NOVEN PHARMACEUTICALS INC
Form 10-Q
November 04, 2002

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, 2002

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 o.

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, 2002
Common stock $.0001 par value	22,554,406

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	
	2002	**2001**	**2002**	**2001**
Revenues:				
Product sales	$12,317	$ 9,705	$39,585	$33,569
License revenue	881	698	2,504	2,117
Total revenues	13,198	10,403	42,089	35,686
Expenses:				
Cost of products sold	5,111	4,982	17,032	15,692
Research and development	2,585	3,716	9,267	8,353
Marketing, general and administrative	3,492	3,383	10,104	9,219
Total expenses	11,188	12,081	36,403	33,264
Income (loss) from operations	2,010	(1,678)	5,686	2,422
Equity in earnings of Novogyne	2,010	5,278	10,657	9,010
Interest income, net	223	398	625	1,499
Income before income taxes	4,243	3,998	16,968	12,931
Provision for income taxes	1,480	1,542	6,109	4,585
Net income	$ 2,763	$ 2,456	$10,859	$ 8,346
Basic earnings per share	$ 0.12	$ 0.11	$ 0.48	$ 0.37
Diluted earnings per share	$ 0.12	$ 0.10	$ 0.46	$ 0.35
Weighted average number of common shares outstanding:				
Basic	22,549	22,427	22,523	22,334
Diluted	23,127	23,542	23,424	23,571

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, 2002	December 31, 2001
Assets		
Current Assets:		
Cash and cash equivalents	$ 59,760	$ 49,389
Accounts receivable trade (less allowance for doubtful accounts of $75 in 2002 and $28 in 2001)	3,521	1,308
Accounts receivable Novogyne	2,328	15,158
Inventories	7,180	4,324
Net deferred income tax asset	3,000	4,800
Prepaid and other current assets	1,032	304
	76,821	75,283
Property, plant and equipment, net	15,718	15,699
Other Assets:		
Investment in Novogyne	30,973	32,043
Net deferred income tax asset	9,922	10,150
Patent development costs, net	1,969	2,046
Deposits and other assets	681	1,007
	$ 136,084	$ 136,228
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable	$ 5,624	$ 5,620
Notes payable current portion	8	252
Due to Aventis Pharmaceuticals		10,000
Accrued compensation and related liabilities	4,085	1,518
Other accrued liabilities	2,448	4,169
Deferred license revenue current portion	3,526	7,936
	15,691	29,495
Long-Term Liabilities:		
Notes payable	7	13
Deferred license revenue	26,801	24,822
	42,499	54,330
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 22,553,006 shares at September 30, 2002 and 22,481,977 at December 31, 2001	2	2
Additional paid-in capital	78,222	77,394
Retained earnings	15,361	4,502
	93,585	81,898

	$ 136,084	$ 136,228

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)

	2002	2001
Cash flows from operating activities:		
Net income	$ 10,859	$ 8,346
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,623	1,730
Amortization of patent costs	231	169
Amortization of non-competition agreement	300	133
Deferred income tax provision	2,099	699
Recognition of deferred license revenue	(2,504)	(2,117)
Equity in earnings of Novogyne	(10,657)	(9,010)
(Increase) decrease in accounts receivable trade	(2,213)	3,341
Decrease (increase) in accounts receivable Novogyne	2,830	(1,896)
(Increase) decrease in inventories	(2,856)	1,341
(Increase) decrease in prepaid and other current assets	(728)	99
Decrease (increase) in deposits and other assets	26	(1,131)
Increase (decrease) in accounts payable	4	(368)
Increase (decrease) in accrued compensation and related liabilities	2,567	(38)
(Decrease) increase in other accrued liabilities	(1,629)	4,164
Increase in deferred license revenue	73	3,500
Cash flows provided by operating activities	25	8,962
Cash flows from investing activities:		
Purchase of property, plant and equipment, net	(1,642)	(2,366)
Investment in Novogyne		(15,680)
Distribution from Novogyne	11,727	13,080
Payments for patent development costs	(154)	(179)
Cash flows provided by (used in) investing activities	9,931	(5,145)
Cash flows from financing activities:		
Issuance of common stock	665	2,557
Payments on notes payable	(250)	(280)
Cash flows provided by financing activities	415	2,277
Net increase in cash and cash equivalents	10,371	6,094
Cash and cash equivalents, beginning of period	49,389	40,976
Cash and cash equivalents, end of period	$ 59,760	$ 47,070

The accompanying notes are an integral part of these statements.

Table of Contents

NOVEN PHARMACEUTICALS, INC.

Notes to Unaudited Condensed Financial Statements

1. DESCRIPTION OF BUSINESS:

Noven Pharmaceuticals, Inc. (Noven) was incorporated in Delaware in 1987 and is engaged in the research, development, manufacture and marketing of prescription transdermal drug delivery products.

Noven and Novartis Pharmaceuticals Corporation (Novartis) entered into a joint venture, Vivelle Ventures LLC (d/b/a Novogyne Pharmaceuticals) (Novogyne), effective May 1, 1998, to market and sell women s prescription healthcare products in the United States and Canada. These products include Noven s transdermal estrogen delivery systems marketed under the brand names Vivelle® and Vivelle-Dot® and, effective March 30, 2001, Noven s transdermal combination estrogen/progestin delivery system marketed under the brand name CombiPatch®. Novogyne s rights to CombiPatch® were acquired from Aventis Pharmaceuticals, the U.S. pharmaceuticals business of Aventis Pharma, AG (Aventis), in March 2001 in a series of transactions involving Noven, Novogyne, Novartis and Aventis. Noven accounts for its 49% investment in Novogyne under the equity method and reports its share of Novogyne s earnings as Equity in earnings of Novogyne on its Statements of Operations. Noven defers the recognition of 49% of its profit on products sold to Novogyne until the products are sold by Novogyne.

2. BASIS OF PRESENTATION:

In management s opinion, the accompanying unaudited condensed financial statements of Noven contain all adjustments (consisting of only normal recurring adjustments) necessary to present fairly, in all material respects, the financial position of Noven as of September 30, 2002, and the results of its operations for the three and nine months ended September 30, 2002 and 2001. Noven s business is subject to numerous risks and uncertainties including, but not limited to, those set forth in Noven s Annual Report on Form 10-K for the year ended December 31, 2001 (Form 10-K) as well as the risk that the results of recent and ongoing studies on the adverse health effects of certain forms of hormone replacement therapy (HRT) may result in lower sales by Noven or Novogyne in future periods and the risk that the increase in inventory levels at Novogyne and Novogyne s trade customers may have a further material adverse impact on Noven s liquidity, results of operations and business. Accordingly, the results of operations and cash flows for the three and nine months ended September 30, 2002 and 2001 are not, and should not be construed as, necessarily indicative of the results of operations or cash flows which may be reported for the remainder of 2002.

The accompanying unaudited condensed financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission for reporting on Form 10-Q. Pursuant to such rules and regulations, certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted. The unaudited condensed financial statements should be read in conjunction with the financial statements and the notes to the financial statements included in Noven s Form 10-K.

Table of Contents

The accounting policies followed for interim financial reporting are the same as those disclosed in Note 2 of the notes to the financial statements included in Noven s Form 10-K.

3. INVENTORIES:

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

	September 30, 2002	December 31, 2001
Finished goods	$1,742	$ 458
Work in process	2,462	1,140
Raw materials	2,976	2,726
Total	$7,180	$4,324

4. CASH FLOW INFORMATION:

Cash payments for income taxes were $4.8 million in 2002 and $0.9 million in 2001. Cash payments for interest were $14,000 in 2002 and $29,000 in 2001.

In connection with the CombiPatch® transaction consummated in March 2001, a final $10.0 million quarterly installment of the purchase price was paid by Novogyne directly to Aventis in March 2002.

Noven recorded $0.2 million and $1.3 million in income tax benefits to additional paid-in capital for the nine months ended September 30, 2002 and 2001, respectively, which were derived from the exercise of non-qualified stock options and disqualifying dispositions of incentive stock options.

5. LICENSE AGREEMENTS:

In the fourth quarter of 2001, Noven received a $5.0 million milestone payment from Novartis Pharma AG (Novartis AG) under the Estradot® license agreement even though the regulatory approval that was to trigger the milestone payment had not yet been received. Novartis AG received the applicable regulatory approval in the first quarter of 2002. Accordingly, the $5.0 million payment was deferred at December 31, 2001 and is being recognized as license revenue beginning in the first quarter of 2002 through the fourth quarter of 2010.

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 2002 and 2001 to meet Novartis annual preferred return for those years and for Noven to recognize earnings from Novogyne under the formula.

Table of Contents

During the three and nine months ended September 30, 2002 and 2001, Noven had the following transactions with Novogyne (in thousands):

	Three Months		Nine Months	
	2002	2001	2002	2001
Revenue:				
Trade product	$5,583	$2,895	$16,187	$ 6,981
Sample product and other	1,213	90	3,906	1,667
Royalty	808	1,320	3,590	3,086
	$7,604	$4,305	$23,683	$11,734
Reimbursed expenses:				
Services	$4,750	$5,016	$14,193	$11,970
Product specific marketing	1,970	2,455	6,155	4,294
	$6,720	$7,471	$20,348	$16,264

As of September 30, 2002, Noven had amounts due from Novogyne of $2.3 million for products sold to, and marketing expenses reimbursable by, Novogyne. At December 31, 2001, Noven had amounts due from Novogyne of $15.2 million, of which $10.0 million related to the license of CombiPatch® (which amount was satisfied in March 2002 with the payment of the final quarterly installment of the CombiPatch® purchase price) and the balance of which represented amounts due 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, 2002 and 2001 are as follows (in thousands):

	Three Months		Nine Months	
	2002	2001	2002	2001
Revenues	$21,507	$28,472	$81,936	$63,192
Cost of sales	6,031	5,199	17,485	11,273
Selling, general and administrative expenses	9,757	9,748	30,705	22,870
Amortization of intangible assets	1,545	1,548	4,635	3,089
Income from operations	4,174	11,977	29,111	25,960
Interest income	73	52	237	675
Net income	$ 4,247	$12,029	$29,348	$26,635

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, 2002 and 2001, Noven received distributions of $11.7 million and $13.1 million from Novogyne, respectively. These amounts were recorded as reductions in the investment in Novogyne when received. There were no distributions from Novogyne for the three months ended September 30, 2002 or 2001.

In connection with the CombiPatch® transaction, for the nine months ended September 30, 2001, Noven contributed $15.7 million to Novogyne. This amount was recorded as an increase in the investment in Novogyne when paid.

7. COMMITMENTS AND CONTINGENCIES:

With respect to the securities complaints filed in November and December 2001 and January 2002, previously reported in Noven s Form 10-K, on March 12, 2002, the Court entered an order consolidating all of the captioned actions into a single consolidated action, appointing lead plaintiff s counsel, and directing lead plaintiff s counsel to file a single amended and consolidated complaint. On April 11, 2002, the plaintiffs filed a Consolidated Amended Class Action Complaint styled In Re Noven Pharmaceuticals, Inc. Securities Litigation (the Consolidated Amended Complaint). On May 13, 2002, the defendants filed Motions to Dismiss, seeking to have the Court dismiss the Consolidated Amended Complaint with prejudice. The plaintiffs have filed with the Court a Memorandum in opposition to the defendants motions and have requested oral argument with regard to defendants motions. On July 26, 2002, defendants filed reply Memoranda with regard to their motions. These developments did not have a material effect on the action or on Noven s financial position or results of operations.

Noven believes the lawsuit is without merit, and intends to vigorously defend the lawsuit, but its outcome cannot be predicted. The lawsuit, 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 the lawsuit is presently not determinable.

Noven is a party to other pending legal proceedings arising in the normal course of business, none of which Noven believes is material to its financial position or results of operations.

8. NEW ACCOUNTING STANDARDS:

In April 2002, the FASB issued Statement No. 145, *Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Correction.* This Statement eliminates extraordinary accounting treatment for reporting gain or loss on debt extinguishment, and amends other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. The provisions of this Statement are effective for Noven with the beginning of fiscal year 2003; however, early application of the Statement is encouraged. Debt extinguishments reported as extraordinary items prior to scheduled or early adoption of this Statement would be reclassified in most cases following adoption. Noven does not anticipate a significant impact on its results of operations from adopting this Statement.

In June 2002, the FASB issued Statement No. 146, *Accounting for Costs Associated with Exit or Disposal Activities.* This Statement requires recording costs associated with exit or disposal activities at their fair values when a liability has been incurred. Under previous guidance, certain exit costs were accrued upon management s commitment to an exit plan, which is generally before an actual liability has been incurred. Adoption of this Statement is required with the beginning of fiscal year 2003. This Statement will impact the timing of exit or disposal activities reported by Noven after adoption.

Table of Contents

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

General

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 Form 10-K for the year ended December 31, 2001 and the condensed 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 and its licensees respective plans, objectives, expectations, estimates, strategies, prospects, 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, could, should, will, would and similar words. These statements are based on Noven s current expectations and be concerning future events and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed herein. 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.

In addition to the important factors described in Noven s Form 10-K for the year ended December 31, 2001, the following important factors, among others, could cause Noven s actual results to differ materially from those expressed in any forward-looking statements: uncertainties associated with the impact on the HRT market of published studies regarding the adverse health effects of certain forms of HRT; uncertainties associated with future prescription trends for CombiPatch®, Vivelle® family, Estalis® and Estradot®, including risks relating to declining physician or patient preference for HRT as a result of the published studies referred to above; risks associated with the commercialization of Noven s products, including CombiPatch®, Estradot®, Estalis®, and MethyPatch®; risks and uncertainties associated with the impact of a Novogyne competitor s strategy of increasing market share by heavily discounting product sales to managed care organizations; risks associated with the expected launch in 2003 of an estrogen cream product, which is a new dosage form in this category; risks associated with a recent significant increase in the level of Vivelle® returns to Novogyne, higher than desirable trade customer inventory levels of Vivelle® and higher than desirable inventory levels at Novogyne; risks and uncertainties relating to Noven s dependence on Novartis to monitor trade inventory levels for Novogyne; uncertainties concerning the timing and extent of Estradot® regulatory approvals and launch orders and Estalis® orders and commercialization efforts by Novartis AG; uncertainties associated with the timing, cost and outcomes of clinical trials and product development, including the regulatory review process for Noven s MethyPatch® and any future generations of Noven s combination estrogen/progestin patch; risks and uncertainties associated with product liability claims that may be brought against Noven as a result of published studies regarding the adverse health effects of HRT; 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, inventory requirements and marketing strategies; the risk that Noven s licensees may favor their own competitive products over the products licensed from Noven; risks associated with the ongoing public debate in the United States regarding the appropriateness of using methylphenidate and other medications to treat children with ADHD; the limited ability of Noven to forecast accurately international product orders from Novartis AG; expected fluctuations in quarterly revenue and research and development expenses, including fluctuations in revenues resulting from factors not within

Table of Contents

Noven s control and the timing of royalty reconciliations and payments under Noven s license agreements; risks and uncertainties relating to the fact that a majority of Noven s cash flow is dependent upon Novogyne s ability to pay distributions to Noven; the potential impact of MethyPatch® launch preparation expenses on Noven s financial results; the inherent risk associated with forecasting sales of a new product such as MethyPatch®; the effect of changes in taxation or accounting principles generally accepted in the United States (including changes in accounting principles relating to the accounting treatment for employee stock options); and economic, competitive, governmental and technological factors affecting Noven s operations, markets, products, prices and prospects.

HRT Studies

In July 2002, the National Institutes of Health (NIH) released data from its Women s Health Initiative (WHI) study on the risks and benefits associated with long-term use of oral HRT by healthy women. The NIH announced that it was discontinuing the arm of the study investigating the use of oral estrogen/progestin combination HRT products after an average follow-up period of 5.2 years because the product used in the study was shown to cause an increase in the risk of invasive breast cancer. The study also found an increased risk of stroke, heart attacks and blood clots and concluded that overall health risks exceeded benefits from use of combined estrogen plus progestin for an average of 5.2 year follow-up among healthy postmenopausal women. Also in July 2002, results of an observational study sponsored by the National Cancer Institute (NCI) on the effects of estrogen replacement therapy (ERT) were announced. The main finding of the study was that postmenopausal women who used ERT for 10 or more years had a higher risk of developing ovarian cancer than women who never used HRT. In October 2002, a significant HRT study being conducted in the United Kingdom was also halted. Noven s transdermal HRT products differ from the products used in the WHI study and the primary products observed in the NCI and United Kingdom studies. There are, however, no studies comparing the safety of Noven s products against other HRT therapies.

Although the range of consequences of these studies and the public debate they have inspired cannot be predicted, it is possible that they could result in a significant permanent decrease in the market for Noven s HRT products either as physicians withdraw their patients from HRT or as women elect to discontinue HRT on their own. It is also possible that health care regulators in the United States and abroad, as a result of these findings, could modify the permitted use of the products by mandatory product label changes, or remove the products from the market. Health care regulators also could delay the approval of new HRT products, such as those presently under development by Noven and Novartis AG, or require that any new HRT products be subject to more extensive or more rigorous study and testing prior to being approved. Further, because these studies show that certain uses of certain HRT products may result in a higher likelihood of certain adverse health effects, it is possible that Noven could be named as a defendant in product liability lawsuits relating to its HRT products.

Other studies evaluating HRT are currently underway or in the planning stages. In particular, the estrogen-only arm of the WHI study is ongoing. Noven is unable to predict the effect of these study results on the short and long-term prospects for the HRT market, generally, or for the market for Noven s transdermal HRT products, specifically. However, since publication of the WHI and NCI study data, United States prescriptions have declined for substantially all HRT

Table of Contents

products, including Noven s products. If the ongoing estrogen-only arm of the WHI study or any other currently ongoing HRT study is halted, the market for HRT products, including Noven s, both in the United States and abroad, could be further adversely impacted. Currently, Noven s liquidity, results of operations and business prospects are almost entirely dependent on sales of, and license royalties and fees related to the sales of, transdermal HRT products. Accordingly, any further adverse change in the market for HRT products (including any adverse changes resulting from the foregoing studies) could have a material adverse impact on Noven s liquidity, results of operations and business prospects.

Novogyne Inventory and Sales

Under the terms of the Novogyne joint venture, Novartis is responsible for distribution of Novogyne s products, including Vivelle®, and for selling Novogyne s products to its trade customers. Novartis regularly reports inventory information to the Novogyne Management Committee. Novartis has reported that trade inventory levels of Vivelle® in the aggregate are higher than in prior periods and appear to have grown to levels that exceed current demand. In each of the first three quarters of 2002, Novogyne increased its reserve for sales allowances and returns. In the third quarter, the increase was significantly higher than in the first and second quarters.

In addition, inventory levels at Novogyne have increased and are higher than desirable. To begin to align inventories with current demand, Novogyne is curtailing product shipments to its trade customers, and Noven is deferring product shipments to Novogyne. These actions will adversely impact Noven and Novogyne s financial results. Sales of Novogyne s products in future periods will be adversely impacted as trade customers reduce their inventories to historical levels (or even lower as a result of the recent studies) and as Novogyne and Noven take affirmative steps to reduce inventory levels. Sales from Noven to Novogyne, and Noven s gross margin on sales, will also be adversely impacted, both as a result of declining orders from trade customers seeking to reduce their inventory levels (which would reduce Novogyne s sales) and Novogyne s higher than normal inventory levels (which would reduce Noven s sales to Novogyne). A decline in prescriptions of Novogyne s HRT products, whether as a result of the recent or ongoing studies or otherwise, could further exacerbate this situation. Noven is unable to predict either the timing or the magnitude of the impact of this situation on future sales and results of operations.

MethyPatch®

In the first quarter of 2002, Noven completed a second Phase III clinical trial for MethyPatch®, and Noven s review of the primary efficacy data from the trial indicates that MethyPatch® reduces the symptoms of Attention Deficit Hyperactivity Disorder (ADHD). Noven filed a New Drug Application (NDA) with the United States Food and Drug Administration (FDA) in June 2002. If Noven s MethyPatch® NDA is approved, Noven intends to establish its own sales force to market the product. In such event, Noven would expect that its sales and marketing expenses would increase during the remainder of 2002 and into 2003 as it prepares for the expected commercialization of the product in late 2003. No assurance can be given that the product will be approved by the FDA or that, if approved, it will be marketed successfully. The FDA will examine efficacy data from the recently completed Phase III study together with safety and other data from this and other MethyPatch® studies sponsored by Noven, and there can be no assurance that the FDA will deem all of such data sufficient to approve the product for marketing or to authorize the product s use in the manner described by Noven. Noven believes that MethyPatch® is the first transdermal ADHD product submitted to FDA for approval, and there can be no assurance that the

Table of Contents

FDA will not have questions or raise objections that could delay or prevent an approval. Additionally, there can be no assurance that the FDA will not place conditions or restrictions on any approval that it may grant, which conditions or restrictions could adversely affect the market potential of MethyPatch®.

Results of Operations

Three and nine months ended September 30, 2002 compared to three and nine months ended September 30, 2001

Revenues:

Total revenues for the three and nine months ended September 30, 2002 and 2001 are summarized as follows (dollar amounts in thousands):

	Three Months			Nine Months		
	2002	2001	Percentage Change	2002	2001	Percentage Change
Product sales	$12,317	$ 9,705	27%	$39,585	$33,569	18%
License revenue	881	698	26%	2,504	2,117	18%
Total revenue	$13,198	$10,403	27%	$42,089	$35,686	18%
Gross profit (product sales less cost of products sold)	$ 7,206	$ 4,723	53%	$22,553	$17,877	26%
Gross margin (as a percentage of product sales)	59%	49%		57%	53%	

The increase in total revenues for the three months ended September 30, 2002 over the same period in 2001 was primarily attributable to an increase in product sales. Product sales were higher in 2002 than 2001 as a result of increases in sales of Vivelle-Dot® and Vivelle® to Novogyne and sales of Estradot® to Novartis AG (which commenced in the first quarter of 2002), partially offset by lower sales of CombiPatch® to Novogyne.

The increase in total revenues for the nine months ended September 30, 2002 over the same period in 2001 was primarily attributable to the same factors stated above, offset by lower sales of Menorest® and Estalis® outside the United States. In addition, product sales for the nine months ended September 30, 2001 included $1.4 million in minimum fee payments related to the sales of Menorest® in certain European countries in 2000. This minimum fee payment did not recur in 2002.

As noted above, trade inventory levels of Vivelle® in the aggregate are higher than in prior periods and appear to have grown to levels that exceed current demand. In each of the first three quarters of 2002, Novogyne increased its reserve for sales allowances and returns. In the third quarter, the increase was significantly higher than in the first and second quarters. In addition, inventory levels at Novogyne have also increased and are higher than desirable. Accordingly, to the extent that Noven s revenues were increased by sales that resulted in those higher inventory levels, sales in future periods will be adversely impacted.

Table of Contents

Gross Margin:

Noven s gross margin was 59% (or gross profit of $7.2 million) for the three months ended September 30, 2002 versus 49% (or gross profit of $4.7 million) for the three months ended September 30, 2001. The increase in gross margin was primarily due to increases in production volume resulting in more favorable overhead absorption and favorable product mix as Noven sold more product in the United States.

Noven s gross margin was 57% (or gross profit of $22.6 million) for the nine months ended September 30, 2002 versus 53% (or gross profit of $17.9 million) for the nine months ended September 30, 2001. The increase in gross margin was primarily due to favorable product mix as Noven sold more product in the United States and to increases in production volume resulting in more favorable overhead absorption, partially offset by a lower minimum fee payment in the 2002 period.

As trade customers or Novogyne reduce their orders in an attempt to return their inventories to desirable levels or as Novogyne takes affirmative steps to reduce trade customer inventory levels, Noven s gross margin (and gross profit) for future periods will be adversely impacted.

Operating Expenses:

Operating expenses for the three and nine months ended September 30, 2002 and 2001 are summarized as follows (dollar amounts in thousands):

	Three Months			Nine Months		
	2002	2001	Percentage Change	2002	2001	Percentage Change
Research and development	$2,585	$3,716	(30%)	$ 9,267	$8,353	11%
Marketing, general and administrative	3,492	3,383	3%	10,104	9,219	10%

Research and Development

The $1.1 million, or 30%, decrease in research and development expenses for the three months ended September 30, 2002 compared to the same period in 2001 was primarily attributable to a decrease in clinical study expenses for MethyPatch® due to the timing of clinical trials. The $0.9 million, or 11%, increase in research and development expenses for the nine months ended September 30, 2002 over the same period in 2001 was primarily attributable to increases in purchases of materials and personnel costs for new product development.

Table of Contents

Marketing, General and Administrative Expenses

The $0.1 million, or 3%, increase in marketing, general and administrative expenses for the three months ended September 30, 2002 over the same period in 2001 was primarily attributable to increases in pre-launch marketing expenses for MethyPatch®, offset by lower outside consulting services related to the implementation of Noven s enterprise resource planning system and nonrecurring reserves for obsolete production equipment in the prior year. The $0.9 million, or 10%, increase in marketing, general and administrative expenses for the nine months ended September 30, 2002 over the same period in 2001 was primarily attributable to the same factors.

Interest Income:

Interest income, net, decreased approximately $0.2 million and $0.9 million, or 44% and 58%, for the three and nine months ended September 30, 2002, respectively, compared to the same periods in 2001, primarily due to lower interest rates.

Income Taxes:

Noven s effective tax rate decreased to 34.9% for the three months ended September 30, 2002 from 38.6% for the three months ended September 30, 2001 and increased to 36.0% for the nine months ended September 30, 2002 from 35.5% for the nine months ended September 30, 2001. The provision for income taxes is based on the Federal statutory and state income tax rates. In addition, net deferred income tax assets are measured using the average graduated tax rate for the estimated amount of annual taxable income in the years that the liability is expected to be settled or the asset recovered. The effect of adjusting the expected tax rate related to the net deferred income tax assets is included in the provision for income taxes. As of September 30, 2002, Noven had a net deferred tax asset of $12.9 million. Realization of this deferred tax asset depends upon the generation of 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.

Table of Contents

Equity in Earnings of 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. Novogyne produced sufficient income in the first quarters of 2002 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.

The financial results of Novogyne for the three and nine months ended September 30, 2002 and 2001 are summarized as follows (dollar amounts in thousands):

	Three Months			Nine Months		
	2002	2001	Percentage Change	2002	2001	Percentage Change
Novogyne s Summary Results:						
Revenues	$21,507	$28,472	(24%)	$81,936	$63,192	30%
Cost of sales	6,031	5,199	16%	17,485	11,273	55%
Gross profit	15,476	23,273	(34%)	64,451	51,919	24%
Gross margin percentage	72%	82%		79%	82%	
Selling, general and administrative expenses	9,757	9,748		30,705	22,870	34%
Amortization of intangible assets	1,545	1,548		4,635	3,089	50%
Income from operations	4,174	11,977	(65%)	29,111	25,960	12%
Interest income	73	52	40%	237	675	(65%)
Net income	$ 4,247	$12,029	(65%)	$29,348	$26,635	10%
Noven s equity in earnings of Novogyne	$ 2,010	$ 5,278	(62%)	$10,657	$ 9,010	18%

The decrease in Novogyne s revenues of $7.0 million, or 24%, for the three months ended September 30, 2002 as compared to the same period in 2001 is primarily attributable to higher sales allowances and returns and decreased sales of each of Novogyne s products. Revenues for the three months ended September 30, 2002 and 2001 are net of sales allowances and returns of $9.4 million and $4.3 million, respectively. The increase in sales allowances and returns is due primarily to higher returns of Vivelle®. The increase in Novogyne s revenues of $18.7 million, or 30%, for the nine months ended September 30, 2002 as compared to the same period in 2001 is primarily attributable to increased sales of Vivelle-Dot® and Vivelle® and the addition of CombiPatch® (licensed by Novogyne in March 2001) offset by higher sales allowances and returns. Revenues for the nine months ended September 30, 2002 and 2001 are net of sales allowances and returns of $20.4 million and $10.2 million, respectively. The increase in sales allowances and returns is primarily attributable to increased sales of all products and higher returns of Vivelle®.

Novogyne s gross margin was 72% (or gross profit of $15.5 million) for the three months ended September 30, 2002 versus 82% (or gross profit of $23.3 million) for the three months ended September 30, 2001. Novogyne s gross margin was 79% (or gross profit of $64.5 million) for the nine months ended September 30, 2002 versus 82% (or gross profit of $51.9 million) for the nine months ended September 30, 2001. The decrease in gross margin is primarily attributable to higher sales allowances and returns in 2002, an increase in inventory obsolescence reserves for 2002 and the addition of CombiPatch® in March 2001.

Table of Contents

Novogyne s selling, general and administrative expenses remained relatively consistent, increasing to $9.8 million for the three months ended September 30, 2002 from $9.7 million in 2001. Novogyne s selling, general and administrative expenses increased to $30.7 million for the nine months ended September 30, 2002 from $22.9 million in 2001 primarily due to higher promotional expenses, an approximate 20% increase in the size of the Novogyne sales force, higher royalties to Noven on product sales and higher sample expense.

Novogyne amortized $1.5 million related to the CombiPatch® acquisition cost during the three months ended September 30, 2002 and 2001, respectively, and $4.6 million and $3.1 million during the nine months ended September 30, 2002 and 2001, respectively. CombiPatch® was licensed by Novogyne in March 2001.

Liquidity and Capital Resources

As of September 30, 2002 and December 31, 2001, Noven had $59.8 million and $49.4 million in cash and cash equivalents, and working capital of $61.1 million and $45.8 million, respectively.

Cash provided by (used in) operating, investing and financing activities for the nine months ended September 30, 2002 and 2001 is summarized as follows (amounts in thousands):

	2002	2001
Cash flows:		
Operating activities	$ 25	$ 8,962
Investing activities	9,931	(5,145)
Financing activities	415	2,277

Operating Activities:

Net cash provided by operating activities for the nine months ended September 30, 2002 primarily resulted from changes in working capital due to the timing and amount of product shipments resulting in a higher inventory balance and the timing and amounts paid for income taxes, research and development, sales and marketing expenses and personnel costs. A non-cash operating item (equity in earnings of Novogyne of $10.7 million) constituted approximately 63% of Noven s income before income taxes of $17.0 million.

Net cash provided by operating activities for the nine months ended September 30, 2001 included the receipt of a one-time license fee in the amount of $3.5 million from Aventis in connection with the CombiPatch® license transaction. Operating results and changes in working capital accounted for most of the remaining increase.

Table of Contents

Investing Activities:

Net cash provided by investing activities for the nine months ended September 30, 2002 was primarily attributable to a distribution received from Novogyne of $11.7 million, partially offset by the purchase of fixed assets and payments for patent development costs.

Net cash of approximately $5.1 million was used in investing activities during the first nine months of 2001. During that period, 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. In addition, Noven purchased $2.4 million in property, plant and equipment, net, of which the most significant asset related to software for the enterprise resource planning system.

Financing Activities:

Net cash provided by financing activities for the nine months ended September 30, 2002 was primarily attributable to cash received in connection with the issuance of common stock from the exercise of stock options, partially offset by the payoff of all borrowings under a master lease facility in March 2002.

Net cash provided by financing activities for the nine months ended September 30, 2001 was attributable to cash received in connection with the issuance of common stock from the exercise of stock options, partially offset by payments made on notes payable.

Short-Term and Long-Term Liquidity:

In December 2000, Noven entered into a secured revolving credit facility (the Credit Facility) providing for borrowings of up to the lesser of $10.0 million or eligible accounts receivable. The term of the Credit Facility was extended in March 2002, and it will now terminate in April 2003. The Credit Facility bears interest at LIBOR plus 1.50% (3.319% at September 30, 2002). At September 30, 2002 and December 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 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, distributions from Novogyne, and, if necessary, borrowings under its Credit Facility. As discussed above, for the nine months ended September 30, 2002, approximately 63% of Noven s income before income taxes was comprised of equity in earnings of Novogyne, and, presently, Noven s short-term liquidity is almost entirely dependent on sales of, license royalties and fees related to sales of, transdermal HRT products. Any continued decrease in the sales of those products by Noven or its licensees or increase in returns of products to Novogyne (including any such changes resulting from the results of the recent or ongoing HRT studies discussed above or decreases resulting from Novogyne and/or Novogyne s trade customers reducing their inventory levels), the failure of the transdermal HRT market to resume its prior growth trends, or the inability or failure of Novogyne to pay distributions would have a material adverse effect on Noven s short-term liquidity and require Noven to rely more heavily on its existing cash reserves or on borrowings under its Credit Facility to support its operations and business. Although Noven expects to receive distributions from Novogyne, Noven did not receive such a

Table of Contents

distribution during the three months ended September 30, 2002, and there can be no assurance that Novogyne will have sufficient profits or cash flow to pay distributions or that Novogyne s Management Committee will authorize such distributions. In addition, sales and marketing expenses for MethyPatch® and capital expenditures in anticipation of the launch of MethyPatch® are expected to increase over the next twelve months, and such increase could have a material adverse effect on Noven s liquidity until such time, if any, as sales of MethyPatch® offset such expenses.

Noven believes that it will have sufficient cash available to meet its operating needs and anticipated short-term capital requirements. 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 or products that Noven may license or acquire from others. 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, for plant and equipment to expand production capacity and for MethyPatch® sales and marketing expenses. 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 or product acquisition arrangements. Because much of the cost associated with product development is incurred prior to product launch, if Noven is unable to launch additional commercially viable products that it develops or that it licenses or acquires from others, Noven will have incurred the up-front costs associated with product development or acquisition without the benefit of the liquidity generated by sales of those products, which could adversely affect Noven s long-term liquidity needs.

In addition, Noven is unable to predict the effect of the results of the discontinued and ongoing HRT studies discussed above on the short and long-term prospects for the HRT market, generally, or for the market for Noven s transdermal HRT products, specifically. Accordingly, Noven is not able to predict the result that those studies may have on Noven s short-term or long-term liquidity, results of operations and business prospects.

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 2003, 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.

New Accounting Standards

In April 2002, the FASB issued Statement No. 145, *Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Correction.* This Statement eliminates extraordinary accounting treatment for reporting gain or loss on debt extinguishment, and amends other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. The provisions of this Statement are effective for Noven with the beginning of fiscal year 2003; however, early application of the Statement is encouraged. Debt extinguishments reported as extraordinary items prior to scheduled or early adoption of this Statement would be reclassified in most cases following adoption. Noven does not anticipate a significant impact on its results of operations from adopting this Statement.

Table of Contents

In June 2002, the FASB issued Statement No. 146, *Accounting for Costs Associated with Exit or Disposal Activities.* This Statement requires recording costs associated with exit or disposal activities at their fair values when a liability has been incurred. Under previous guidance, certain exit costs were accrued upon management s commitment to an exit plan, which is generally before an actual liability has been incurred. Adoption of this Statement is required with the beginning of fiscal year 2003. This Statement will impact the timing of exit or disposal activities reported by Noven after adoption.

Critical Accounting Policies

Noven s discussion and analysis of its financial condition and results of operations are based upon its condensed financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States for interim reporting. The preparation of these condensed financial statements requires Noven to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, Noven evaluates its estimates, including those related to allowance for doubtful accounts, inventories, intangible assets, accrued liabilities, income and other tax accruals, revenue recognition and contingencies and litigation. Noven bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Many of Noven s critical accounting policies are those which Noven believes require the most subjective or complex judgments; often as a result of the need to make estimates about the effect of matters that are inherently uncertain. As a result, applying different assumptions or estimates in the application of those critical accounting policies could result in materially different amounts being reported in Noven s financial results. A discussion of Noven s critical accounting policies, the underlying judgments and uncertainties affecting their application and the likelihood that materially different amounts would be reported under different conditions or using different assumptions, is as follows:

Revenue Recognition:

Substantially all of Noven s product sales are to its licensees, Novogyne and Novartis AG. Revenues from product sales are recognized at the time of shipment. However, as discussed in Note 1 to the condensed financial statements included in Item 1 of this Quarterly Report on Form 10-Q, Noven defers the recognition of 49% of the profit on its product sales to Novogyne until those products are sold by Novogyne. 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 sufficient 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 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.

Table of Contents

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 the estimated product life cycle or the length of relevant patents, whichever is shorter. These estimates of product life cycle or the length of relevant patents may prove to be inaccurate, in which case any resulting adjustments to the associated license revenue would be recognized in Noven s revenue at the time of such determination.

Contract revenue consists of contract development fees and milestone payments earned under contracts with third parties. Noven recognizes revenue under the agreements as the work is performed. These estimates of work completed under the contract may prove to be inaccurate, in which case any resulting adjustments to contract revenue recorded would be recognized in Noven s revenue at the time of such determination. Deferred revenue represents the portion of all refundable and nonrefundable payments received that have not been earned. Costs incurred in performing contract development services are included in research and development expenses. Refundable development and license fee payments are deferred until the specified performance criteria are achieved. Contract revenue is included in product sales.

Fair Value of Stock Options:

Noven has elected to follow Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees and related Interpretations in accounting for its employee stock options as allowed pursuant to FASB Statement No. 123. Accordingly, no compensation expense has been recognized in the three and nine months ended September 30, 2002 and 2001 and for the years ended December 31, 2001, 2000 and 1999.

Noven s accounting for its employee stock options complies with accounting practices generally accepted in the United States. However, from time to time, proposals have been put forth to change the method of accounting for employee stock options that, if adopted, would require Noven to include the fair value of employee stock options in its compensation expense. As a result of recent events in the business and financial community of the United States, Congress, the Securities and Exchange Commission and the accounting profession have been engaged in the process of reevaluating practices concerning employee compensation and its accounting, and several new proposals concerning the proper accounting for employee stock options have recently been put forth. It is not possible to predict whether any such proposal will ultimately be adopted, or, if such a policy is adopted, what its requirements may be. However, it is possible that Noven may in the future be required under accounting principles generally accepted in the United States to include the fair value of its employee stock options in its compensation expense.

Had compensation cost for Noven s stock option plans been determined on the basis of the fair value at the grant date for awards under those plans, consistent with FASB Statement No. 123 and Noven s existing valuation method for its employee stock options, the Black-Scholes option pricing model, Noven estimates that its net income for the years ended December 31, 2001, 2000 and 1999 would have been reduced by 50%, 16% and 20%, respectively. However, FASB Statement No. 123 requires the use of option valuation models that require the input of highly subjective assumptions, including expected stock price volatility, and to date, a uniform standard for calculating the fair value of employee stock options in accordance with FASB Statement No. 123 has not been adopted. Because Noven s stock options have characteristics significantly different from traded options and because changes in the subjective input assumptions can materially affect the fair value estimate, in management s opinion, the existing models do not necessarily provide a reliable measure

Table of Contents

of the fair value of its employee stock options. In addition, the effect of applying the fair value method of accounting for stock options on reported net income for 2001, 2000 and 1999 may not be representative of the effects for future years because outstanding options vest over a period of several years and additional awards are generally made each year.

Income Taxes:

Accounting principles generally accepted in the United States require that Noven not record a valuation allowance against its net deferred tax asset if it is more likely than not that Noven will be able to generate sufficient future taxable income to utilize its net deferred tax asset. Although realization is not assured, Noven believes it is more likely than not that the net deferred income tax asset will be realized based upon estimated future taxable income of Noven and, accordingly, no valuation allowance for the net deferred income tax asset was deemed necessary. Subsequent revisions to the estimated net realizable value of the net deferred tax asset could cause Noven s provision for income taxes to vary significantly from period to period.

Investment in Novogyne:

Noven and Novartis entered into a joint venture (Novogyne), effective May 1, 1998, to market and sell women s prescription healthcare products in the United States and Canada. Noven accounts for its 49% investment in Novogyne under the equity method and reports its share of Novogyne s earnings as Equity in earnings of Novogyne on its Condensed Statements of Operations. Noven defers the recognition of 49% of its profit on products sold to Novogyne until the products are sold by Novogyne.

As of September 30, 2002, Novogyne had a long-term asset of $52.5 million related to the acquisition of the marketing rights to CombiPatch®. Accounting principles generally accepted in the United States require that Novogyne record this asset at cost and that the asset be tested for recoverability whenever events or changes in circumstances indicate that its carrying amount may not be recoverable. Testing for impairment requires Novogyne to estimate the undiscounted future cash flow of the asset and compare that amount to the carrying value of the asset. If such analysis indicates that a possible impairment exists (undiscounted future cash flows are less than the carrying value), Novogyne would be required to estimate the fair value of the asset. The determination of fair value of this asset involves numerous uncertainties because there is no viable actively traded market for the marketing rights of a pharmaceutical product. As permitted by accounting principles generally accepted in the United States, Novogyne determines the estimated fair value of the marketing rights of CombiPatch® utilizing a discounted cash flows analysis. A discounted cash flow analysis values an asset on the basis of the net present value of the cash expected to be generated by that asset over its estimated useful life. This analysis requires Novogyne to make a number of significant assumptions and judgments. For example, estimates need to be made regarding prescription growth, sales price and unit cost among many other factors including the applicable discount rate to be applied to the estimated cash generated by the marketing rights. If there is a material change in any of these assumptions, Novogyne may be required to record a valuation allowance, which would adversely affect Novogyne s operating results during the period in which the determination or allowance were made, and would, consequently, also reduce the amount of Noven s earnings attributable to its investment in Novogyne for that period and the amount of Noven s investment in Novogyne. Neither Noven nor Novogyne is able to predict the effect of the results of the recently discontinued and currently ongoing HRT studies on the short and long-term

Table of Contents

prospects for the HRT market, generally, or for the market for CombiPatch® specifically. Any adverse change in the market for HRT products (including any adverse changes resulting from the foregoing studies) could have a material adverse impact on the ability of Novogyne to recover its investment in its marketing rights of CombiPatch® which could require Novogyne to impair that asset.

Novogyne records its sales net of sales allowances for chargebacks, Medicaid rebates, managed healthcare rebates, cash discounts, product returns and other allowances. The returns portion of the sales allowance is based in part on Novartis returned goods policy. Novartis controls and maintains the reserves associated with such sales allowances and returns on behalf of Novogyne and pays all monies owed and issues credits to individual customers as deemed necessary. The contracts that underlie these transactions are maintained by Novartis for its business as a whole and those transactions relating to Novogyne are estimated by Novartis. Based on an analysis of the underlying activity, the amounts recorded by Novogyne represents Novartis best estimate of these charges that apply to sales of Novogyne. However, neither Novogyne nor Noven can control Novartis analysis of the underlying activity or its application of that analysis to Novogyne. If Novartis materially changes the assumptions it uses in allocating reserves or in the actual determination of the gross reserve, Novogyne may be required to record an additional reserve allowance on its financial statements, which would adversely affect Novogyne s operating results during the period in which the determination or reserve were made, and would, consequently also reduce Noven s earnings attributable to its investment in Novogyne for that period.

The critical accounting policies discussed herein are not intended to be a comprehensive list of all of Noven s accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by accounting principles generally accepted in the United States, with no need for management s judgment in their application. There are also areas in which management s judgment in selecting any available alternative would not produce a materially different result.

Outlook

The forecasts provided in this section supersede forecasts provided in Noven s prior Quarterly Reports on Form 10-Q and Annual Report on Form 10-K.

For the fourth quarter of 2002, Noven expects to report revenues in the $12 million range. Fourth quarter 2002 operating expenses should be in line with the first three quarters of 2002. For full year 2002, Noven expects to report revenues in the $54 million range. Noven s 2003 first quarter revenues are expected to be lower than the 2002 fourth quarter.

HRT Market

In assessing Noven s financial prospects for 2003, there is considerable uncertainty regarding the impact of the HRT studies (as described above) on the market for Noven s HRT products. Until sufficient HRT prescription trends and other information become available, Noven is unable to predict what impact these study results will have on Noven or Novogyne s revenues and earnings for 2003 or thereafter.

In addition, Noven cannot predict the impact that the HRT studies may have on the market for HRT products outside the United States, on Novartis AG s global HRT strategy, on development plans involving Noven s HRT products, or on the commercialization of Noven s international products. In

Table of Contents

October 2002, Noven received a $1.0 million milestone payment from Novartis AG relating to the continuing development of a next-generation transdermal estrogen-progestin patch. Diminished demand for HRT products outside the United States, or any change in strategy that has the effect of delaying or limiting commercialization of Noven s international products, could have a material adverse effect on Noven s business and prospects.

International Product Launches

Novartis AG began European launches of Estradot® in the first quarter of 2002, and Noven expects Novartis AG s launches to continue through 2003. Although Novartis AG has advised Noven that it expects to receive government approvals of Estradot® in time for planned launches, not all approvals have been received and there is no assurance that remaining approvals will be received on a timely basis or at all, or if they are received, that the product will be launched. In addition, Novartis does not have HRT sales resources in all countries in which the product is intended to be launched, and the establishment of such resources may delay launches. Failure to receive approvals or establish sales resources on a timely basis could adversely affect Novartis AG s launch plans for Estradot®, which would adversely impact Noven s Estradot® sales. The timing of Novartis AG s product launches, and the various factors that influence that timing, are outside the control of Noven.

MethyPatch®

Noven is currently incurring sales, marketing and other expenses in anticipation of a MethyPatch® approval and launch in the second half of 2003. These expenses are expected to cause Noven s marketing, general and administrative expenses for 2003 to increase as compared to 2002. There can be no assurance that MethyPatch® will be approved or launched in this time frame or at all. Due in part to school-year seasonality in the market for ADHD medications, the timing of a MethyPatch® approval and launch will affect the timing and magnitude of MethyPatch® revenues and launch-related expenses.

Clinical Spending

Noven expects to begin and/or advance clinical trials for the development of new prescription transdermal therapies over the next several quarters. These projects may increase Noven s research and development expense in 2003 as compared to 2002. Future levels 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. Noven s research and development expenses may vary significantly from quarter to quarter depending on product development cycles and the timing of clinical studies.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Noven had no variable rate debt outstanding during the nine months ended September 30, 2002. Therefore, changes in interest rates did not affect interest expense, earnings or cash flows in 2002. 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

With respect to the cases styled Deborah A. Kaliser v. Noven Pharmaceuticals, Inc., Robert C. Strauss, James B. Messiry and Steven Sablotsky; Bernard Middleton et. al., v. Noven Pharmaceuticals, Inc., Robert C. Strauss, James B. Messiry, and Steven Sablotsky; Evelyne Shabo, et. al., v. Noven Pharmaceuticals, Inc., Robert C. Strauss, James B. Messiry, and Steven Sablotsky; Leah Constantine, et. al., v. Noven Pharmaceuticals, Inc., Robert C. Strauss, James B. Messiry, and Steven Sablotsky; and Joseph A. Papa, et. al., v. Noven Pharmaceuticals, Inc., Robert C. Strauss, James B. Messiry, and Steven Sablotsky, previously reported in Noven s Annual Report on Form 10-K for the year ended December 31, 2001, on March 12, 2002, the Court entered an order consolidating all of the captioned actions into a single consolidated action, appointing lead plaintiff s counsel, and directing lead plaintiff s counsel to file a single amended and consolidated complaint. On April 11, 2002, the plaintiffs filed a Consolidated Amended Class Action Complaint styled In Re Noven Pharmaceuticals, Inc. Securities Litigation (the Consolidated Amended Complaint). On May 13, 2002, the defendants filed Motions to Dismiss, seeking to have the Court dismiss the Consolidated Amended Complaint with prejudice. The plaintiffs have filed with the Court a Memorandum in opposition to the defendants motions and have requested oral argument with regard to defendants motions. On July 26, 2002, defendants filed reply Memoranda with regard to their motions. These developments did not have a material effect on the action or on Noven s financial position or results of operations.

Noven believes the lawsuit is without merit, and intends to vigorously defend the lawsuit, but its outcome cannot be predicted. The lawsuit, if determined adversely to Noven, could have a material adverse effect on Noven s financial position and results of operations. Noven s ultimate liability, if any, with respect to the lawsuit is presently not determinable.

Item 4. Controls and Procedures

Within the 90 days prior to the date of this report, Noven carried out an evaluation, under the supervision and with the participation of Noven s management, including Noven s Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of Noven s disclosure controls and procedures pursuant to Exchange Act Rule 13a-15. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that Noven s disclosure controls and procedures are effective in timely alerting them to material information relating to Noven required to be included in Noven s periodic Securities and Exchange Commission filings. No significant changes were made in Noven s internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

99.1 Certification of Robert C. Strauss, President, Chief Executive Officer and Chairman of the Board, pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

99.2 Certification of James B. Messiry, Vice President and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(b) Reports on Form 8-K

No reports on Form 8-K were filed by the Registrant during the three months ended September 30, 2002.

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 4, 2002

By: /s/ James B. Messiry

James B. Messiry
Vice President and Chief Financial Officer

Table of Contents

Certifications

Certification of Principal Executive Officer

I, Robert C. Strauss, President, Chief Executive Officer and Chairman of the Board of Noven Pharmaceuticals, Inc., certify that:

1) I have reviewed this quarterly report on Form 10-Q of Noven Pharmaceuticals, Inc.;

2) Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3) Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4) The registrant s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and

c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5) The registrant s other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of the registrant s board of directors (or persons performing the equivalent function):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6) The registrant s other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ Robert C. Strauss

Name: Robert C. Strauss
Title: President, Chief Executive Officer and Chairman of the Board
Date: November 4, 2002

Table of Contents

Certifications

Certification of Principal Financial Officer

I, James B. Messiry, Vice President and Chief Financial Officer of Noven Pharmaceuticals, Inc., certify that:

1) I have reviewed this quarterly report on Form 10-Q of Noven Pharmaceuticals, Inc.;

2) Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3) Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4) The registrant s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and

c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5) The registrant s other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of the registrant s board of directors (or persons performing the equivalent function):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6) The registrant s other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ James B. Messiry

Name: James B. Messiry
Title: Vice President and Chief Financial Officer
Date: November 4, 2002