

NOVEN PHARMACEUTICALS INC

Form 10-Q

May 07, 2007

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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q**

**Quarterly Report Pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934
For the quarterly period ended March 31, 2007
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 April 30, 2007
Common stock \$.0001 par value	24,837,695

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<u>Cautionary Factors:</u> 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, 2006 as supplemented by Part II Item 1A Risk Factors of the quarterly reports on Form 10-Q filed in 2007, as well as other reports filed from time to time with the Securities and Exchange Commission.	
<u>Trademark Information:</u> Vivelle®, Vivelle-Dot®, Estradot® and Menorest are trademarks of Novartis AG or its affiliated companies; CombiPatch® and Estalis® are registered trademarks of Vivelle Ventures LLC; and Daytrana is a trademark of Shire Pharmaceuticals Ireland Limited.	

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements**NOVEN PHARMACEUTICALS, INC.**

Condensed Statements of Operations
 Three Months Ended March 31,
 (in thousands, except per share amounts)
 (unaudited)

	2007	2006
Revenues:		
Product revenues Novogyne:		
Product sales	\$ 5,369	\$ 3,087
Royalties	1,765	1,689
Total product revenues Novogyne	7,134	4,776
Product revenues third parties	8,472	3,871
Total product revenues	15,606	8,647
Contract and license revenues:		
Contract	(130)	664
License	3,839	881
Contract and license revenues	3,709	1,545
Net revenues	19,315	10,192
Expenses:		
Cost of products sold Novogyne	2,959	2,143
Cost of products sold third parties	5,968	3,997
Total cost of products sold	8,927	6,140
Research and development	3,466	3,482
Marketing, general and administrative	5,421	4,738
Total expenses	17,814	14,360
Income (loss) from operations	1,501	(4,168)
Equity in earnings of Novogyne	4,903	4,327
Interest income, net	1,632	611
Income before income taxes	8,036	770

Provision for income taxes	3,000	266
Net income	\$ 5,036	\$ 504
Basic earnings per share	\$ 0.20	\$ 0.02
Diluted earnings per share	\$ 0.20	\$ 0.02
Weighted average number of common shares outstanding:		
Basic	24,738	23,657
Diluted	25,384	23,774

The accompanying notes are an integral part of these statements.

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

	March 31, 2007	December 31, 2006
<u>Assets</u>		
Current Assets:		
Cash and cash equivalents	\$ 34,625	\$ 9,144
Short-term investments available-for-sale, at fair value	149,869	144,455
Trade receivable (less allowance for doubtful accounts of \$52 in 2007 and \$67 in 2006)	4,693	5,038
Milestone payment receivable - Shire		25,000
Accounts receivable - Novogyne, net	8,109	7,693
Inventories	9,660	8,651
Net deferred income tax asset, current portion	6,900	4,400
Prepaid income taxes	11	3,416
Prepaid and other current assets	2,784	2,410
	216,651	210,207
Property, plant and equipment, net	36,605	37,010
Other Assets:		
Investment in Novogyne	18,439	23,296
Net deferred income tax asset	9,195	8,308
Patent development costs, net	2,253	2,317
Deposits and other assets	501	227
	30,388	34,148
	\$ 283,644	\$ 281,365
<u>Liabilities and Stockholders' Equity</u>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 4,572	\$ 5,184
Capital lease obligation - current portion	122	109
Accrued compensation and related liabilities	2,895	5,308
Other accrued liabilities	3,899	2,085
Deferred rent credit	89	89
Deferred contract revenues	1,477	1,527
Deferred license revenues - current portion	14,994	15,084
	28,048	29,386
Long-Term Liabilities:		
Capital lease obligation	247	279
Deferred license revenues	70,439	74,188
Other liabilities	1,076	837

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	99,810	104,690
Commitments and Contingencies (Note 12)		
Stockholders' Equity:		
Preferred stock authorized 100,000 shares of \$.01 par value; no shares issued or outstanding		
Common stock authorized 80,000,000 shares, par value \$.0001 per share; issued and outstanding 24,770,532 at March 31, 2007 and 24,661,169 at December 31, 2006	2	2
Additional paid-in capital	112,565	109,912
Retained earnings	71,267	66,761
Common stock held in trust	(375)	
Deferred compensation obligation	375	
	183,834	176,675
	\$ 283,644	\$ 281,365

The accompanying notes are an integral part of these statements.

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NOVEN PHARMACEUTICALS, INC.
Condensed Statements of Cash Flows
Three Months Ended March 31,
(in thousands)
(unaudited)

	2007	2006
Cash flows from operating activities:		
Net income	\$ 5,036	\$ 504
Adjustments to reconcile net income to net cash flows provided by (used in) operating activities:		
Depreciation, amortization and certain other noncash items	1,301	1,012
Stock-based compensation expense	988	549
Income tax benefits on exercise of stock options	253	137
Excess tax deduction from exercise of stock options	(195)	(137)
Deferred income tax benefit	(3,387)	(9)
Recognition of deferred license revenues	(3,839)	(881)
Equity in earnings of Novogyne	(4,903)	(4,327)
Distributions from Novogyne	9,760	7,318
Changes in operating assets and liabilities:		
Decrease (increase) in trade receivable, net	345	(1,181)
Decrease in milestone payment receivable Shire	25,000	
(Increase) decrease in accounts receivable Novogyne, net	(416)	3,488
Increase in inventories	(1,009)	(2,537)
Decrease in prepaid income taxes	3,405	135
Increase in prepaid and other current assets	(374)	(657)
Increase in deposits and other assets	(1)	(15)
Decrease in accounts payable and accrued expenses	(612)	(1,410)
Decrease in accrued compensation and related liabilities	(2,413)	(3,314)
Increase in other accrued liabilities	1,284	188
Decrease in deferred contract revenue, net	(50)	(231)
Increase in deferred license revenue		1,000
Increase in other liabilities	252	31
Amounts recoverable from Shire and offset against deferred license revenue related to Daytrana approval		61
Cash flows provided by (used in) operating activities	30,425	(276)
Cash flows from investing activities:		
Purchases of property, plant and equipment, net	(689)	(2,429)
Payments for patent development costs, net	(66)	(182)
Purchase of company-owned life insurance	(260)	(185)
Purchases of short-term investments	(226,470)	(285,375)
Proceeds from sale of short-term investments	220,953	252,350
Cash flows used in investing activities	(6,532)	(35,821)
Cash flows from financing activities:		
Issuance of common stock from exercise of stock options	1,412	444
Excess tax benefit from exercise of stock options	195	137
Payments under capital leases	(19)	(30)

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Cash flows provided by financing activities	1,588	551
Net increase (decrease) in cash and cash equivalents	25,481	(35,546)
Cash and cash equivalents, beginning of period	9,144	66,964
Cash and cash equivalents, end of period	\$ 34,625	\$ 31,418

The accompanying notes are an integral part of these statements.

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NOVEN PHARMACEUTICALS, INC.

Notes to Unaudited Condensed Financial Statements

1. DESCRIPTION OF BUSINESS:

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

Noven and Novartis Pharmaceuticals Corporation (Novartis) entered into a joint venture, Vivelle Ventures LLC (d/b/a Novogyne Pharmaceuticals) (Novogyne), effective May 1, 1998, to market and sell women s prescription healthcare products in the United States and Canada. These products include Noven s transdermal estrogen delivery systems marketed under the brand names Vivelle®, Vivelle-Dot® and CombiPatch®. Noven accounts for its 49% investment in Novogyne under the equity method and reports its share of Novogyne s earnings as Equity in earnings of Novogyne on its Condensed 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 March 31, 2007, and the results of its operations and its cash flows for the three months ended March 31, 2007 and 2006. 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, 2006 (Form 10-K), and as supplemented by Part II Item 1A Risk Factors of the quarterly reports on Form 10-Q filed in 2007. Accordingly, the results of operations and cash flows for the three months ended March 31, 2007 and 2006 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 2007 or for periods thereafter.

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

3. RECLASSIFICATIONS:

Certain reclassifications have been made to the prior period s balance sheet and statement of cash flows to conform to the current period s presentation.

4. CASH FLOW INFORMATION:

Cash payments for income taxes, net of refunds, were \$1.5 million and \$0.1 million for the three months ended March 31, 2007 and 2006, respectively. Cash payments for interest were not material for the three months ended March 31, 2007 and 2006.

Table of Contents**5. RECENT ACCOUNTING PRONOUNCEMENTS:**

In February 2007, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115 (SFAS 159). This Statement permits entities to choose to measure many financial instruments and certain other items at fair value and applies to all entities, including not-for-profit organizations. Most of the provisions of this statement apply only to entities that elect the fair value option. However, the amendment to FASB Statement No. 115, Accounting for Certain Investments in Debt and Equity Securities, applies to all entities with available-for-sale and trading securities. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. Early adoption is permitted as of the beginning of a fiscal year that begins on or before November 15, 2007, provided the entity also elects to apply the provisions of FASB Statement No. 157, Fair Value Measurements. Noven is currently assessing the impact of adopting SFAS 159 and is unable to estimate the impact it may have on Noven's results of operations and financial condition.

6. INVENTORIES:

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

	March 31, 2007	December 31, 2006
Finished goods	\$ 2,132	\$ 893
Work in process	2,256	2,851
Raw materials	5,272	4,907
Total	\$ 9,660	\$ 8,651

The Drug Enforcement Administration (DEA) controls access to controlled substances, including methylphenidate, the active ingredient in Daytrana. 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 manufacturing risks of loss related to the AMI. These risks include the contractual obligation of Noven to reimburse Shire for the cost of AMI if Noven does not meet certain yield requirements of the finished product. Shire has a reciprocal obligation to pay Noven if the yield requirements are exceeded. Noven slightly exceeded the yield requirements for the three months ended March 31, 2007, resulting in an immaterial payment from Shire to Noven. During the three months ended March 31, 2007, Noven used \$1.8 million of AMI in the finished product. Noven had \$2.0 million and \$1.0 million of consignment AMI inventory on hand at March 31, 2007 and December 31, 2006, respectively, which is not reflected in the table above.

7. EMPLOYEE STOCK PLANS:

Prior to January 1, 2006, all awards granted to employees under Noven's 1999 Long-Term Incentive Plan (the 1999 Plan) were stock options. In 2006, Noven began granting stock-settled stock appreciation rights (SSARs) to employees and non-vested shares (restricted stock) to non-employee directors in lieu of stock options. Noven accounts for these awards in accordance with Statement of Financial Accounting Standards No. 123 (revised 2004),

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Share-Based Payment . At March 31, 2007, there were 2,773,540 stock options and 403,041 SSARs issued and outstanding under the 1999 Plan.

In May 2006, Noven issued a total of 34,344 shares of restricted stock to its non-employee directors. 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. As the shares vest, those shares that have been deferred by non-employee directors under Noven's deferred compensation plan are transferred into a rabbi trust maintained by Noven. In accordance with Emerging Issues Task Force 97-14, Accounting for Compensation Arrangements Where Amounts Earned are Held in a Rabbi Trust and Invested, the deferred shares were recorded at its fair value and classified as common stock held in trust. Since the deferral relates to Noven common stock, an offsetting amount was recorded as deferred compensation obligation in the stockholders' equity section of the balance sheet. As of March 31, 2007, there were a total of 21,465 shares of common stock in the rabbi trust. As of March 31, 2007, there was no restricted stock outstanding as all shares of restricted stock previously issued were fully vested.

There were no stock-based compensation grants in the three months ended March 31, 2007. The assumptions used to value option grants for the three months ended March 31, 2006 were as follows:

Volatility	52.2%
Risk free interest rate	4.94%
Expected life (years)	5

Total stock-based compensation recognized in Noven's statements of operations for the three months ended March 31, 2007 and 2006 was as follows (in thousands):

	2007	2006
Marketing, general and administrative	\$ 739	\$ 397
Research and development	127	91
Cost of products sold	122	61
	\$ 988	\$ 549
Tax benefit recognized related to compensation expense	\$ 309	\$ 119

There were no stock-based compensation costs capitalized as part of inventory or fixed assets for the three months ended March 31, 2007 or 2006.

Cash received from options exercised under all share-based payment arrangements for the three months ended March 31, 2007 and 2006 was \$1.4 million and \$0.4 million, respectively. The tax benefit realized on the tax deductions from option exercises under stock-based compensation arrangements totaled \$0.3 million and \$0.1 million for the three months ended March 31, 2007 and 2006, of which \$0.2 million and \$0.1 million was reported as cash flow from financing activities for the three months ended March 31, 2007 and 2006, respectively.

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Stock option and SSARs transactions related to the 1999 Plan are summarized as follows for the three months ended March 31, 2007 (options/SSARs and aggregate intrinsic value in thousands):

	Options/ SSARs	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Term
Outstanding at beginning of the period	3,275	\$ 19.26		
Granted				
Exercised	(88)	16.42	\$ 853	
Canceled and expired	(10)	17.33		
Outstanding at end of the period	3,177	\$ 19.35	\$ 16,142	3.8
Outstanding and exercisable at end of period	2,059	\$ 21.12	\$ 8,179	3.0
Vested or expected to vest at end of period	2,775	\$ 19.52	\$ 13,803	3.8

As of March 31, 2007, the unamortized compensation expense that Noven expects to record in future periods related to currently outstanding unvested stock options, SSARs and restricted stock is approximately \$7.3 million before the effect of income taxes, of which \$2.5 million, \$2.4 million, \$1.6 million and \$0.8 million is expected to be incurred in the remainder of 2007 and in 2008, 2009 and 2010, respectively. The weighted-average period over which this compensation cost is expected to be recognized is 2 years.

8. ACCOUNTING FOR UNCERTAINTY IN INCOME TAXES:

On January 1, 2007, Noven adopted the provisions of, and began accounting for uncertainty in income taxes in accordance with, FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement 109 (FIN 48). This interpretation requires companies to determine whether it is more likely than not that a tax position will be sustained upon examination by the appropriate taxing authorities before any part of the benefit can be recorded in the financial statements. FIN 48 clarifies the accounting for income taxes by prescribing a minimum recognition threshold a tax position is required to meet before recognition in the financial statements. FIN 48 requires a two-step approach when evaluating a tax position based on recognition (Step 1) and measurement (Step 2).

Upon adoption of FIN 48, and as a result of the recognition and measurement of Noven's tax positions as of January 1, 2007, Noven recognized a charge of approximately \$0.5 million to the January 1, 2007 retained earnings balance. The gross amount of unrecognized tax benefits as of the date of adoption, January 1, 2007, was \$1.2 million, including \$0.3 million in interest and penalties. If the \$1.2 million were ultimately recognized, only \$0.9 million would affect the effective tax rate due to approximately \$0.3 million in federal benefit. As of March 31, 2007 the gross amount of unrecognized tax benefits was approximately \$1.4 million. Interest and penalties related to income taxes are classified as a component of income tax expense. It is reasonably possible that the gross amount of unrecognized tax benefits may increase by approximately \$0.6 million within 12 months of March 31, 2007.

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Noven is periodically audited by federal and state taxing authorities. The outcome of these audits may result in Noven being assessed taxes in addition to amounts previously paid. The years 2004–2006 remain open and subject to examination by the Internal Revenue Service. Noven files and remits state income taxes in various states where Noven has determined it is required to file state income taxes, and those states remain open for audit, inclusively, for the years 2002–2006. There are no examinations currently taking place related to income taxes in any jurisdiction. It is possible that examinations may be initiated by any jurisdiction where Noven operates, or where it can be determined that Noven operates, and the results of which can materially change the amount of unrecognized income tax benefits for tax positions taken, which may increase Noven's income tax liabilities or decrease the amount of deferred tax assets.

9. CONTRACT AND LICENSE AGREEMENTS:*Daytrana*

Noven has developed a once-daily transdermal methylphenidate patch for Attention Deficit Hyperactivity Disorder (ADHD) called Daytrana. In the first quarter of 2003 Noven licensed to Shire the exclusive global rights to market Daytrana for payments by Shire of up to \$150.0 million. In consideration for this licensing transaction, Shire agreed to pay Noven as follows: (i) \$25.0 million was paid upon closing of the transaction in April 2003; (ii) \$50.0 million was paid in April 2006 upon receipt of final marketing approval by the FDA; and (iii) three installments of \$25.0 million each are payable upon Shire's achievement of \$25.0 million, \$50.0 million and \$75.0 million in annual Daytrana net sales, respectively. Shire launched the product in June 2006. Shire's net sales of Daytrana exceeded the threshold for the first sales milestone in the fourth quarter of 2006 and, accordingly, Noven received a \$25.0 million payment from Shire in the first quarter of 2007. Noven is currently deferring and recognizing approval and sales milestones as license revenues on a straight-line basis, beginning on the date the milestone is achieved through the first quarter of 2013, which is Noven's current best estimate of the end of the useful economic life of the product. Noven also manufactures and supplies finished product for Shire.

Amphetamine Transdermal System

In addition to Noven's agreements with Shire related to Daytrana in June 2004 Noven entered into an agreement with Shire for the development of a transdermal amphetamine patch for ADHD, and in July 2006, Noven and Shire amended this agreement. Under the amended agreement, Shire paid Noven a non-refundable \$1.0 million in August 2006, in exchange for the option of purchasing, for an additional \$5.9 million, the exclusive developmental rights to the product. The amended agreement further provided that Noven would perform certain early-stage development activities which were previously to be performed by Shire. Noven completed a Phase I clinical study for the product in March 2007, and Shire is currently reviewing the results of this study to determine whether it will exercise its option to acquire the exclusive development rights to the product. If Shire does not exercise this option, rights to further develop the product will revert to Noven. The \$1.0 million was included in deferred contract revenues on Noven's balance sheet as of March 31, 2007.

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

Noven shares in the earnings of Novogyne, after satisfaction of an annual preferred return of \$6.1 million to Novartis, according to an established formula. Noven's share of Novogyne's earnings increases as Novogyne's product sales increase, subject to a cap of 49%. Novogyne earned sufficient income in the first quarter of 2007 and 2006 to meet Novartis' annual preferred return for those years and for Noven to recognize earnings from Novogyne under the formula.

During the three months ended March 31, 2007 and 2006, Noven had the following transactions with Novogyne (in thousands):

	2007	2006
Revenues:		
Product sales	\$ 5,369	\$ 3,087
Royalties	1,765	1,689
	\$ 7,134	\$ 4,776
Reimbursed expenses	\$ 7,085	\$ 7,269

As of March 31, 2007 and December 31, 2006, Noven had amounts due from Novogyne of \$8.1 million and \$7.7 million, respectively.

The unaudited condensed statements of operations of Novogyne for the three months ended March 31, 2007 and 2006 are as follows (in thousands):

	2007	2006
Gross revenues	\$ 37,293	\$ 37,269
Sales allowances	4,162	3,793
Sales return allowances	51	1,896
Sales allowances and returns	4,213	5,689
Net revenues	33,080	31,580
Cost of sales	7,047	7,521
Selling, general and administrative expenses	10,133	9,157
Income from operations	15,900	14,902
Interest income	332	152