

Edgar Filing: NOVEN PHARMACEUTICALS INC - Form 10-Q

NOVEN PHARMACEUTICALS INC

Form 10-Q

May 14, 2001

1

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 March 31, 2001

Commission file number 0-17254

NOVEN PHARMACEUTICALS, INC.

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.

Class	Outstanding at April 30, 2001
-----	-----
Common stock \$.0001 par value	22,275,890

2

NOVEN PHARMACEUTICALS, INC.

INDEX

Page No.

1

Edgar Filing: NOVEN PHARMACEUTICALS INC - Form 10-Q

PART I - FINANCIAL INFORMATION

Item 1 - Financial Statements

Statements of Operations for the Three Months Ended
March 31, 2001 and 2000 3

Balance Sheets as of March 31, 2001 and December 31, 2000 4

Statements of Cash Flows for the Three Months Ended
March 31, 2001 and 2000 5

Notes to Financial Statements 6

Item 2 - Management's Discussion and Analysis of Financial
Condition and Results of Operations 10

Item 3 - Quantitative and Qualitative Disclosures About Market Risk 13

PART II - OTHER INFORMATION

Item 6 - Exhibits and Reports on Form 8-K 14

SIGNATURES 15

2

3

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

NOVEN PHARMACEUTICALS, INC.
Statements of Operations
Three Months Ended March 31,
(in thousands, except per share amounts)
(unaudited)

	2001

Revenues:	
Product sales	\$ 12,022
License revenue	667

Total revenues	12,689
Expenses:	
Cost of products sold	4,816
Research and development	2,227
Marketing, general and administrative	2,660

Edgar Filing: NOVEN PHARMACEUTICALS INC - Form 10-Q

Total expenses	9,703

Income from operations	2,986
Equity in earnings of Novogyne	595
Interest income, net	619

Income before income taxes	4,200
Provision for income taxes	1,533

Net income	\$ 2,667
	=====
Basic earnings per share	\$.12
	=====
Diluted earnings per share	\$.11
	=====
Weighted average number of common shares outstanding:	
Basic	22,236
	=====
Diluted	23,606
	=====

The accompanying notes are an integral part of these statements.

3

4

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

	MARCH 31, 2001

	(unaudited)
ASSETS	
Current Assets:	
Cash and cash equivalents	\$ 46,235
Accounts receivable (less allowance for doubtful accounts of \$78 in 2001 and \$121 in 2000)	3,743
Due from Novogyne	42,534
Inventories	6,726
Net deferred income tax asset	4,400
Prepaid and other current assets	464

	104,102

Edgar Filing: NOVEN PHARMACEUTICALS INC - Form 10-Q

Property, plant and equipment, net	15,058
Other Assets:	
Investment in Novogyne	18,076
Net deferred income tax asset	10,633
Patent development costs, net	1,994
Deposits and other assets	60

	30,763

	\$ 149,923
	=====
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current Liabilities:	
Accounts payable	\$ 5,375
Notes payable - current portion	291
Due to Aventis Pharmaceuticals	40,000
Accrued compensation and related liabilities	1,897
Other accrued liabilities	2,551
Deferred license revenue - current portion	3,010

	53,124
Long-Term Liabilities:	
Notes payable	222
Deferred license revenue	27,043

	80,389
Commitments and Contingencies	
Stockholders' Equity:	
Preferred stock - authorized 100,000 shares of \$.01 par value; no shares issued or outstanding	--
Common stock - authorized 40,000,000 shares, par value \$.0001 per share; issued and outstanding 22,271,742 shares at March 31, 2001 and 22,177,598 at December 31, 2000	2
Additional paid-in capital	74,454
Accumulated deficit	(4,922)

	69,534

	\$ 149,923
	=====

The accompanying notes are an integral part of these statements.

Edgar Filing: NOVEN PHARMACEUTICALS INC - Form 10-Q

	200

Cash flows from operating activities:	
Net income	\$ 2
Adjustments to reconcile net income to net cash provided by operating activities:	
Depreciation and amortization	
Amortization of patent costs	
Deferred income tax provision	
Recognition of deferred license revenue	
Equity in earnings of Novogyne	
Decrease in accounts receivable	1
Decrease (increase) in due from Novogyne	
Increase in inventories	
Decrease in prepaid and other current assets	
Decrease in deposits and other assets	
(Decrease) increase in accounts payable	(1
Decrease in accrued compensation and related liabilities	
Increase (decrease) in other accrued liabilities	1
Increase in deferred license revenue	3

Cash flows provided by (used in) operating activities	6
Cash flows from investing activities:	
Purchase of property, plant and equipment, net	
Investment in Novogyne	(12
Distribution from Novogyne	10
Payments for patent development costs	

Cash flows used in investing activities	(2
Cash flows from financing activities:	
Issuance of common stock	
Payments on notes payable	

Cash flows provided by financing activities	

Net increase in cash and cash equivalents	5
Cash and cash equivalents, beginning of period	40

Cash and cash equivalents, end of period	\$ 46
	=====

The accompanying notes are an integral part of these statements.

Edgar Filing: NOVEN PHARMACEUTICALS INC - Form 10-Q

NOVEN PHARMACEUTICALS, INC. NOTES TO UNAUDITED FINANCIAL STATEMENTS

1. Basis of Presentation:

In management's opinion, the accompanying unaudited 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 March 31, 2001, and the results of its operations for the three months ended March 31, 2001 and 2000. The results of operations and cash flows for the three months ended March 31, 2001 are not necessarily indicative of the results of operations or cash flows which may be reported for the remainder of 2001.

The accompanying 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 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.

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(R) and Vivelle-Dot(TM) and, effective March 30, 2001, Noven's transdermal combination estrogen/progestin delivery system marketed under the brand name CombiPatch(TM). 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 that remain in Novogyne's inventory until the products are sold.

2. Inventories:

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

	March 31, 2001	December 31, 2000
	-----	-----
Finished goods	\$ 915	\$ 319
Work in process	1,765	1,567
Raw materials	4,046	4,212
	-----	-----
Total	\$ 6,726	\$ 6,098
	=====	=====

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". Provision for income taxes for the three months ended March 31, 2001 approximates the Federal statutory and state income tax rates. Provision for income taxes for the three months ended March 31, 2000 reflects provisions for the Federal alternative minimum tax and state income taxes.

4. Cash Flow Information (in thousands):

Cash payments for income taxes were \$450 in 2001 and \$137 in 2000. Cash payments for interest were \$12 in 2001 and \$19 in 2000.

In connection with the CombiPatch(TM) transaction described in Note 5 below, Noven recorded a \$40 million receivable from Novogyne and a \$40 million payable to Aventis.

Accrued compensation and related liabilities for the year ended December 31, 1999 includes bonuses for employees and officers of \$782 that were settled by issuance of 55,000 shares of common stock during the quarter ended March 31, 2000.

Noven recorded a \$741 income tax benefit to additional paid-in capital in 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(TM) (estradiol/norethindrone acetate transdermal system) in a series of transactions involving Novogyne, Noven, Novartis and Aventis Pharmaceuticals, the U.S. pharmaceuticals business of Aventis Pharma AG ("Aventis"). Prior to the transaction, Aventis had been Noven's exclusive licensee for CombiPatch(TM) 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(TM), 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. 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, and Novogyne expects to sublicense the United States rights to these product improvements. If and when any future

Edgar Filing: NOVEN PHARMACEUTICALS INC - Form 10-Q

generation combination products are commercialized, Novogyne will pay a royalty to Novartis AG on the United States sales of such products. Noven will manufacture CombiPatch(TM) and any future combination products and will supply such products to Novogyne and to Novartis AG.

7

8

Prior to closing of the transaction in March 2001, Novogyne distributed a total of \$37.2 million to Noven and Novartis, and each joint venture member then contributed back to Novogyne its proportionate share of the \$25 million up-front payment to Aventis, resulting in a net \$2.1 million contribution from Noven to Novogyne at closing.

6. Investment in Novogyne:

Noven shares in the earnings of Novogyne according to an established formula after satisfaction of an annual preferred return of \$6.1 million to Novartis. Noven's share of earnings increases as product sales increase, subject to a cap of 49%. Novogyne produced sufficient income in the first quarters of 2001 and 2000 to meet Novartis' preferred return and for Noven to recognize earnings from Novogyne under the formula.

During the three months ended March 31, 2001 and 2000, Noven had the following transactions with Novogyne (in thousands):

	2001 -----	2000 -----
Revenue:		
Trade product	\$ 1,244	\$ 4,435
Sample product and other	18	743
Royalty	816	792
	-----	-----
	\$ 2,078	\$ 5,970
	=====	=====
Reimbursed Expenses:		
Services	\$ 2,954	\$ 2,144
Product specific marketing expenses	625	383
	-----	-----
	\$ 3,579	\$ 2,527
	=====	=====

As of March 31, 2001 and December 31, 2000, Noven had amounts due from Novogyne of \$42.5 million and \$2.9 million, respectively, representing \$40 million related to the license of CombiPatch(TM) (see Note 5) for 2001 and the balance representing amounts due for products sold to and marketing expenses reimbursable by Novogyne.

The condensed unaudited Statements of Operations of Novogyne for the three months ended March 31, 2001 and 2000 are as follows (in thousands):

	2001 -----	2000 -----
Revenues	\$ 13,868	\$ 13,249
Cost of sales	2,187	2,115
Selling, general and administrative expenses	4,799	4,176
	-----	-----

Edgar Filing: NOVEN PHARMACEUTICALS INC - Form 10-Q

Income from operations	6,882	6,958
Interest income	559	354
	-----	-----
Net income	\$ 7,441	\$ 7,312
	=====	=====

8

9

Subject to the approval of Novogyne's management committee, cash may be distributed to Novartis and Noven based upon a contractual formula. In March 2001, Noven received a distribution of \$10.2 million from Novogyne based on the results of operations for the year ended December 31, 2000 and the three months ended March 31, 2001. In April 2000, Noven received a cash distribution of \$2.2 million from Novogyne based upon the results of operations for the year ended December 31, 1999. These amounts were recorded as a reduction in the investment in Novogyne in the first quarter of 2001 and in the second quarter of 2000, respectively.

In connection with the CombiPatch(TM) transaction described in Note 5 above, Noven contributed \$12.3 million to Novogyne in March 2001. This amount was recorded as an increase in the investment in Novogyne in the first quarter of 2001.

7. Commitments:

In September 2000, Noven entered into a Severance and Non-Competition Agreement with Steven Sablotsky, its Chairman of the Board of Directors. Pursuant to the agreement, Mr. Sablotsky's employment as an officer of Noven will terminate on June 1, 2001. Noven will pay Mr. Sablotsky \$1.2 million on that date, which will be amortized over the period of his three-year non-competition agreement.

9

10

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with the financial statements, the related notes and management's discussion and analysis of financial condition and results of operations included in Noven's Annual Report on Form 10-K for the year ended December 31, 2000 and the financial statements and related notes included in Item 1 of this Quarterly Report on Form 10-Q. Except for historical information contained herein, the matters discussed below are forward looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such statements involve risks and uncertainties, including but not limited to economic, competitive, governmental and technological factors affecting Noven's operations, markets, products, prices, and other factors. These factors, which are discussed elsewhere in this report and in the documents filed by Noven with the Securities and Exchange Commission ("SEC"), may cause Noven's results to differ materially from the forward looking statements made in this report or otherwise made by or on behalf of Noven.

Edgar Filing: NOVEN PHARMACEUTICALS INC - Form 10-Q

Substantially all of Noven's product sales were to its licensees, Novogyne, Novartis AG and Aventis. Revenues from product sales are recognized at the time of shipment. Certain license agreements provide for an adjustment to the price of the product based upon the licensee's actual sales price. Noven records such adjustments to revenues at the time that the information necessary to make the determination is received from the licensees. Royalty revenue consists of royalties payable by Novogyne and Novartis from sales of Vivelle(R) and Vivelle-Dot(TM) in the United States and Canada. Royalty revenue is recognized when earned and determinable and is included in product sales.

License revenue consists of up-front, milestone and similar payments under license agreements and is recognized when earned under the terms of the applicable agreements. In some cases, license revenue will be deferred and recognized as license revenue over time.

Certain license agreements entitle Noven to minimum fees. Noven records revenue related to minimum fees as soon as supporting data is provided by the licensee. If the minimum fees are not determinable, Noven records these fees on a cash basis. These fees are included in product revenue.

Revenues from product sales to licensees may fluctuate from quarter to quarter depending on various factors not in Noven's control, including but not limited to, the marketing efforts of each licensee, the inventory requirements of each licensee, the impact of competitive products, the timing and scope of Estalis(R) and Estradot(TM) launches by Novartis AG, the product pricing of each licensee and the timing of certain royalty reconciliations and payments under Noven's license agreements.

Noven shares in the earnings of Novogyne according to an established formula after satisfaction of an annual preferred return of \$6.1 million to Novartis. In the first quarters of 2001 and 2000, Novartis' preferred return was satisfied. Noven reports its share of Novogyne's earnings as "Equity in earnings of Novogyne" on its Statements of Operations.

RESULTS OF OPERATIONS

THREE MONTHS ENDED MARCH 31, 2001 COMPARED TO THREE MONTHS ENDED MARCH 31, 2000

Total revenues for the three months ended March 31, 2001 were \$12.7 million, an increase of \$3.1 million, or 32%, over the same period in the prior year. The increase in revenues was primarily

10

11

attributable to an increase in product sales of \$2.6 million, or 27%, for the three months ended March 31, 2001 over the same period in the prior year. Product sales in the 2001 period included \$1.4 million in minimum fee payments related to sales of Menorest(R) in certain European countries in 2000. The remaining \$1.2 million of the increase in product sales was primarily attributable to higher sales of Estalis(R) outside of the United States and, to a lesser extent, sales of CombiPatch(TM) in the United States. A decline in sales of Vivelle(R) and Vivelle-Dot(TM) to Novogyne partially offset the increased sales of Noven's other products. License revenue increased \$0.5 million, or 354%, primarily due to the amortization of license fees received in connection with the license of Estradot(TM) to Novartis AG in the fourth quarter of 2000.

Gross profit (product sales less cost of products sold) for the three months ended March 31, 2001 was \$7.2 million (60% of product sales), compared to \$4.9 million (52% of product sales) for the same period in the prior year. The increase in gross margin resulted from higher minimum fee payments, and lower

Edgar Filing: NOVEN PHARMACEUTICALS INC - Form 10-Q

profit deferral related to sales of product to Novogyne. Novogyne's inventory declined during the first quarter of 2001, which resulted in a decrease in the profit that Noven was required to defer with respect to product sold to Novogyne that remained in Novogyne's inventory at March 31, 2001. Noven expects its gross profit percentage to be in the mid-50 percent range in 2001.

Research and development expenses increased approximately \$0.4 million, or 22%, for the three months ended March 31, 2001 compared to the same period in the prior year, attributable primarily to clinical studies and related expenses for Noven's methylphenidate transdermal delivery system. The future level of research and development expenditures will depend on, among other things, the status of products under development and the outcome of clinical trials, strategic decisions by management, the consummation of new collaborative arrangements and Noven's liquidity. Further, such expenses may vary significantly from quarter to quarter depending on product development cycles and the timing of clinical studies.

Marketing, general and administrative expenses increased approximately \$0.6 million, or 28%, for the three months ended March 31, 2001 compared to the same period in the prior year. This increase was primarily due to higher outside consulting services related to the implementation of an enterprise resource planning system and to improvements in production efficiency, and to higher legal fees related to the CombiPatch(TM) transaction.

For the three months ended March 31, 2001 and 2000, Noven reported equity in earnings of Novogyne of \$0.6 million and \$0.5 million, respectively. Novogyne's revenue increased from \$13.2 million in the three months ended March 31, 2000 to \$13.9 million in the comparable 2001 period. All of this increase was attributable to increased sales of Vivelle-Dot(TM) partially offset by decreased sales of Vivelle(R). For the first three months of 2001, Novogyne had net income of \$7.4 million, compared to \$7.3 million for the same period in the prior year.

Interest income, net increased approximately \$0.4 million, or 210%, for the three months ended March 31, 2001 compared to the same period in the prior year, primarily due to higher average balances in cash and cash equivalents.

Noven's effective tax rate increased from 1.9% for the three months ended March 31, 2000 to 36.5% for the three months ended March 31, 2001. The provision for income taxes for the three months ended March 31, 2001 approximates the Federal statutory and state income tax rates. The provision for income taxes for the three months ended March 31, 2000 reflects provisions for the Federal alternative minimum tax and state income taxes. As of March 31, 2001, Noven had a net

11

12

deferred tax asset of \$15 million. Realization of this deferred tax asset depends upon generating sufficient future taxable income. Although realization is not assured, management believes it is more likely than not that the deferred income tax asset will be realized based upon estimated future taxable income. Noven expects its effective tax rate to be between 34% and 38% in 2001.

LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2001 and December 31, 2000, Noven had \$46.2 million and \$41.0 million, respectively, in cash and cash equivalents. Working capital increased by \$4.3 million from \$46.7 million at December 31, 2000 to \$51.0 million at March 31, 2001.

Net cash of approximately \$6.9 million was provided by operating

Edgar Filing: NOVEN PHARMACEUTICALS INC - Form 10-Q

activities during the first three months of 2001, compared to approximately \$0.1 million used in operating activities during the same period in the prior year. Net cash generated by operating activities primarily resulted from the receipt of a license fee in the amount of \$3.5 million from Aventis in connection with the CombiPatch(TM) license transaction. Changes in working capital and improved operating results accounted for most of the remaining fluctuation.

Net cash of approximately \$2.4 million was used in investing activities during the first three months of 2001, compared to approximately \$0.3 million used in investing activities during the same period of the prior year. In March 2001, Noven received a distribution of \$10.2 million from Novogyne based on Novogyne's results for the year ended December 31, 2000 and the three months ended March 31, 2001. In connection with the CombiPatch(TM) transaction, Noven contributed \$12.3 million to Novogyne as its proportionate share of the \$25 million up-front payment to Aventis.

Net cash of approximately \$0.8 million was provided by financing activities during the first three months of 2001, compared to approximately \$0.3 million provided by financing activities during the same period of the prior year, primarily resulting from an increase in cash received from the issuance of common stock in connection with the exercise of stock options.

In December 2000, Noven entered into a secured revolving credit facility (the "Credit Facility") providing for borrowings of up to the lesser of \$10 million or eligible accounts receivable. The Credit Facility will terminate in April 2002 and bears interest at LIBOR plus 1.50% (6.6% at March 31, 2001). At March 31, 2001, there were no amounts outstanding under the Credit Facility. Terms of the Credit Facility include, among other things, minimum net worth, revenue and operating results requirements, as well as compliance with certain financial ratios, measured on a quarterly basis.

Noven's principal sources of short term liquidity are existing cash, cash generated from product sales, fees and royalties under license agreements and borrowings under its Credit Facility. In November 2000, Noven entered into an exclusive license agreement with Novartis AG relating to Estradot(TM), pursuant to which Noven received an up-front license payment of \$20 million and will receive an additional milestone payment upon registration by Novartis AG of the licensed product in certain European countries. There can be no assurance that Novartis AG's registration efforts will be successful, and therefore there can be no assurance that Noven will receive the additional milestone payment.

12

13

Over the next year, Noven expects to invest up to \$5 million in plant and equipment and software to increase production capacity and to implement an enterprise resource planning system. Further, pursuant to a Severance and Non-Competition Agreement entered into with Steven Sablotsky, Noven's Co-Chairman of the Board of Directors, Noven is required to pay Mr. Sablotsky \$1.2 million in June 2001 in consideration for, among other things, a three-year non-competition agreement. Cash requirements for federal and state income taxes are also expected to increase. Additionally, as part of the CombiPatch(TM) transaction entered into in March 2001, the consideration payable for certain intellectual property rights 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 obligations to Aventis. Novogyne expects to fund most of these installment payments from cash flows from operations. There can be no assurance that Novogyne will be able to generate sufficient income and cash flows from operations to meet these installment obligations. To the extent that Novogyne pays these obligations from cash generated by operations, the cash available for distribution to the members will be reduced correspondingly. If Novogyne's cash

Edgar Filing: NOVEN PHARMACEUTICALS INC - Form 10-Q

generated by operations is not sufficient to fund all or a portion of the remaining installments, Noven and Novartis may contribute additional capital to Novogyne. If Noven and Novartis elect not to contribute the necessary additional capital, Novogyne would be required to raise additional funds in order to meet its obligation to Aventis, whether through the incurrence of indebtedness or otherwise.

Noven believes that it will have sufficient cash available to meet its operating needs and anticipated short-term capital requirements, including any additional capital contributions to Novogyne. For the long term, Noven intends to utilize funds derived from the above sources, as well as funds generated through sales of products under development. Noven expects that such funds will be comprised of payments received pursuant to future licensing arrangements, as well as Noven's direct sales of its own products. Noven expects that its cash requirements will continue to increase, primarily to fund clinical studies for products under development and for plant and equipment to expand production capacity. There can be no assurance that Noven will successfully complete the development of such products, that Noven 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 Noven will successfully negotiate future licensing arrangements. To the extent that capital requirements exceed available capital, Noven will seek alternative sources of financing to fund its operations. In addition to the Credit Facility, alternative financing may be needed to fund further activities. No assurance can be given that alternative financing will be available, if at all, in a timely manner, or on favorable terms. If Noven is unable to obtain satisfactory alternative financing, Noven may be required to delay or reduce its proposed expenditures, including expenditures for research and development and plant and equipment, in order to meet its future cash requirements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Market risks relating to Noven's operations may result from changes in LIBOR interest rates if Noven borrows under its Credit Facility. Noven had no variable rate debt outstanding during the three months ended March 31, 2001. Therefore, changes in interest rates did not affect interest expense, earnings or cash flows in 2001. Noven cannot predict market fluctuations in interest rates and their impact on any variable rate debt that Noven may have outstanding from time to time, nor can there be any assurance that fixed rate long-term debt will be available at favorable rates, if at all.

13

14

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) EXHIBITS

- 10.1 License Agreement, dated as of March 29, 2001, between Noven Pharmaceuticals, Inc. and Vivelle Ventures LLC (with certain provisions omitted pursuant to Rule 24b-2).*
- 10.2 Amendment No. 2 to Amended and Restated License Agreement, dated as of March 29, 2001, between Rorer Pharmaceutical Products, Inc. and Noven Pharmaceuticals, Inc. (with certain provisions omitted pursuant to Rule 24b-2).*

Edgar Filing: NOVEN PHARMACEUTICALS INC - Form 10-Q

- 10.3 Sublicense Agreement, dated as March 29, 2001, among Rorer Pharmaceutical Products, Inc., Rhone-Poulenc Rorer Inc., Aventis Pharmaceuticals Products Inc., Rhone-Poulenc Rorer International Holdings Inc., Novartis Pharma AG and Noven Pharmaceuticals, Inc. (with certain provisions omitted pursuant to Rule 24b-2).*
- 10.4 Purchase Agreement, dated as of March 29, 2001, among Rorer Pharmaceutical Products, Inc., Aventis Pharmaceuticals Products Inc. and Vivelles Ventures LLC (with certain provisions omitted pursuant to Rule 24b-2).*
- 10.5 Supply Agreement, dated as of March 29, 2001, between Vivelles Ventures LLC and Noven Pharmaceuticals, Inc. (with certain provisions omitted pursuant to Rule 24b-2).*
- 10.6 First Amendment to Marketing and Promotional Services Agreement, dated as of March 29, 2001, between Vivelles Ventures LLC and Noven Pharmaceuticals, Inc.
- 10.7 Amendment to Operating Agreement, dated as of March 29, 2001, between Novartis Pharmaceuticals Corporation and Noven Pharmaceuticals, Inc.

(b) REPORTS ON FORM 8-K

On April 4, 2001, Noven filed a Current Report on Form 8-K relating to the acquisition of CombiPatch(TM) by Novogyne and the results of Noven's preliminary analysis of the Phase III clinical study for its transdermal methylphenidate product.

* Noven agrees to furnish a copy of the exhibits and schedules to this agreement to the Securities and Exchange Commission upon request.

14

15

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: May 14, 2001

By: /s/ James B. Messiry

James B. Messiry
Vice President and
Chief Financial Officer

15

