NOVEN PHARMACEUTICALS INC
Form 10-Q
November 14, 2001

Table of Contents

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 [X] 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 October 31, 2001
Common stock $.0001 par value	22,457,480

TABLE OF CONTENTS

Table of Contents

NOVEN PHARMACEUTICALS, INC.

INDEX

Table of Contents

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	
	2001	2000	2001	2000
Revenues:				
Product sales	$9,705	$11,016	$33,569	$30,807
License revenue	698	147	2,117	440
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
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

Diluted earnings per share			
$0.10	$0.15	$0.35	$0.39
Weighted average number of common shares outstanding:			
Basic			
22,427	22,042	22,334	21,841
Diluted			
23,542	23,586	23,571	23,104

The accompanying notes are an integral part of these statements.

Table of Contents

NOVEN PHARMACEUTICALS, INC.

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

	September 30, 2001	December 31, 2000
Assets		
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
	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
	$140,215	$104,031

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	2	2
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.

Table of Contents

NOVEN PHARMACEUTICALS, INC.

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

	2001	2000
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.

Table of Contents

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):

	September 30, 2001	December 31, 2000
Finished goods	$862	$319
Work in process	1,182	1,567
Raw materials	2,713	4,212
Total	$4,757	$6,098

Table of Contents

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

Table of Contents

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):

	Three Months		Nine Months	
	2001	2000	2001	2000
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	$5,016	$3,064	$11,970	$7,600
Product specific marketing	2,455	999	4,294	2,324

$7,471 $4,063 $16,264 $9,924

As of September 30, 2001, Noven had amounts due from Novogyne of $24.8 million, of which $20 million related to the license of CombiPatch® (see Note 5) and the balance of which represented amounts due for products sold to, and marketing expenses reimbursable by, Novogyne. At December 31, 2000, Noven had amounts due from Novogyne of $2.9 million for products sold to, and marketing expenses reimbursable by, Novogyne.

The unaudited condensed Statements of Operations of Novogyne for the three and nine months ended September 30, 2001 and 2000 are as follows (in thousands):

	Three months		Nine months	
	2001	2000	2001	2000
Revenues	$28,472	$13,534	$63,192	$42,623
Cost of sales	5,199	2,285	11,273	6,998
Selling, general and administrative expenses	9,748	5,118	22,870	14,610
Amortization of intangible assets	1,548		3,089	
Income from operations	11,977	6,131	25,960	21,015
Interest income	52	388	675	1,028

Net income	$12,029	$6,519	$26,635	$22,043

Table of Contents

Subject to the approval of Novogyne s management committee, cash may be distributed to Novartis and Noven based upon a contractual formula. For the nine months ended September 30, 2001 and 2000, Noven received distributions of $13.1 million and $2.2 million, respectively, from Novogyne. These amounts were recorded as reductions in the investment in Novogyne when received. For the nine months ended September 30, 2001, Noven contributed $15.7 million to Novogyne in connection with the CombiPatch® transaction described in Note 5 above. This amount was recorded as an increase in the investment in Novogyne when paid.

7. Recent Accounting Pronouncements:

In June 2001, the Financial Accounting Standards Board (FASB) issued SFAS No. 141, Business Combinations , and SFAS No. 142, Goodwill and Other Intangible Assets . These standards establish accounting and reporting for business combinations. SFAS No. 141 requires all business combinations entered into subsequent to June 30, 2001 to be accounted for using the purchase method of accounting. SFAS No. 142 provides that goodwill and other intangible assets with indefinite lives will not be amortized, but will be tested for impairment on an annual basis. SFAS No. 142 is effective for fiscal years beginning after December 15, 2001; however, early adoption is permitted. Noven does not expect the adoption of these statements to have a material effect on its financial statements or disclosures.

In June 2001, the FASB issued SFAS No. 143, Accounting for Asset Retirement Obligations , which addresses financial accounting and reporting for legal obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. SFAS No. 143 is effective for fiscal years beginning after June 15, 2002, with early adoption encouraged. Noven does not expect the adoption of SFAS No. 143 to have a material effect on its financial statements or disclosures.

In August 2001, the FASB issued SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, which addresses financial accounting and reporting for the impairment or disposal of long-lived assets. SFAS No. 144 is effective for the fiscal years beginning after December 15, 2001, and interim periods within those fiscal years, with early adoption encouraged. The provisions of SFAS No. 144 generally are to be applied prospectively. Noven does not expect the adoption of SFAS No. 144 to have a material effect on its financial statements or disclosures.

8. Other:

In September 2000, Noven entered into a Severance and Non-Competition Agreement with Steven Sablotsky, then Co-Chairman of its Board of Directors. Pursuant to the agreement, Mr. Sablotsky s employment as an officer of Noven terminated on June 1, 2001. Noven paid Mr. Sablotsky $1.2 million on that date, which is being amortized over the period of his three-year non-competition agreement. In July 2001, Mr. Sablotsky resigned as a director of Noven.

In June 2001, Noven s stockholders approved an increase in the number of authorized common shares from 40 million to 80 million.

Table of Contents

9. Subsequent Events:

On November 6, 2001, Noven s Board of Directors adopted a Stockholder Rights Plan under which Noven declared a dividend of one right for each share of common stock outstanding. Prior to the Distribution Date referred to below, the rights will be evidenced by, and trade with the certificates for, the common stock. After the Distribution Date, Noven will mail rights certificates to the stockholders and the rights will become transferable apart from the common stock. Rights will separate from the common stock and become exercisable following (a) the tenth day after a public announcement that a person or group acquires beneficial ownership of 15% or more of Noven s common stock in a transaction or series of transactions not approved by Noven s Board of Directors or (b) the tenth business day (or such later date as may be determined by a majority of the directors) after a person or group announces a tender or exchange offer (with respect to which the Board of Directors does not issue a favorable recommendation), the consummation of which would result in ownership by a person or group of 15% or more of Noven s common stock (in either case, such date is referred to as the Distribution Date). After the Distribution Date, each right will entitle the holder to purchase for $110 a fraction of a share of Noven s preferred stock with economic terms similar to that of one share of Noven s common stock. In addition, upon the occurrence of certain events, holders of the rights (other than rights owned by an acquiring person or group) would be entitled to purchase either Noven s preferred stock or shares in an acquiring entity at approximately half of market value. The rights will expire on November 6, 2011 and Noven generally will be entitled to redeem the rights at $0.01 per right at any time prior to the close of business on the tenth day after there has been a public announcement of the beneficial ownership by any person or group of 15% or more of Noven s voting stock, subject to certain exceptions. The plan is intended to protect the interests of Noven s stockholders against certain coercive tactics sometimes employed in takeover attempts. The adoption of the Stockholder Rights Plan could make it more difficult for a third party to acquire a majority of Noven s common stock in a transaction that does not have the support of Noven s Board of Directors.

On November 8, 2001, an individual purporting to be a Noven stockholder filed a class action complaint in federal court against Noven and certain officers and directors. Plaintiff purports to represent a class of purchasers of Noven s common stock during the period March 27 through November 1, 2001. Plaintiff alleges that during that period, Noven and its officers and directors named as defendants violated Sections 10 and 20 of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder by making material misstatements and omissions regarding sales and sales prospects of certain of Noven s products in Europe that are the subject of an exclusive license agreement with Novartis AG. Plaintiff seeks unspecified damages, for herself and the class, based on the allegedly artificially inflated prices they paid for their shares of Noven s common stock. Noven is also aware, but has not received copies, of two addition complaints that it has been advised contains similar allegations. One of the additional complaints expands the class period by one day through November 2, 2001. Noven intends to vigorously defend these lawsuits, but their respective outcomes cannot be predicted. Any of such lawsuits, if determined adversely to Noven, could have a material adverse effect on Noven s financial position and results of operations. Noven s ultimate liability with respect to any of the foregoing proceedings is not presently determinable.

Table of Contents

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 in this report are forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements about Noven s plans, objectives, expectations, estimates, strategies, product approvals and development plans, and anticipated financial results. These statements are typically identified by the use of terms such as anticipates, believes, estimates, expects, intends, may, plans, sho and similar words. These statements are based on Noven s current expectations and beliefs concerning future events but are subject to risks and uncertainties that could cause actual results to differ materially from those expressed therein. In addition to the important factors described in Noven s Annual Report on Form 10-K, the following important factors, among others, could cause Noven s actual results to differ materially from those expressed in any forward-looking statements: Noven s dependence on strategic alliances and its relationships with its licensees, and the vulnerability of Noven to the risks and uncertainties of its licensees businesses; risks associated with the commercialization of Noven s products, including CombiPatch®; uncertainties associated with the projected growth of CombiPatch® prescriptions; uncertainties associated with clinical trials and product development, including Noven s MethyPatch® and any future generations of Noven s combination estrogen/progestin patch; the decline in international product orders received and expected to be received from Novartis AG; uncertainties concerning the timing and extent of Estradot and Estalis® launch orders; the ability of Novogyne to generate sufficient operating income to service the obligations owing to Aventis with respect to the CombiPatch® transaction; fluctuations in quarterly revenue; the effect of changes in taxation; and economic, competitive, governmental and technological factors affecting Noven s operations, markets, products and prices. Noven does not undertake to update any of these forward-looking statements or to announce the results of any revisions to these forward-looking statements except as required by law.

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. Certain license agreements entitle Noven to minimum fees. Noven records revenue related to minimum fees when 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 sales. Royalty revenue consists of royalties payable by Novogyne and Novartis from sales of Vivelle® and Vivelle-Dot 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 most cases, license revenue is deferred and recognized over time.

Revenues from product sales to licensees may fluctuate from quarter to quarter depending on various factors not in Noven s control, including the marketing efforts of each licensee, the inventory requirements of each licensee, the impact of competitive products, the timing and scope of Estalis® and

Table of Contents

Estradot 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, after satisfaction of an annual preferred return of $6.1 million to Novartis, according to an established formula. 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. Noven reports its share of Novogyne s earnings as Equity in earnings of Novogyne on its Statements of Operations.

Results of Operations

Nine months ended September 30, 2001 compared to nine months ended September 30, 2000

Total revenues for the nine months ended September 30, 2001 were $35.7 million, an increase of $4.4 million, or 14%, over the same period in the prior year. The increase in revenues was primarily attributable to an increase in product sales of $2.8 million, or 9%, for the nine months ended September 30, 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® in certain European countries in 2000. The remaining increase in product sales was primarily attributable to higher sales of Estalis® outside of the United States and, to a lesser extent, sales of CombiPatch® in the United States. A decline in sales of Vivelle® and Vivelle-Dot to Novogyne due to planned inventory reductions at Novogyne partially offset the increased sales of Noven s other products. License revenue increased $1.7 million, primarily due to the amortization of license fees received in connection with the license of Estradot to Novartis AG in the fourth quarter of 2000 and the license of CombiPatch® to Novogyne in the first quarter of 2001.

International product orders for the second half of 2001 from Novartis AG have been substantially less than anticipated. As a result, Noven expects that total revenues for the fourth quarter of 2001 will be approximately equal to the third quarter of 2001. Estalis® orders received from Novartis AG declined significantly in the second half of 2001, and that decline is expected to continue at least through 2002. Noven expects to receive some launch orders for Estradot in 2002, but those orders are expected to be insufficient to offset Estalis® declines. As a result, Noven expects its international sales to decline substantially in 2002 compared to 2001. If Noven s 2002 sales targets for CombiPatch® and Vivelle-Dot are achieved, growth in Noven s United States revenues would be expected to approximately offset international declines. In such a case, Noven would expect full year 2002 total revenues to be comparable to forecasted 2001 levels.

Gross profit (product sales less cost of products sold) for the nine months ended September 30, 2001 was $17.9 million (53% of product sales), compared to $16.9 million (55% of product sales) for the same period in the prior year. The decrease in gross margin resulted from unfavorable product mix as Noven sold more product outside of the United States, while United States sales declined. Noven s foreign sales have a lower gross margin. The decrease in gross margin was partially offset by higher minimum fee payments and a decrease in the deferred profit related to sales of product to Novogyne. The decrease in deferred profit on sales to Novogyne resulted from a planned reduction in Novogyne s inventory during the first nine months of 2001. See Note 1 to Notes to Unaudited Condensed Financial Statements. Noven expects its gross margin percentage to be in the low 50% range for full year 2001, primarily due to anticipated reductions in production volume. Noven expects its gross margin percentage for full year 2002 to be comparable to anticipated full year 2001 levels.

Table of Contents

Research and development expenses decreased approximately $0.3 million, or 4%, for the nine months ended September 30, 2001 compared to the same period in the prior year. The decrease was attributable primarily to the completion of certain clinical studies for MethyPatch®, partially offset by increases related to additional personnel. Noven expects research and development expenses in the fourth quarter of 2001 to be approximately equal to the third quarter of 2001. Research and development expenses in 2002 are expected to increase over 2001 levels as MethyPatch® clinical trials continue and other anticipated clinical trials begin. 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 license agreements 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 $2.9 million, or 45%, for the nine months ended September 30, 2001 compared to the same period in the prior year. This increase was due primarily to higher outside consulting services related to the implementation of an enterprise resource planning system, consulting services related to improvements in production efficiency, reserves for obsolete production equipment, and higher legal fees related to the CombiPatch® transaction. Marketing expenses in 2002 are expected to increase as Noven prepares for the anticipated launch of MethyPatch® in 2003.

For the nine months ended September 30, 2001 and 2000, Noven reported equity in earnings of Novogyne of $9.0 million and $6.4 million, respectively. Novogyne s revenue increased to $63.2 million for the nine months ended September 30, 2001 from $42.6 million in the comparable 2000 period. This increase was attributable to increased sales of Vivelle-Dot and the addition of CombiPatch® (licensed in March 2001), partially offset by decreased sales of Vivelle®. Novogyne s selling, general and administrative expenses increased to $22.9 million for the nine months ended September 30, 2001 from $14.6 million in the comparable 2000 period, primarily due to expenses relating to the relaunch of CombiPatch® and to expansion of the Novogyne sales force. Novogyne amortized $3.1 million related to the CombiPatch® acquisition cost during the nine months ended September 30, 2001. For the first nine months of 2001, Novogyne had net income of $26.6 million, compared to $22.0 million for the same period in the prior year. If Novogyne s sales targets for CombiPatch® and Vivelle-Dot are achieved, Noven s sales to Novogyne, and Noven s reported equity in earnings of Novogyne, would be expected to increase for full year 2002 compared to anticipated full year 2001 levels.

Interest income, net increased approximately $0.7 million, or 94%, for the nine months ended September 30, 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 5.0% for the nine months ended September 30, 2000 to 35.5% for the nine months ended September 30, 2001. The provision for income taxes for the nine months ended September 30, 2001 is based on the Federal and state statutory income tax rates. The provision for income taxes for the nine months ended September 30, 2000 reflects provisions for the Federal alternative minimum tax and state income taxes. As of September 30, 2001, Noven had a net deferred tax asset of $14.9 million. Realization of this deferred tax asset depends upon Noven 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

Table of Contents

realized based upon estimated future taxable income. Noven expects its effective tax rate to be between 34% and 36% for full year 2001 and between 34% and 37% for full year 2002.

Net income for the nine months ended September 30, 2001 was $8.3 million ($0.35 diluted earnings per share), compared to $8.9 million ($0.39 diluted earnings per share) for the same period in the prior year. Noven expects that diluted earnings will be $0.45 to $0.47 per share for full year 2001, and $0.45 to $0.55 per share for full year 2002.

Three months ended September 30, 2001 compared to three months ended September 30, 2000

Total revenues for the three months ended September 30, 2001 were $10.4 million, a decrease of $0.8 million, or 7.0%, from the same period in the prior year. The decrease in revenues was primarily attributable to a decrease in product sales of $1.3 million, or 12%, for the three months ended September 30, 2001 from the same period in the prior year. The decrease in product sales was primarily attributable to a planned inventory reduction at Novogyne and lower sales of Menorest® outside of the United States. License revenue increased $0.6 million, primarily due to the amortization of license fees received in connection with the license of Estradot to Novartis AG in the fourth quarter of 2000 and the license of CombiPatch® to Novogyne in the first quarter of 2001.

Gross profit (product sales less cost of products sold) for the three months ended September 30, 2001 was $4.7 million (49% of product sales) compared to $6.1 million (55% of product sales) for the same period in the prior year. The decline in gross margin was attributable to anticipated reductions in production volume and additional international product costs.

Research and development expenses increased approximately $0.4 million, or 12%, for the three months ended September 30, 2001 compared to the same period in the prior year, primarily attributable to costs associated with MethyPatch®.

Marketing, general and administrative expenses increased approximately $1.4 million, or 71%, for the three months ended September 30, 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 reserves for obsolete production equipment.

For the three months ended September 30, 2001 and 2000, Noven reported equity in earnings of Novogyne of $5.3 million and $2.7 million, respectively. Novogyne s revenue increased to $28.5 million in the three months ended September 30, 2001 from $13.5 million in the comparable 2000 period. This increase was attributable to increased sales of Vivelle-Dot and the addition of CombiPatch® (licensed in March 2001), partially offset by decreased sales of Vivelle®. Novogyne s selling, general and administrative expenses increased to $9.7 million for the three months ended September 30, 2001 from $5.1 million in the comparable 2000 period, primarily due to expenses relating to the relaunch of CombiPatch® and to expansion of the Novogyne sales force. Novogyne amortized $1.5 million related to the CombiPatch® acquisition cost during the three months ended September 30, 2001. For the three months ended September 30, 2001, Novogyne had net income of $12.0 million, compared to $6.5 million for the same period in the prior year.

Interest income, net increased approximately $0.1 million, or 30%, for the three months ended September 30, 2001 compared to the same period in the prior year, primarily due to higher average balances in cash and cash equivalents.

Table of Contents

Noven s effective tax rate increased from 7.2% for the three months ended September 30, 2000 to 38.6% for the three months ended September 30, 2001. The provision for income taxes for the three months ended September 30, 2001 is based on the Federal and state statutory income tax rates. The provision for income taxes for the three months ended September 30, 2000 reflects provisions for the Federal alternative minimum tax and state income taxes.

Net income for the three months ended September 30, 2001 was $2.5 million ($0.10 diluted earnings per share), compared to $3.6 million ($0.15 diluted earnings per share) for the same period in the prior year.

Liquidity and Capital Resources

As of September 30, 2001 and December 31, 2000, Noven had $47.1 million and $41.0 million, respectively, in cash and cash equivalents. Working capital remained at $46.7 million from December 31, 2000 to September 30, 2001.

Net cash of approximately $9.0 million was provided by operating activities during the first nine months of 2001, compared to approximately $1.7 million provided by 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® license transaction and deferral of the payment for Federal income taxes until the fourth quarter of 2001. Changes in working capital accounted for most of the remaining fluctuation.

Net cash of approximately $5.1 million was used in investing activities during the first nine months of 2001, compared to approximately $0.9 million provided by investing activities during the same period of the prior year. During the nine months ended September 30, 2001, Noven received distributions totaling $13.1 million from Novogyne. In connection with the CombiPatch® transaction, Noven contributed $15.7 million to Novogyne as its proportionate share of the payments to Aventis. During the nine months ended September 30, 2001, Noven purchased $2.4 million in property, plant and equipment, net, primarily related to software and implementation costs for an enterprise resource planning system and manufacturing equipment.

Net cash of approximately $2.3 million was provided by financing activities during the first nine months of 2001, compared to approximately $2.8 million provided by financing activities during the same period of the prior year, primarily resulting from a decrease 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% (4.1% at September 30, 2001). At September 30, 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 , 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

Table of Contents

certain European countries. Noven expects to receive the additional milestone payment in the fourth quarter of 2001, although there can be no assurance that Novartis AG s registration efforts will be successful.

Over the next year, Noven expects to invest up to $2 million in plant and equipment and software implementation costs. Cash requirements for Federal and state income taxes are also expected to increase. Additionally, as part of the CombiPatch® 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. The first two $10 million quarterly installments were paid by Novogyne to Aventis in June and September 2001, respectively. Noven expects that most of these installment payments will be funded from cash flows from Novogyne s 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 its members (including Noven) will be reduced correspondingly. If Novogyne s cash 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 obligations, 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 (which expires in April 2002), 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

Noven had no variable rate debt outstanding during the nine months ended September 30, 2001. Therefore, changes in interest rates did not affect interest expense, earnings or cash flows in that period. Market risks relating to Noven s operations may result from changes in LIBOR interest rates if Noven borrows under its Credit Facility. 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.

Table of Contents

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

Deborah A. Kaliser v. Noven Pharmaceuticals, Inc., Robert C. Strauss, James B. Messiry, and Steven Sablotsky, United States District Court, Southern District of Florida; November 8, 2001.

Plaintiff purports to represent a class of purchasers of Noven s common stock during the period March 27 through November 1, 2001. Plaintiff alleges that during that period, Noven and its officers and directors named as defendants violated Sections 10 and 20 of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder by making material misstatements and omissions regarding sales and sales prospects of certain of Noven s products in Europe that are the subject of an exclusive license agreement with Novartis Pharma AG. Plaintiff seeks unspecified damages, for herself and the class, based on the allegedly artificially inflated prices they paid for their shares of Noven s common stock. Noven is also aware, but has not received copies, of two additional complaints that it has been advised contain similar allegations. One of the additional complaints expands the class period by one day through November 2, 2001.

Noven intends to vigorously defend these lawsuits, but their respective outcomes cannot be predicted. Any of such lawsuits, if determined adversely to Noven, could have a material adverse effect on Noven s financial position and results of operations. Noven s ultimate liability with respect to any of the foregoing proceedings is not presently determinable.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

No exhibits filed. (b) Reports on Form 8-K

No reports on Form 8-K were filed by the Registrant during the three months ended September 30, 2001.

Table of Contents

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: November 14, 2001

By: /s/ James B. Messiry

James B. Messiry
Vice President and
Chief Financial Officer