \$0.14 diluted earnings per share), compared to \$5.1 million (or \$0.21 diluted earnings per share) for the three months ended June 30, 2005.

Current quarter net revenues at Novogyne decreased 4% to \$30.6 million, reflecting increased sales returns allowances, partially offset by increased sales of Vivelle-Dot and increased sales of Estradot<sup>®</sup> to Canada. Novogyne's selling, general and administrative expense increased 24% to \$9.6 million, primarily reflecting the timing of sample purchases from Noven, increased administrative, advertising and promotional expenses and increased HT litigation expense at Novogyne. Novogyne's net income for the current quarter was \$14.0 million, compared to \$16.9 million reported in the 2005 quarter.

Total prescriptions for Vivelle-Dot increased 6% in the three months ended June 30, 2006 compared to the three months ended June 30, 2005, and total prescriptions for Novogyne's products, taken as a whole, increased 2%. For the same period, the overall U.S. HT market declined 5%.

**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<sup>®</sup>, Vivelle-Dot and CombiPatch<sup>®</sup> 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<sup>®</sup> is marketed under the brand name Menorest, Vivelle-Dot is marketed under the brand name Estradot<sup>®</sup> and CombiPatch<sup>®</sup> is marketed under the brand name Estalis<sup>®</sup>.

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<sup>®</sup>, Vivelle-Dot and CombiPatch<sup>®</sup> 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<sup>®</sup>, Vivelle-Dot and CombiPatch<sup>®</sup> 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 \$11.1 million and \$9.0 million

**Table of Contents**

for the six months ended June 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 recognize from Novogyne for that period. For the six months ended June 30, 2006 and 2005, we received \$10.2 million and \$8.9 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 second quarter of 2006, total prescriptions dispensed in the HT market in the United States decreased by 53.7%. For the same period, aggregate prescriptions for Noven's United States HT products decreased 7.3%. The estrogen segment of the HT market in the United States declined 49.3%, while our Vivelle® line of products decreased 6.3%. Vivelle-Dot, which represented 86.6% of our total United States prescriptions in the second quarter of 2006, increased 34.9% from the second quarter of 2002 to the second 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 approximately 10.0% of our total United States prescriptions in the second quarter of 2006) declined 57.0% from the second quarter of 2002 to the second 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, 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.

*Stock-Based Compensation*

Currently, our outstanding stock-based compensation consists of: (i) stock options; (ii) SSARs; and (iii) restricted stock awards granted to non-employee directors. 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 six months ended June 30, 2006, we accounted for stock-based compensation in accordance with, SFAS 123(R). We

**Table of Contents**

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 six months ended June 30, 2006 was \$1.5 million, of which \$1.1 million was recognized in marketing, general and administrative and \$0.2 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 six months ended June 30, 2006.

At June 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 \$6.4 million before the effect of income taxes, of which \$1.7 million, \$2.6 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 six months ended June 30, 2006 compared to the three and six months ended June 30, 2005****Revenues**

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

	Three Months			Six Months		
	2006	2005	% Change	2006	2005	% Change
Product revenues						
Novogyne:						
Product sales	\$ 5,630	\$ 4,714	19%	\$ 8,717	\$ 9,692	(10%)
Royalties	1,658	1,713	(3%)	3,347	2,827	18%
	7,288	6,427	13%	12,064	12,519	(4%)
Product revenues third parties:						
Product sales	5,931	3,858	54%	9,731	7,823	24%
Royalties	85	75	13%	156	148	5%
	6,016	3,933	53%	9,887	7,971	24%
Total product revenues	13,304	10,360	28%	21,951	20,490	7%
Contract and license revenues:						
Contract	404	429	(6%)	1,068	1,024	4%
License	3,839	982	291%	4,720	1,993	137%
	4,243	1,411	201%	5,788	3,017	92%
Net revenues	\$ 17,547	\$ 11,771	49%	\$ 27,739	\$ 23,507	18%

**Net Revenues**

As described in more detail below, the 49% increase in net revenues for the three months ended June 30, 2006 as compared to the same period in 2005 was primarily attributable to the product 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 inventory restocking.

As described in more detail below, the 18% increase in net revenues for the six months ended June 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 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-DolEstradot<sup>®</sup>, CombiPatch<sup>®</sup> and Vivelle<sup>®</sup> 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-Dol and Vivelle<sup>®</sup>.

**Table of Contents**

The \$0.9 million increase in product revenues from Novogyne for the three months ended June 30, 2006 as compared to the same period in the prior year primarily related to a \$0.8 million, \$0.3 million, and \$0.2 million increase in unit sales of Vivelle-Dot, Vivelle<sup>®</sup> and Estradot<sup>®</sup>, respectively, partially offset by a \$0.4 million decline in CombiPatch<sup>®</sup> unit sales. The increase in Vivelle-Dot related to the timing of sample shipments to Novogyne and the increases in Vivelle<sup>®</sup> and Estradot<sup>®</sup> were attributable to the timing of trade product orders. The decline in CombiPatch<sup>®</sup> 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 \$0.5 million decline in product revenues from Novogyne for the six months ended June 30, 2006 as compared to the same period in the prior year primarily related to a \$0.5 million decline in both unit sales of Vivelle-Dot and CombiPatch<sup>®</sup>, respectively, partially offset by a \$0.5 million increase in royalties. The decline in Vivelle-Dot was primarily attributable to a \$1.3 million decline in unit sales of trade product partially offset by a \$0.8 million increase in unit sales of samples. 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 samples and the decline in CombiPatch<sup>®</sup> were attributable to the same factors as discussed above for the comparable three-month periods. The increase in royalties was attributable to higher sales by Novogyne for the six months ended June 30, 2006.

**Product Revenues – Third Parties**

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

The \$2.1 million increase in product revenues from third parties for the three months ended June 30, 2006 as compared to the same period in the prior year primarily related to a \$3.6 million and a \$0.3 million increase in Daytrana and Femiest (the brand equivalent of Menorest in Japan) unit sales, respectively, partially offset by a \$1.0 million and \$0.8 million decline in unit sales of Estalis<sup>®</sup> and Estradot<sup>®</sup>, respectively. Changes in product pricing were not a contributing factor for the period. The increase in Daytrana was due to the initial product launch that occurred during the period while the increase in Femiest is attributable to the timing of orders. The decline in Estalis and Estradot was primarily attributable to inventory restocking in the prior period by Novartis Pharma.

The \$1.9 million increase in product revenues from third parties for the six months ended June 30, 2006 as compared to the same period in the prior year primarily related to a \$3.6 million increase in unit sales of Daytrana partially offset by a decline in unit sales of \$0.8 million, \$0.3 million and \$0.2 million of Estalis<sup>®</sup>, Menorest, and Estradot<sup>®</sup>, respectively. In addition, the six month period included a decline of \$0.4 million related to pricing. The increase in Daytrana and the decrease in Estalis<sup>®</sup> and Estradot<sup>®</sup> are attributable to the same factors as discussed above for the three-month comparable periods. The decline in Menorest is attributable to the continued transition from Menorest to Estradot<sup>®</sup>. The decline related to pricing was due to a decline in price reconciliation payments from Novartis Pharma.

**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

**Table of Contents**

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

Contract revenues were approximately the same for the three and six months ended June 30, 2006 as compared to the same periods in the prior year. License revenues increased \$2.9 million and \$2.7 million for the three and six months ended June 30, 2006, respectively, due primarily to the recognition in the three months ended June 30, 2006 of \$2.0 million in deferred license revenues related to Daytrana and the recognition of a \$1.0 million one-time 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).

**Gross Margin Total**

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

	Three Months		Six Months	
	2006	2005	2006	2005
<b>Gross Margin Total:</b>				
Product revenues	\$ 13,304	\$ 10,360	\$ 21,951	\$ 20,490
Cost of products sold	11,887	5,236	18,027	11,110
Gross profit (product revenues less cost of products sold)	1,417	5,124	3,924	9,380
Gross margin (gross profit as a percentage of product revenues)	11%	49%	18%	46%

Our overall gross margin was materially and adversely affected by a negative gross margin on product sales of Daytrana (i.e. the costs we incurred to produce the product were greater than the revenues we realized from the sales of that product). The negative Daytrana gross margin resulted primarily from start-up expenses associated with commencing production of Daytrana, and production inefficiencies including lower than desired yields and increased costs associated with meeting launch timelines. For the reasons discussed below in **Gross Margin Sales to Third Parties**, we believe that Daytrana gross margins will improve significantly in the second half of 2006. The quarter ended June 30, 2006 included \$2.0 million in license revenues related to Daytrana that are not included in the calculation of gross margin.

Other factors adversely affecting our overall gross margin included increased personnel and other resources dedicated to quality control in our HT operations (which increased approximately \$0.3 million and \$0.6 million for the three and six months ended June 30, 2006, respectively, in relation to the comparable 2005 periods); a higher percentage of sample product in our sales to Novogyne (which has a lower margin than trade product sold to Novogyne); and lower production volume in our HT business due to the timing of orders.

Over the past two years, we expanded our facilities and increased staffing for the production of fentanyl, Daytrana and other developmental products. Our results of operations and gross margins for future periods are expected to continue to be adversely affected by these actions and the related continuing overhead expenses unless and until we are able to improve the utilization of these resources through the commercialization of additional products or reduce overhead expenses. Although we are implementing programs intended to reduce overhead, no assurance can be given



**Table of Contents**

that we will be able to improve the utilization of these resources or meaningfully reduce overhead expenses.

Changes in deferred profit on Noven's sale of product to Novogyne (as described below in Gross Margin Novogyne) did not materially affect our overall gross margins for the three or six month period ended June 30, 2006.

Gross Margin - Sales to Novogyne

	Three Months		Six Months	
	2006	2005	2006	2005
<b>Gross Margin Novogyne:</b>				
Product revenues	\$ 7,288	\$ 6,427	\$ 12,064	\$ 12,519
Cost of products sold	4,459	2,449	6,602	5,698
Gross profit (product revenues less cost of products sold)	2,829	3,978	5,462	6,821
Gross margin (gross profit as a percentage of product revenues)	39%	62%	45%	54%
Changes in deferred profit on sales of product to Novogyne <sup>1</sup>	71	148	(226)	290
Gross profit excluding changes in deferred profit on sales of product to Novogyne <sup>1</sup>	2,900	4,126	5,236	7,111
Gross margin excluding impact of deferred profit <sup>1</sup>	40%	64%	43%	57%

<sup>1</sup> 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. As a result of our 49% equity investment in Novogyne, we are required to defer 49% of our profit on product that we sell to Novogyne until that product is sold by

Novogyne to trade customers. Since our cost of products sold is adjusted to reflect changes in deferred profit, our gross margin can vary from period to period based on the timing of our shipments to Novogyne and Novogyne's sale of our products to trade customers. If Novogyne sells more product than we provide it in a given period (i.e., if Novogyne's inventories decline), we will defer less profit from sales to Novogyne. In light of the significant historic fluctuations in our deferred profit on sales of product to Novogyne, we have also disclosed our gross margin net of the changes in deferred profit on sales of product to Novogyne, which, Noven's management believes, is useful to investors in order to

meaningfully evaluate Noven's ongoing, underlying business and compare Noven's financial results for the three and six months ended June 30, 2006 to those in the same period of 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.

Gross margin on product sales to Novogyne for the three and six months ended June 30, 2006 declined due to 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 18% and 14% of total product sales to Novogyne, not including royalties, for the three and six months ended

**Table of Contents**

June 30, 2006, respectively, as compared to 3% for each of the comparable periods in 2005. In addition, increased personnel and other resources dedicated to quality control in our HT operations, and to a lesser extent lower production volume of trade product due to the timing of orders, contributed to the decline in gross margin.

**Gross Margin Sales to third parties**

	Three Months		Six Months	
	2006	2005	2006	2005
<b>Gross Margin Third Parties:</b>				
Product revenues	\$ 6,016	\$ 3,933	\$ 9,887	\$ 7,971
Cost of products sold	7,428	2,787	11,425	5,412
Gross (loss) profit (product revenues less cost of products sold)	(1,412)	1,146	(1,538)	2,559
Gross margin (gross profit as a percentage of product revenues)	(23%)	29%	(16%)	32%

Gross margin on sales to third parties for the three and six months ended June 30, 2006 declined due to increased cost of products sold resulting from start-up manufacturing expenses associated with Daytrana, increased personnel and other resources dedicated to quality control in our HT operations, and to a lesser extent lower production volume in our HT business due to the timing of orders.

For the three month period ended June 30, 2006, Daytrana product revenues were \$3.6 million and cost of products sold related to Daytrana were \$5.0 million. The quarter ended June 30, 2006 included \$2.0 million in license revenues related to Daytrana that are not included in the calculation of gross margin as presented. We estimate that approximately \$1.4 million of the Daytrana costs resulted from start-up costs associated with the initial commercial production of Daytrana, including increased costs associated with meeting launch timelines. These start-up costs are not expected to continue as Daytrana moves past the initial start-up phase of production. We are also implementing programs designed to increase Daytrana production yields and reduce manufacturing costs, which contributed to our negative margins for Daytrana. Although no assurance can be given that these programs will be successful, we believe these programs, coupled with the reduction or elimination of start-up expenses, will cause Daytrana gross margins to improve significantly in the second half of 2006.

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 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 six months ended June 30, 2006, we reimbursed Shire approximately \$0.4 million for excess AMI used in production, which amount is included in costs of products sold.

Our ability to produce Daytrana and improve the gross margins from the sale of this product is contingent on, among other things, receiving a sufficient supply of the AMI from Shire as well as sufficient quota from the Drug Enforcement Agency ( DEA ) for this controlled substance. At any given time, we expect to have applications pending with the DEA for annual or additional procurement quota that may be critical to continued production. Any delay or stoppage in the supply of the AMI could cause us to lose revenues or incur additional costs (including those related to expedited production), which could have an adverse effect on our results of operations.

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

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

	Three Months			Six Months		
	2006	2005	% Change	2006	2005	% Change
Research and development	\$2,890	\$3,033	(5%)	\$ 6,372	\$5,926	8%
Marketing, general and administrative	5,638	4,189	35%	10,376	8,244	26%

**Research and Development**

Research and development expense includes 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 June 30, 2006 was primarily attributable to a \$1.2 million decline in development engineering related to our fentanyl transdermal system. This was partially offset by a \$0.5 million increase in production for clinical and regulatory purposes related to Daytrana and other products, \$0.2 million increase in testing supplies, \$0.1 million increase in clinical trial costs and \$0.1 million of stock-based compensation.

The increase in research and development expenses for the six months ended June 30, 2006 was primarily attributable to a \$1.1 million increase in development engineering and production for clinical and regulatory purposes related to Daytrana, \$0.7 million increase in pre-clinical and clinical costs related to other products under development, \$0.3 million in personnel costs, \$0.2 million in stock-based compensation expense and \$0.2 million increase in the purchase of testing supplies. These increases were partially offset by a \$2.3 million decline in development engineering related to our fentanyl transdermal system.

**Marketing, General and Administrative**

Our increase in marketing, general and administrative expenses for the three months ended June 30, 2006 was primarily attributable to \$0.7 million in stock-based compensation, \$0.6 million in salary and related benefits and \$0.1 million increase in professional fees in connection 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 compensation consulting costs.

Our increase in marketing, general and administrative expenses for the six months ended June 30, 2006 was primarily attributable to \$1.1 million in stock based compensation, a \$0.6 million increase in salary and related benefits and a \$0.3 million increase in professional fees in connection 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 \$0.1 million reduction in compensation consulting costs.

**Table of Contents**

**Other Income and Expenses**

*Interest Income*

Interest income for the three and six months ended June 30, 2006 rose by \$0.5 million and \$0.6 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 34% and 36% for the six months ended June 30, 2006 and 2005, respectively. The decline in our effective tax rate was primarily caused by our non-taxable interest income exclusion representing a higher proportion of our income before taxes thereby creating a lower effective tax rate. The higher non-taxable interest income is due to higher investments in short term investments due to increased cash balances primarily driven by the receipt of the \$50 million Daytrana approval milestone. The provision for income taxes is based on the Federal statutory and state income tax rates. Net deferred income tax assets are measured using the average graduated tax rate for the estimated amount of annual taxable income in the years that the liability is expected to be settled or the asset recovered. The effect of adjusting the expected tax rate related to the net deferred income tax assets is included in the provision for income taxes. As of June 30, 2006, we had a net deferred tax asset of \$12.6 million. Realization of this deferred tax asset depends upon the generation of sufficient future taxable income. Although realization is not assured, we believe it is more likely than not that the deferred income tax asset will be realized based upon estimated future taxable income.

*Equity in Earnings of Novogyne*

We share in the earnings of Novogyne according to an established formula after satisfaction of an annual preferred return of \$6.1 million to Novartis. Our share of Novogyne's earnings (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.

**Table of Contents**

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

	Three Months			Six Months		
	2006	2005	% Change	2006	2005	% Change
Gross revenues <sup>1</sup>	\$ 35,665	\$ 35,211	1%	\$ 72,934	\$ 62,545	17%
Sales allowances	3,546	3,676	(4%)	7,339	7,071	4%
Sales returns allowances	1,487	(401)	N/M	3,383	865	291%
<b>Sales and returns allowances</b>	<b>5,033</b>	<b>3,275</b>	<b>54%</b>	<b>10,722</b>	<b>7,936</b>	<b>35%</b>
Net revenues	30,632	31,936	(4%)	62,212	54,609	14%
Cost of sales <sup>2</sup>	7,162	7,307	(2%)	14,683	13,407	10%
Gross profit	23,470	24,629	(5%)	47,529	41,202	15%
Gross margin percentage	77%	77%		76%	75%	
Selling, general and administrative expenses	9,596	7,770	24%	18,753	16,440	14%
Income from operations	13,874	16,859	(18%)	28,776	24,762	16%
Interest income	162	42	286%	314	135	133%
Net income	\$ 14,036	\$ 16,901	(17%)	\$ 29,090	\$ 24,897	17%
Noven's equity in earnings of Novogyne	\$ 6,762	\$ 8,101	(17%)	\$ 11,089	\$ 9,013	23%

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 \$3.1 million for each of the three and six months ended June 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's gross revenues increased \$0.5 million for the three months ended June 30, 2006 compared to the same period in the prior year, primarily due to a \$0.9 million increase in sales of Vivelle-Dot and a \$0.5 million increase in unit sales of Estradot® to Canada, partially offset by a \$0.5 million decline in unit sales of CombiPatch®. In addition, Vivelle®, our first generation estrogen patch declined \$0.4 million in unit sales. We expect to complete our planned discontinuation of Vivelle® production by the end of 2006. The higher Vivelle-Dot unit sales were primarily attributable to a \$1.1 million increase related to pricing, offset by a \$0.2 million decrease in unit sales attributable to



the timing of orders. The \$0.5 million increase in sales of Estradot<sup>®</sup> was attributable to timing of orders as sales are expected to be in line with 2005 results.

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.

**Table of Contents**

Approximately \$0.6 million of the CombiPatch<sup>®</sup> decrease was due to a decline in unit sales which we believe is a result of the continuing decline in the market for combination therapies after the publication of the combination arm of the WHI and other studies on combination therapy products as well as the impact of a competitive product. This decline was partially offset by a \$0.1 million CombiPatch<sup>®</sup> increase related to price increases.

Novogyne's gross revenues increased \$10.4 million for the six months ended June 30, 2006 compared to the same period in the prior year, primarily due to an \$11.0 million increase in sales of Vivelle-Dot and a \$0.1 million increase in sales of Estradot<sup>®</sup> to Canada, partially offset by a \$0.2 million decline in sales of CombiPatch<sup>®</sup>. In addition, Vivelle<sup>®</sup> declined \$0.5 million in unit sales. The higher Vivelle-Dot sales were primarily attributable to an \$8.3 million increase in unit sales as well as a \$2.7 million increase related to pricing. The increase in unit sales is a result of the higher prescription trends as compared to the same period in the prior year. The increase in sales of Estradot<sup>®</sup> were attributable to the same factors as discussed above for the three month comparable periods. The decline in CombiPatch<sup>®</sup> is primarily attributable to a \$0.5 million decline in unit sales as a result of the declining market and the impact of a competitive product, partially offset by a \$0.3 million increase related to pricing.

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 10% of gross revenues for each of the three months ended June 30, 2006 and 2005, and 10% and 11% of gross revenues for the six months ended June 30, 2006 and 2005, respectively.

Sales returns allowances consist of: (i) allowances for returns of expiring product, and (ii) allowances for returns for product recalls. The activity for sales returns allowances for the three and six months ended June 30, 2006 and 2005 was as follows:

	Three Months		Six Months	
	2006	2005	2006	2005
Changes in allowances for returns of expiring product	\$ 1,487	\$ (338)	\$ 3,383	\$ 928
Changes in allowances for returns for product recalls		(63)		(63)
Net change in sales returns allowances	\$ 1,487	\$ (401)	\$ 3,383	\$ 865
Actual returns for expiring product	\$ (1,149)	\$ (767)	\$ (2,320)	\$ (1,695)
Actual returns for product recalls		(40)		(40)
Actual returns for the period	\$ (1,149)	\$ (807)	\$ (2,320)	\$ (1,735)

The increase in allowances for returns of expiring product for the three and six months ended June 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<sup>®</sup>. In addition, the three and six months ended June 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<sup>®</sup> at the time. The current three and six month period did not benefit from such a reduction.

**Novogyne Gross Margin**

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

**Table of Contents****Novogyne Selling, General and Administrative Expenses**

Novogyne's selling, general and administrative expenses for the three months ended June 30, 2006 increased \$1.8 million compared to the same period in 2005, due primarily to a \$0.9 million increase in sample expense due to timing of shipments from Noven, a \$0.7 million increase in administrative, advertising and promotional expenses and a \$0.5 million increase in litigation expenses related to HT litigation.

Novogyne's selling, general and administrative expenses for the six months ended June 30, 2006 increased \$2.3 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 \$0.7 million increase in administrative, advertising and promotional expenses and a \$0.7 million increase in litigation expenses related to HT litigation.

**Liquidity and Capital Resources**

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

	June 30, 2006	December 31, 2005
Cash and cash equivalents	\$ 11,570	\$ 66,964
Short-term investments	114,660	17,900
Working capital	137,656	91,122

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

	Six Months	
	2006	2005
Cash flows:		
Operating activities	\$ 45,619	\$(12,206)
Investing activities	(101,766)	(49,423)
Financing activities	753	1,004

***Operating Activities***

Net cash provided by operating activities for the six months ended June 30, 2006 primarily resulted from the receipt of \$50.0 million related to the Daytrana approval and \$10.2 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 six months ended June 30, 2005 primarily resulted from changes in working capital due to the timing of certain payments, including those related to expenses incurred in pursuit of Daytrana regulatory approval, purchases of fentanyl, compensation and related liabilities and insurance payments. These payments were offset by \$8.9 million in distributions from Novogyne.

**Table of Contents**

***Investing Activities***

Net cash used in investing activities for the six months ended June 30, 2006 was primarily attributable to \$96.8 million in net purchases of short-term investments, as well as the purchase of \$4.4 million in fixed assets to expand production capacity for future products.

Net cash used in investing activities for the six months ended June 30, 2005 was primarily attributable to \$44.6 million in net purchases of short-term investments, as well as the purchase of \$4.6 million in fixed assets to expand production capacity for future products. Beginning in the first quarter of 2005, Noven invested a portion of its cash in short-term investments, which primarily consist of investment grade, asset backed, variable rate debt obligations and municipal auction rate securities, which are categorized as available-for-sale under the provisions of SFAS No. 115 Accounting for Certain Investments in Debt and Equity Securities .

***Financing Activities***

Net cash provided by financing activities for the six months ended June 30, 2006 and June 30, 2005 was primarily attributable to \$0.8 million and \$1.1 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 six months ended June 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 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.

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.

Capital expenditures were \$4.4 million for the six months ended June 30, 2006. We expect to continue to invest in capital expenditures during 2006 as we continue to expand our manufacturing and storage facilities for products under development, but we expect such expenditures to be significantly below 2005 levels. We expect to fund these capital expenditures from our existing cash balances. As a general matter, we believe that we have sufficient liquidity available to meet our operating needs and anticipated short-term capital requirements.

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

**Table of Contents**

fund plant and equipment purchases to expand production capacity for new products. If our products under development with Shire, Endo Pharmaceuticals Inc., Procter & Gamble Pharmaceuticals, Inc. and others 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 as well as in Part II Item 1A of this quarterly report on Form 10-Q.

Our cash and short-term investments are available for potential strategic acquisitions of technologies, products or businesses complementary to our business. 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 debt securities. If a material acquisition is completed, our results of operations and financial condition could change materially in future periods.

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 and 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 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:

*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

**Table of Contents**

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 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. This interpretation 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

**Table of Contents**

reporting period that begins after December 15, 2006. As we believe we currently perform both the recognition and measurement process prescribed by FIN 48, we do not expect that the adoption of this interpretation will have a material impact on our results of operations, financial condition and cash flows.

**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 stock-based 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);

disruptions in supply of AMI necessary for the production of Daytrana, whether due to the failure to receive sufficient procurement quota from the DEA, Shire's inability to provide us with AMI or otherwise;

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 this quarterly report on Form 10-Q.

*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 \$1.5 million of such expenses recorded in the first six 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. 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.

**Table of Contents**

*HT Product Revenues.* Given customer orders, prescription trends and other factors, we expect HT product revenues for full-year 2006 to approximate 2005 levels.

*Gross Margin.* Over the past two years, we expanded our facilities and increased staffing for the production of fentanyl, Daytrana and other developmental products. Our results of operations and gross margins for future periods are expected to continue to be adversely affected by these actions and the related continuing overhead expenses unless and until we are able to improve the utilization of these resources through the commercialization of additional products or reduce overhead expenses, and no assurance can be given that we will be able to improve the utilization or meaningfully reduce overhead. In addition, our overall gross margin in the first half of 2006 was materially and adversely affected by costs and inefficiencies associated with the start-up of commercial production of Daytrana. We are working to reduce costs and improve yields, and although we cannot assure that we will be successful, we expect to report significant improvement in our overall gross margin in the second half of 2006 compared to first half levels.

*Research and Development.* We expect our research and development expense in 2006 to increase in the 10% range compared to full-year 2005 levels. We are working to formulate certain new transdermal products that, if successfully formulated, may enter human studies during 2006. These studies, if initiated, would be funded by Noven and would cause our research and development expense in 2006 to increase substantially over 2005 levels.

*Marketing, General and Administrative Expense.* We expect Noven's marketing, general and administrative expense to increase in the 20% - 25% range over 2005 levels, primarily reflecting stock-based compensation expenses that commenced in 2006.

*Novogyne.* Based on current prescription trends and other factors, we expect an increase in Novogyne's full-year 2006 net income approaching 10% over 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.

**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 Securities and Exchange Commission filings. However, that conclusion should be considered in light of the various limitations described below on the effectiveness of those controls and procedures, some of which pertain to most if not all business enterprises, and some of which arise as a result of the nature of our business. Our management, including the Chief Executive Officer and Chief Financial Officer, does



**Table of Contents**

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

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

**Table of Contents**

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

In September 2005, Noven, Novogyne and Novartis were served with a summons and complaint from an individual 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<sup>®</sup>. The plaintiff claims compensatory, punitive and other damages in an unspecified amount. We do not expect any activity in this case in the near future, as the court has indicated that it intends 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 our CombiPatch<sup>®</sup> product. The plaintiffs claim compensatory and other damages in an unspecified amount.

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<sup>®</sup> in one case and CombiPatch<sup>®</sup> in two of the cases. The plaintiffs in each case claim compensatory and other damages in an unspecified amount.

Novartis has advised us that Novartis has been named as a defendant in at least 26 additional lawsuits that include approximately 33 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<sup>®</sup>, and CombiPatch<sup>®</sup> products. In addition, in July 2006, Novartis was named as a defendant in at least 71 additional lawsuits (along with several other defendants) in which the plaintiff's complaints do not identify the HT products used by the plaintiffs and therefore these cases may also involve our 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.

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**

Except as described below, there have been no material changes to the risk factors previously disclosed in our Form 10-K. These risk factors may cause our results to differ from the forward-looking statements made in this report or otherwise made by or on our behalf. The risks and uncertainties described in the Form 10-K 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**

**If we are unable to improve our margins on Daytrana our results of operations will be adversely affected.**

The price at which we sell Daytrana to Shire is determined in accordance with the terms of our Toll Conversion and Supply Agreement with Shire. Because the price at which we sell Daytrana to Shire is generally fixed, our margin on sales of Daytrana is determined by the production costs we incur to produce the product. For both the three months and the six months ended June 30, 2006, our gross margin on Daytrana was negative (i.e. the costs we incurred to produce the product were greater than the revenue we realized from the sales of that product). The negative gross margin resulted primarily from start-up expenses associated with the production of Daytrana, and production inefficiencies including lower than desired yields and increased costs associated with meeting launch timelines. If we are unable to improve production yields and reduce our costs of production for Daytrana, we will be unable to improve our margin on sales of the product and our operating results will be adversely affected. Our ability to produce Daytrana and improve the gross margins from the sale of this product is contingent on, among other things, receiving a sufficient supply of the AMI from Shire as well as sufficient quota from the DEA for this controlled substance. At any given time, we expect to have applications pending with the DEA for annual or additional procurement quota that may be critical to continued production. Any delay or stoppage in the supply of the AMI could cause us to lose revenues or incur additional costs (including those related to expedited production), which could have an adverse effect on our results of operations.

**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 first quarter of 2006:

	Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Program	Approximate Dollar Value That May Yet be Purchased under the Program <sup>(1)</sup>
April 1, 2006 to April 30, 2006				\$23,711,040
May 1, 2006 to May 31, 2006				\$23,711,040
June 1, 2006 to June 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 4. Submission of Matters to a Vote of Security Holders**

The following proposals were approved at our Annual Meeting of Stockholders held on May 23, 2006:

1. **Election of Directors**

	<b>For</b>	<b>Withheld</b>
Sidney Braginsky	21,220,785	442,153
John G. Clarkson, M.D.	21,439,298	223,640
Donald A. Denkhaus	21,547,119	115,819
Pedro P. Granadillo	21,480,199	182,739
Robert G. Savage	21,480,299	182,639
Robert C. Strauss	21,530,540	132,398
Wayne P. Yetter	21,533,445	129,493

2. **Ratification of the Appointment of Deloitte & Touche LLP as Noven's Independent Registered Public Accounting Firm for 2006****For****Against****Abstained**

21,608,167

10,279  
40

44,492

---

**Table of Contents**

**Item 6. Exhibits**

- 10.1 Form of Restricted Stock Agreement (incorporated by reference to Exhibit 10.1 of Noven's Form 8-K dated May 22, 2006 (File No. 0-17254))
- 10.2 Changes to Compensation and Reimbursement Practices for Non-employee Directors (incorporated by reference to Noven's Form 8-K dated May 22, 2006 (File No. 0-17254))
- 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

**Table of Contents**

Signatures

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

NOVEN PHARMACEUTICALS, INC.

Date: August 9, 2006

By: /s/ Diane M. Barrett

Diane M. Barrett  
Vice President and  
Chief Financial Officer

42