

NOVEN PHARMACEUTICALS INC

Form 10-Q

August 08, 2007

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, 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
Common stock \$.0001 par value

Outstanding at July 31, 2007
24,851,829

NOVEN PHARMACEUTICALS, INC. AND SUBSIDIARIES
INDEX

	Page No.
<u>PART I FINANCIAL INFORMATION</u>	
<u>Item 1 Unaudited Condensed Consolidated Financial Statements</u>	
<u>Condensed Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2007 and 2006</u>	3
<u>Condensed Consolidated Balance Sheets as of June 30, 2007 and December 31, 2006</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2007 and 2006</u>	5
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	6
<u>Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	16
<u>Item 3 Quantitative and Qualitative Disclosures About Market Risk</u>	34
<u>Item 4 Controls and Procedures</u>	34
<u>PART II OTHER INFORMATION</u>	
<u>Item 1 Legal Proceedings</u>	35
<u>Item 1A Risk Factors</u>	35
<u>Item 4 Submission of Matters to a Vote of Security Holders</u>	38
<u>Item 5 Other Information</u>	39
<u>Item 6 Exhibits</u>	39
<u>SIGNATURES</u>	40
<u>EX-10.1 Letter Agreement between Shire and Noven</u>	
<u>EX-10.2 Amendment dated May 3, 2007, to Letter Agreement</u>	
<u>EX-10.3 Amendment dated June 4, 2007, to Letter Agreement</u>	
<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, 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.

Trademark Information: 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; Daytrana is a trademark of Shire Pharmaceuticals Ireland Limited; Lithobid[®] and Pexeva[®] are registered trademarks of JDS Pharmaceuticals, LLC.

Table of Contents**PART I. FINANCIAL INFORMATION**

Item 1 Unaudited Condensed Consolidated Financial Statements

NOVEN PHARMACEUTICALS, INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations

Three and Six Months Ended June 30,

(in thousands, except per share amounts)

(unaudited)

	Three Months		Six Months	
	2007	2006	2007	2006
Revenues:				
Product revenues Novogyne:				
Product sales	\$ 4,804	\$ 5,630	\$ 10,173	\$ 8,717
Royalties	1,899	1,658	3,664	3,347
Total product revenues Novogyne	6,703	7,288	13,837	12,064
Product revenues third parties	8,359	6,016	16,831	9,887
Total product revenues	15,062	13,304	30,668	21,951
Contract and license revenues:				
Contract	29	404	(101)	1,068
License	3,748	3,839	7,587	4,720
Contract and license revenues	3,777	4,243	7,486	5,788
Net revenues	18,839	17,547	38,154	27,739
Expenses:				
Cost of products sold Novogyne	3,285	4,459	6,244	6,602
Cost of products sold third parties	6,029	7,428	11,997	11,425
Total cost of products sold	9,314	11,887	18,241	18,027
Research and development	3,185	2,890	6,651	6,372
Marketing, general and administrative	5,709	5,638	11,130	10,376
Total expenses	18,208	20,415	36,022	34,775
Income (loss) from operations	631	(2,868)	2,132	(7,036)
Equity in earnings of Novogyne	9,174	6,762	14,077	11,089
Interest income, net	1,813	1,111	3,445	1,722

Edgar Filing: NOVEN PHARMACEUTICALS INC - Form 10-Q

Income before income taxes	11,618	5,005	19,654	5,775
Provision for income taxes	4,042	1,672	7,042	1,938
Net income	\$ 7,576	\$ 3,333	\$ 12,612	\$ 3,837
Basic earnings per share	\$ 0.31	\$ 0.14	\$ 0.51	\$ 0.16
Diluted earnings per share	\$ 0.30	\$ 0.14	\$ 0.50	\$ 0.16
Weighted average number of common shares outstanding:				
Basic	24,832	23,685	24,785	23,673
Diluted	25,379	24,071	25,381	23,925

The accompanying notes are an integral part of these statements.

Table of Contents**NOVEN PHARMACEUTICALS, INC. AND SUBSIDIARIES**

Condensed Consolidated Balance Sheets

(in thousands, except share data)

(unaudited)

	June 30, 2007	December 31, 2006
<u>Assets</u>		
Current Assets:		
Cash and cash equivalents	\$ 5,403	\$ 9,144
Short-term investments available-for-sale, at fair value	181,256	144,455
Trade receivable (less allowance for doubtful accounts of \$56 in 2007 and \$67 in 2006)	3,545	5,038
Milestone payment receivable Shire	25,000	25,000
Accounts receivable Novogyne, net	6,074	7,693
Inventories	9,564	8,651
Net deferred income tax asset, current portion	6,900	4,400
Prepaid income taxes	7,565	3,416
Prepaid and other current assets	3,240	2,410
	248,547	210,207
Property, plant and equipment, net	36,211	37,010
Other Assets:		
Investment in Novogyne	22,006	23,296
Net deferred income tax asset	12,469	8,308
Patent development costs, net	2,396	2,317
Deposits and other assets	1,768	227
	38,639	34,148
	\$ 323,397	\$ 281,365
<u>Liabilities and Stockholders Equity</u>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 4,690	\$ 5,184
Capital lease obligation current portion	126	109
Accrued compensation and related liabilities	4,376	5,308
Other accrued liabilities	4,743	2,085
Deferred rent credit	89	89
Deferred contract revenues	728	1,527
Deferred license revenues current portion	19,342	15,084
	34,094	29,386
Long-Term Liabilities:		

Edgar Filing: NOVEN PHARMACEUTICALS INC - Form 10-Q

Capital lease obligation	204	279
Deferred license revenues	87,343	74,188
Deferred contract revenues	6,875	
Other liabilities	1,165	837
	129,681	104,690

Commitments and Contingencies (Note 11)

Stockholders' Equity:

Preferred stock authorized 100,000 shares of \$.01 par value; no shares issued or outstanding

Common stock authorized 80,000,000 shares, par value \$.0001 per share; issued and outstanding 24,851,104 at June 30, 2007 and 24,661,169 at December 31, 2006

Additional paid-in capital	114,871	109,912
Retained earnings	78,843	66,761
Common stock held in trust	(500)	
Deferred compensation obligation	500	
	193,716	176,675
	\$ 323,397	\$ 281,365

The accompanying notes are an integral part of these statements.

Table of Contents**NOVEN PHARMACEUTICALS, INC. AND SUBSIDIARIES**

Condensed Consolidated Statements of Cash Flows

Six Months Ended June 30,

(in thousands)

(unaudited)

	2007	2006
Cash flows from operating activities:		
Net income	\$ 12,612	\$ 3,837
Adjustments to reconcile net income to net cash flows provided by operating activities:		
Depreciation, amortization and certain other noncash items	2,539	2,052
Stock-based compensation expense	1,976	1,529
Income tax benefits on exercise of stock options	462	256
Excess tax deduction from exercise of stock options	(392)	(214)
Deferred income tax benefit	(6,661)	(183)
Recognition of deferred license revenues	(7,587)	(4,720)
Equity in earnings of Novogyne	(14,077)	(11,089)
Distributions from Novogyne	10,975	10,210
Changes in operating assets and liabilities:		
Decrease (increase) in trade receivable, net	1,493	(2,947)
Decrease in accounts receivable Novogyne, net	1,619	1,845
(Increase) decrease in inventories	(913)	29
Decrease in prepaid income taxes	243	3,664
Increase in prepaid and other current assets	(830)	(1,057)
Increase in deposits and other assets		(15)
Decrease in accounts payable and accrued expenses	(494)	(6,179)
Decrease in accrued compensation and related liabilities	(932)	(2,164)
Increase in other accrued liabilities	2,128	375
Increase (decrease) in deferred contract revenue, net	6,076	(930)
Increase in deferred license revenue	25,000	51,000
Increase in other liabilities	342	92
Amounts recoverable from Shire and offset against deferred license revenue related to Daytrana approval		14
Cash flows provided by operating activities	33,579	45,405
Cash flows from investing activities:		
Purchases of property, plant and equipment, net	(1,421)	(4,405)
Payments for patent development costs, net	(348)	(416)
Payments for deferred acquisition costs	(1,241)	
Purchase of company-owned life insurance	(260)	(185)
Purchases of short-term investments	(767,769)	(685,035)
Proceeds from sale of short-term investments	730,864	588,275
Cash flows used in investing activities	(40,175)	(101,766)
Cash flows from financing activities:		
Issuance of common stock from exercise of stock options	2,521	822
Excess tax benefit from exercise of stock options	392	214
Payments under capital leases	(58)	(69)

Edgar Filing: NOVEN PHARMACEUTICALS INC - Form 10-Q

Cash flows provided by financing activities	2,855	967
Net decrease in cash and cash equivalents	(3,741)	(55,394)
Cash and cash equivalents, beginning of period	9,144	66,964
Cash and cash equivalents, end of period	\$ 5,403	\$ 11,570

The accompanying notes are an integral part of these statements.

5

Table of Contents

NOVEN PHARMACEUTICALS, INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated 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 Consolidated 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.

On July 9, 2007, Noven entered into an agreement to acquire JDS Pharmaceuticals, LLC (JDS). JDS is a privately-held specialty pharmaceutical company that currently markets two branded prescription psychiatry products through a targeted sales force and is advancing a pipeline of products in development (see Note 12 Subsequent Event).

2. BASIS OF PRESENTATION:

In management s opinion, the accompanying unaudited condensed consolidated financial statements of Noven contain all adjustments (consisting of only normal recurring adjustments) necessary to present fairly, in all material respects, the consolidated financial position of Noven, the consolidated results of its operations, and its cash flows for the periods presented. 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 periods presented 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 consolidated 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 consolidated 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.

Table of Contents**4. CASH FLOW INFORMATION:***Income Tax and Interest Payments*

Cash payments for income taxes, net of refunds, were \$14.1 million and \$0.2 million for the six months ended June 30, 2007 and 2006, respectively. Cash payments for interest were not material for the six months ended June 30, 2007 and 2006.

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. Through June 30, 2007 and in 2006, Novogyne paid \$4.4 million and \$2.2 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.

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 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):

	June 30, 2007	December 31, 2006
Finished goods	\$ 2,327	\$ 893
Work in process	2,273	2,851
Raw materials	4,964	4,907
 Total	 \$ 9,564	 \$ 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 six months ended June 30, 2007, resulting in an immaterial payment from Shire to Noven. During the six months ended June 30, 2007, Noven used \$3.9 million of AMI in the finished product. Noven had \$1.5 million and \$1.0 million of consignment AMI inventory on hand at June 30, 2007 and December 31, 2006, respectively, which is not reflected in the table above.

Table of Contents**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),

Share-Based Payment. At June 30, 2007, there were 2,697,186 stock options and 402,796 SSARs issued and outstanding under the 1999 Plan.

Noven granted 26,244 and 34,344 shares of restricted stock to its non-employee directors in May 2007 and 2006, respectively. The shares vest over each director's one-year service period at the end of each calendar quarter beginning with the end of the second quarter. 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 their 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 June 30, 2007, there were a total of 28,620 shares of common stock in the rabbi trust.

The following table summarizes information regarding Noven's restricted stock at June 30, 2007 (shares in thousands):

	Shares	2007 Weighted Average Grant-Date Fair Value
Nonvested at December 31, 2006	8	\$ 17.47
Granted	26	22.86
Vested	(14)	19.80
Forfeited		
Nonvested at June 30, 2007	20	\$ 22.86

Table of Contents

During the three months ended June 30, 2007, Noven granted 4,238 SSARs. The assumptions used to value the SSARs for the three months ended June 30, 2007 and 2006 were as follows:

	2007	2006
Volatility	45.8%	55.1%
Risk free interest rate	4.59%	4.95%
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, 2007 and 2006 was as follows (in thousands):

	Three Months		Six Months	
	2007	2006	2007	2006
Marketing, general and administrative	\$ 739	\$ 745	\$ 1,478	\$ 1,142
Research and development	127	133	254	224
Total cost of products sold	122	102	244	163
	\$ 988	\$ 980	\$ 1,976	\$ 1,529
Tax benefit recognized related to compensation expense	\$ 302	\$ 239	\$ 661	\$ 358

There were no stock-based compensation costs capitalized as part of inventory or fixed assets for the six months ended June 30, 2007 or 2006.

Cash received from options exercised under all share-based payment arrangements for the six months ended June 30, 2007 and 2006 was \$2.5 million and \$0.8 million, respectively. The tax benefit realized on the tax deductions from option exercises under stock-based compensation arrangements totaled \$0.5 million and \$0.3 million for the three and six months ended June 30, 2007 and 2006, of which \$0.4 million and \$0.2 million was reported as cash flow from financing activities for the six months ended June 30, 2007 and 2006, respectively.

Table of Contents

Stock option and SSAR transactions related to the 1999 Plan are summarized as follows for the six months ended June 30, 2007 (options/SSARs and aggregate intrinsic value in thousands):

		2007		
	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	4	23.08		
Exercised	(161)			