

NOVEN PHARMACEUTICALS INC

Form 10-Q

November 14, 2001

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

FORM 10-Q

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

For the quarterly period ended September 30, 2001

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

<u>Class</u>	<u>Outstanding at October 31, 2001</u>
Common stock \$.0001 par value	22,457,480

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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)

	<u>Three Months</u>		<u>Nine Months</u>	
	<u>2001</u>	<u>2000</u>	<u>2001</u>	<u>2000</u>
Revenues:				
Product sales	\$9,705	\$11,016	\$33,569	\$30,807
License revenue	698	147	2,117	440
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Total revenues	10,403	11,163	35,686	31,247
Expenses:				
Cost of products sold	4,982	4,928	15,692	13,951
Research and development	3,716	3,307	8,353	8,687
Marketing, general and administrative	3,383	1,980	9,219	6,369
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Total expenses	12,081	10,215	33,264	29,007

Income (loss) from operations
(1,678) 948 2,422 2,240
Equity in earnings of Novogyne
5,278 2,653 9,010 6,383
Interest income, net
398 306 1,499 773

Income before income taxes
3,998 3,907 12,931 9,396
Provision for income taxes
1,542 282 4,585 470

Net income
\$2,456 \$3,625 \$8,346 \$8,926

Basic earnings per share
\$0.11 \$0.16 \$0.37 \$0.41

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Diluted earnings per share
\$0.10 \$0.15 \$0.35 \$0.39

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Weighted average number of common shares
outstanding:

Basic
22,427 22,042 22,334 21,841

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Diluted
23,542 23,586 23,571 23,104

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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)

	<u>September 30, 2001</u>	<u>December 31, 2000</u>
<u>Assets</u>		
Current Assets:		
Cash and cash equivalents	\$47,070	\$40,976
Accounts receivable (less allowance for doubtful accounts of \$55 in 2001 and \$121 in 2000)	2,336	5,677
Due from Novogyne	24,813	2,917
Inventories	4,757	6,098
Net deferred income tax asset	4,400	4,500
Prepaid and other current assets	396	495
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	83,772	60,663
Property, plant and equipment, net	15,790	15,154
Other Assets:		
Investment in Novogyne	27,041	15,431
Net deferred income tax asset	10,521	10,700
Patent development costs, net	1,982	1,972
Deposits and other assets	1,109	111
	<hr/>	
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	\$140,215	\$104,031
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Liabilities and Stockholders

Equity

Current Liabilities:

Accounts payable

\$5,429 \$5,797

Notes payable - current portion

191 340

Due to Aventis Pharmaceuticals

20,000

Accrued compensation and related liabilities

2,466 2,504

Other accrued liabilities

6,064 2,739

Deferred license revenue - current portion

2,936 2,586

37,086 13,966

Long-Term Liabilities:

Notes payable

134 265

Deferred license revenue

25,556 24,523

62,776 38,754

Commitments and contingencies

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 22,435,011 shares at
September 30, 2001 and
22,177,598 at December 31, 2000

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Additional paid-in capital

76,680 72,864

Retained earnings (accumulated deficit)

757 (7,589)

77,439 65,277

\$140,215 \$104,031

The accompanying notes are an integral part of these statements.

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Condensed Statements of Cash Flows
 Nine Months Ended September 30,
 (in thousands)
 (unaudited)

	<u>2001</u>	<u>2000</u>
Cash flows from operating activities:		
Net income		
\$8,346	\$8,926	
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization		
1,730	963	
Amortization of patent costs		
169	158	
Amortization of non-competition agreement		
133		
Deferred income tax provision		
699		
Recognition of deferred license revenue		
(2,117)	(440)	
Equity in earnings of Novogyne		
(9,010)	(6,383)	
Decrease (increase) in accounts receivable		
3,341	(3,709)	
(Increase) decrease in due from Novogyne		
(1,896)	1,253	
Decrease (increase) in inventories		
1,341	(1,760)	
Decrease in prepaid and other current assets		
99	143	
(Increase) decrease in deposits and other assets		
(1,131)	197	
(Decrease) increase in accounts payable		
(368)	1,649	
(Decrease) increase in accrued compensation and related liabilities		
(38)	867	
Increase (decrease) in other accrued liabilities		
4,164	(165)	
Increase in deferred license revenue		
3,500		

Cash flows provided by
operating activities
8,962 1,699
Cash flows from investing
activities:

Purchase of property, plant and
equipment, net
(2,366) (1,036)
Investment in Novogyne
(15,680)
Distribution from Novogyne
13,080 2,228
Payments for patent
development costs
(179) (243)

Cash flows (used in) provided
by investing activities
(5,145) 949
Cash flows from financing
activities:

Issuance of common stock
2,557 3,072
Payments on notes payable
(280) (258)

Cash flows provided by
financing activities
2,277 2,814

Net increase in cash and cash
equivalents
6,094 5,462
Cash and cash equivalents,
beginning of period
40,976 15,338

Cash and cash equivalents, end
of period
\$47,070 \$20,800

The accompanying notes are an integral part of these statements.

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NOVEN PHARMACEUTICALS, INC.

Notes to Unaudited Condensed Financial Statements

1. Basis of Presentation:

In management's opinion, the accompanying unaudited condensed financial statements of Noven Pharmaceuticals, Inc. ("Noven") contain all adjustments (consisting of only normal recurring adjustments) necessary to present fairly the financial position of Noven as of September 30, 2001, and the results of its operations for the three and nine months ended September 30, 2001 and 2000. The results of operations and cash flows for the nine months ended September 30, 2001 are not necessarily indicative of the results of operations or cash flows which may be reported for the remainder of 2001.

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 Annual Report on Form 10-K for the year ended December 31, 2000. Certain amounts presented in the financial statements for prior periods have been reclassified to the current period's presentation.

The accounting policies followed for interim financial reporting are the same as those disclosed in Note 1 of the notes to the financial statements included in Noven's Annual Report on Form 10-K for the year ended December 31, 2000.

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 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, effective March 30, 2001, 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. Inventories:

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

	<u>September 30, 2001</u>	<u>December 31, 2000</u>
Finished goods	\$ 862	\$ 319
Work in process		
1,182	1,567	
Raw materials		
2,713	4,212	
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Total		
\$4,757	\$6,098	
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3. Income Taxes:

Noven accounts for income taxes in accordance with the provisions of Statement of Financial Accounting Standards No. 109, Accounting for Income Taxes. Provisions for income taxes for the three and nine months ended September 30, 2001 are based on the Federal and state statutory income tax rates. Provisions for income taxes for the three and nine months ended September 30, 2000 reflect provisions for the Federal alternative minimum tax and state income taxes.

4. Cash Flow Information:

Cash payments for income taxes were \$0.9 million in 2001 and \$0.5 million in 2000. Cash payments for interest were \$29,000 in 2001 and \$51,000 in 2000.

In connection with the CombiPatch® transaction described in Note 5 below, in March 2001, Noven recorded a \$40 million receivable from Novogyne and a \$40 million payable to Aventis Pharmaceuticals, the United States pharmaceuticals business of Aventis Pharma AG (Aventis). In June and September 2001, Novogyne paid the first two \$10 million installments, respectively, to Aventis.

Accrued compensation and related liabilities for the year ended December 31, 1999 included bonuses for employees and officers of \$0.8 million that were settled by issuance of 55,000 shares of common stock during the quarter ended March 31, 2000.

Noven recorded a \$1.3 million income tax benefit to additional paid-in capital for the nine months ended September 30, 2001 derived from the exercise of non-qualified stock options and disqualifying dispositions of incentive stock options.

5. License Agreements:

On March 30, 2001, Novogyne acquired the exclusive United States marketing rights to CombiPatch® (estradiol/norethindrone acetate transdermal system) in a series of transactions involving Novogyne, Noven, Novartis and Aventis. Prior to the transaction, Aventis had been Noven's exclusive licensee for CombiPatch® in the United States. The transaction was structured as (a) a direct purchase by Novogyne from Aventis of certain assets for \$25 million, which was paid at closing, (b) a grant-back by Aventis to Noven of certain intellectual property rights relating to CombiPatch®, and (c) a simultaneous license by Noven to Novogyne of these intellectual property rights. The consideration payable by Noven to Aventis, and by Novogyne to Noven, is \$40 million, due in four quarterly installments of \$10 million each, payable beginning June 1, 2001. Novogyne agreed to indemnify Noven against Noven's obligation to Aventis. The first two \$10 million quarterly installments were paid by Novogyne to Aventis in June and September 2001, respectively. As a consequence of the transaction and under the terms of Noven's existing license agreement with Aventis, Noven received \$3.5 million from Aventis, which amount was deferred and recognized as license revenue over ten years beginning in the first quarter of 2001.

In a related transaction, Novartis Pharma AG (Novartis AG) acquired from Aventis the development and marketing rights to future generations of Noven's combination estrogen/progestin patch in all markets other than Japan. Novogyne expects to sublicense the United States rights to these product improvements, and, if and when future generation combination products are commercialized, Novogyne will pay a royalty to Novartis AG on the

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United States sales of such products. Noven will manufacture CombiPatch® and any future combination products and will supply such products to Novogyne and to Novartis AG. In June 2001, Noven and Novartis entered into a development agreement relating to future generations of combination estrogen/progestin patch products.

6. Investment in 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 quarters of 2000 and 2001 to meet Novartis' annual preferred return for those years and for Noven to recognize earnings from Novogyne under the formula.

During the three and nine months ended September 30, 2001 and 2000, Noven had the following transactions with Novogyne (in thousands):

	<u>Three Months</u>		<u>Nine Months</u>	
	<u>2001</u>	<u>2000</u>	<u>2001</u>	<u>2000</u>
Revenue:				
Trade product				
\$2,895 \$4,401 \$6,981 \$12,038				
Sample product and other				
90 674 1,667 2,218				
Royalty				
1,320 776 3,086 2,472				

\$4,305 \$5,851 \$11,734 \$16,728				

Reimbursed Expenses:				
Services				
\$				