

NOVEN PHARMACEUTICALS INC

Form 10-Q

November 13, 2003

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

**FORM 10-Q**

Quarterly Report Pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934

For the quarterly period ended September 30, 2003

Commission file number 0-17254

NOVEN PHARMACEUTICALS, INC.

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(Exact name of registrant as specified in its charter)

STATE OF DELAWARE

59-2767632

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(State or other jurisdiction of  
incorporation or organization)

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(I.R.S. Employer  
Identification Number)

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

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(Address of principal executive offices) (Zip Code)  
(305) 253-5099

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(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 an accelerated filer (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.

<b>Class</b>	<b>Outstanding at October 31, 2003</b>
Common stock \$.0001 par value	22,521,813

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**EX-10.1 Agreement dated November 5, 2003**

**EX-10.2 Employment Agreement - Robert C. Strauss**

**EX-31.1 CEO Certification Pursuant to Section 302**

**EX-31.2 CFO Certification Pursuant to Section 302**

**EX-32.1 CEO Certification Pursuant to Section 906**

**EX-32.2 CFO Certification Pursuant to Section 906**

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## PART I. FINANCIAL INFORMATION

## Item 1. Financial Statements

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

	Three Months		Nine Months	
	2003	2002	2003	2002
<b>Revenues:</b>				
Product revenues Novogyne	\$ 3,938	\$ 7,604	\$ 15,153	\$ 23,683
Product revenues third parties	4,045	4,610	12,788	14,445
Total product revenues	7,983	12,214	27,941	38,128
License and contract revenues	1,113	984	3,441	3,961
Total revenues	9,096	13,198	31,382	42,089
<b>Expenses:</b>				
Cost of products sold	3,936	5,111	14,261	17,032
Research and development	1,916	2,585	6,563	9,267
Marketing, general and administrative	4,791	3,492	12,265	10,104
Total expenses	10,643	11,188	33,089	36,403
Income (loss) from operations	(1,547)	2,010	(1,707)	5,686
Equity in earnings of Novogyne	4,529	2,010	9,849	10,657
Interest income, net	159	223	505	625
Income before income taxes	3,141	4,243	8,647	16,968
Provision for income taxes	1,130	1,480	3,113	6,109
Net income	\$ 2,011	\$ 2,763	\$ 5,534	\$ 10,859
Basic earnings per share	\$ 0.09	\$ 0.12	\$ 0.25	\$ 0.48
Diluted earnings per share	\$ 0.09	\$ 0.12	\$ 0.24	\$ 0.46
<b>Weighted average number of common shares outstanding:</b>				
Basic	22,506	22,549	22,526	22,523
Diluted	22,949	23,127	22,935	23,424

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

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

	<u>September 30, 2003</u>	<u>December 31, 2002</u>
<b>Assets</b>		
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 86,913	\$ 58,684
Accounts receivable trade (less allowance for doubtful accounts of \$84 in 2003 and \$79 in 2002)	3,283	4,359
Accounts receivable Novogyne	4,243	2,581
Inventories	5,194	5,613
Net deferred income tax asset	5,400	2,600
Prepaid income taxes and other current assets	5,716	541
	<u>110,749</u>	<u>74,378</u>
Property, plant and equipment, net	18,418	16,232
<b>Other Assets:</b>		
Investment in Novogyne	25,968	34,684
Net deferred income tax asset	9,646	9,831
Patent development costs, net	1,979	1,996
Deposits and other assets	281	581
	<u>37,874</u>	<u>47,092</u>
	<u>\$ 167,041</u>	<u>\$ 137,702</u>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current Liabilities:</b>		
Accounts payable	5,709	5,062
Notes payable current portion	7	8
Accrued compensation and related liabilities	3,454	3,549
Other accrued liabilities	1,953	1,578
Allowance for returns	1,975	485
Deferred contract revenues	1,301	829
Deferred license revenues current portion	20,526	3,525
	<u>34,925</u>	<u>15,036</u>
<b>Long-Term Liabilities:</b>		
Notes payable		5
Deferred license revenues	30,774	25,920
	<u>65,699</u>	<u>40,961</u>
<b>Commitments and Contingencies (Note 11)</b>		
<b>Stockholders' Equity:</b>		
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 22,517,430 shares at September 30, 2003 and 22,579,112 at December 31, 2002	2	2
Additional paid-in capital	77,425	78,358
Retained earnings	23,915	18,381

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	<u>101,342</u>	<u>96,741</u>
	<u>\$ 167,041</u>	<u>\$ 137,702</u>

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



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

	<u>2003</u>	<u>2002</u>
Cash flows from operating activities:		
Net income	\$ 5,534	\$ 10,859
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,683	1,623
Amortization of patent costs	252	231
Amortization of non-competition agreement	300	300
Deferred income tax (benefit) expense	(2,615)	2,099
Non-cash expense related to issuance of stock to charitable organization	31	
Recognition of deferred contract revenues	(296)	(1,457)
Recognition of deferred license revenues	(3,145)	(2,504)
Distributed earnings in excess of equity in earnings of Novogyne	7,045	1,070
Changes in operating assets and liabilities:		
Decrease (increase) in accounts receivable trade, net	1,076	(2,213)
(Increase) decrease in accounts receivable Novogyne	(1,662)	2,830
Decrease (increase) in inventories	419	(2,856)
Increase in prepaid income taxes and other current assets	(3,504)	(728)
Decrease in deposits and other assets		26
Increase in accounts payable	647	4
(Decrease) increase in accrued compensation and related liabilities	(95)	2,567
Increase (decrease) in other accrued liabilities	442	(304)
Increase in allowance for returns	1,490	
Increase in deferred contract revenues	768	132
Increase in deferred license revenues	25,000	73
	<u>33,370</u>	<u>11,752</u>
Cash flows provided by operating activities		
Cash flows from investing activities:		
Purchase of property, plant and equipment, net	(3,869)	(1,642)
Payments for patent development costs	(235)	(154)
	<u>(4,104)</u>	<u>(1,796)</u>
Cash flows used in investing activities		
Cash flows from financing activities:		
Issuance of common stock	258	665
Purchase and retirement of common stock	(1,289)	
Repayments of notes payable	(6)	(250)
	<u>(1,037)</u>	<u>415</u>
Cash flows (used in) provided by financing activities		
Net increase in cash and cash equivalents	28,229	10,371
Cash and cash equivalents, beginning of period	58,684	49,389
	<u>\$ 86,913</u>	<u>\$ 59,760</u>
Cash and cash equivalents, end of period		

*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® and Vivelle-Dot® and Noven s transdermal combination estrogen/progestin delivery system marketed under the brand name CombiPatch®. Noven accounts for its 49% investment in Novogyne under the equity method and reports its share of Novogyne s earnings as Equity in earnings of Novogyne on its Statements of Operations. Noven defers the recognition of 49% of its profit on products sold to Novogyne until the products are sold by Novogyne.

2. BASIS OF PRESENTATION:

In management s opinion, the accompanying unaudited condensed financial statements of Noven contain all adjustments (consisting of only normal recurring adjustments) necessary to present fairly, in all material respects, the financial position of Noven as of September 30, 2003, and the results of its operations for the three and nine months ended September 30, 2003 and 2002. Noven s business is subject to numerous risks and uncertainties including, but not limited to, those set forth in Noven s Annual Report on Form 10-K/A for the year ended December 31, 2002 ( Form 10-K ), and in Item 2 Management s Discussion and Analysis of Financial Condition and Results of Operations of this quarterly report on Form 10-Q. Accordingly, the results of operations and cash flows for the three and nine months ended September 30, 2003 and 2002 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 2003.

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 and in Note 5 Revenue Recognition .

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## 3. RECLASSIFICATIONS:

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

## 4. INVENTORIES:

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

	September 30, 2003	December 31, 2002
Finished goods	\$ 824	\$ 830
Work in process	1,905	1,390
Raw materials	2,465	3,393
	<hr/>	<hr/>
Total	\$5,194	\$5,613
	<hr/>	<hr/>

## 5. REVENUE RECOGNITION:

Substantially all of Noven's product revenues were to its licensees, Novogyne, Novartis Pharma AG and its affiliates (Novartis AG) and Aventis Pharma AG. Revenues from product sales are recognized at the time of shipment when both title and the risks and rewards of ownership have been transferred to the buyer. Certain of our license agreements provide that the ultimate supply price is based on a percentage of the licensee's net selling price. Each of those agreements also establishes a fixed minimum supply price per unit that represents the lowest price Noven could receive on sales to the licensee. Noven receives the minimum price at the time of shipment with the possibility of an upward adjustment later when the licensee's net selling price is known. Revenues under these agreements are recorded at the minimum price at the time of shipment. Noven records any upward adjustments to revenues at the time that the information necessary to make the determination is received from the licensee. If the upward adjustments are not determinable, Noven records the adjustments (which historically have not been significant) on a cash basis. These amounts are included in product revenues.

Royalty revenues consist of royalties payable by Novogyne and Novartis AG from sales of Vivelle® and Vivelle-Dot®/Estradot® in the United States and Canada. Noven accrues royalties from Novogyne's and Novartis AG's product sales each quarter based on Novogyne's and Novartis AG's net sales for that quarter. Royalties are included in product revenues.

License revenues consist of up-front, milestone and similar payments under license agreements and are recognized when earned under the terms of the applicable agreements. In most cases, license revenues are deferred and recognized over the estimated product life cycle or the length of relevant patents, whichever is shorter.

Contract revenues consist of contract payments related to research and development projects performed for third parties. The work performed by Noven includes feasibility studies to determine if a specific drug is amenable to transdermal drug delivery, the actual formulation of a specific drug into a transdermal drug delivery system, studies to address the ongoing stability of

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the drug in a transdermal drug delivery system, and manufacturing of batches of product that can be used in human clinical trials. Noven receives contract payments for the work it performs in the following forms:

nonrefundable up-front payments prior to commencing the work (or certain phases of the work);

additional payments upon completion of additional phases; and

in some cases, success milestone payments based on achievement of specified performance criteria.

As prescribed by EITF 00-21 *Accounting for Revenue Arrangements with Multiple Deliverables*, Noven analyzes each contract in order to separate each deliverable into separate units of accounting and then recognizes revenues for those separated units at their fair value, as delivered, based on the proportionate share of the work performed by Noven as it performs the specified acts under the contract. If each deliverable does not qualify as a separate unit of accounting, the deliverables are combined and the amounts under the contract are allocated to the combined deliverables. The appropriate recognition of revenue is then determined for the combined deliverables as a single unit of accounting. The difference between the amount of the payments received and the amount recognized is recorded as deferred revenues until that amount is earned in accordance with Staff Accounting Bulletin 101, *Revenue Recognition in Financial Statements* (SAB 101).

Milestone payments are recorded when the specified performance criteria are achieved, as determined by the customer. Each contract may have different payment terms. Therefore, the timing of revenue recognition may vary from contract to contract.

Revenues are net of an allowance for returns. Noven establishes allowances for returns for product that has been recalled or that it believes is probable of being recalled. The methodology used by Noven to estimate product recall returns is based on the distribution and expiration dates of the affected product and overall trade inventory levels. These estimates are based on currently available information, and the ultimate outcome may be significantly different than the amounts estimated given the subjective nature and complexities inherent in this area and in the pharmaceutical industry.

Noven's revenue recognition policy is in compliance with the requirements of SAB 101.

6. **EMPLOYEE STOCK PLANS:**

In accordance with the provisions of Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* (SFAS 123), as amended by Statement of Financial Accounting Standards No. 148, *Accounting for Stock-Based Compensation -Transition and Disclosure* (SFAS 148), Noven may elect to continue to apply the provisions of the Accounting Principles Board's Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and related interpretations in accounting for its employee stock option plans, or adopt the fair value method of accounting prescribed by SFAS 123. Noven has elected to continue to account for its stock plans using APB 25, and therefore no stock-based employee compensation cost is reflected in net income, as all options granted under those plans had an exercise price equal to the market value of the underlying common stock on the date of grant.

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The following table illustrates the effect on net income and earnings per share for the three and nine months ended September 30, 2003 and 2002 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		Nine Months	
	2003	2002	2003	2002
Net income:				
As reported	\$ 2,011	\$ 2,763	\$ 5,534	\$ 10,859
Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(1,138)	(1,270)	(3,247)	(3,499)
Pro forma	\$ 873	\$ 1,493	\$ 2,287	\$ 7,360
Basic earnings per share:				
As reported	\$ 0.09	\$ 0.12	\$ 0.25	\$ 0.48
Pro forma	\$ 0.04	\$ 0.07	\$ 0.10	\$ 0.33