NOVEN PHARMACEUTICALS INC
Form 10-Q
May 09, 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 March 31, 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 [ ].

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

Class	Outstanding at April 30, 2002
Common stock $.0001 par value	22,514,303

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 Months Ended March 31,
(in thousands, except per share amounts)
(unaudited)

	2002	2001
Revenues:		
Product sales	$11,991	$12,022
License revenue	744	667
Total revenues	12,735	12,689
Expenses:		
Cost of products sold	5,900	4,816
Research and development	3,369	2,227
Marketing, general and administrative	2,933	2,660
Total expenses	12,202	9,703
Income from operations	533	2,986
Equity in earnings of Novogyne	1,515	595
Interest income, net	207	619
Income before income taxes	2,255	4,200
Provision for income taxes	802	1,533
Net income	$ 1,453	$ 2,667
Basic earnings per share	$ .06	$ .12
Diluted earnings per share	$ .06	$ .11
Weighted average number of common shares outstanding:		
Basic	22,491	22,236
Diluted	23,456	23,606

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)

	March 31, 2002	December 31, 2001
Assets		
Current Assets:		
Cash and cash equivalents	$ 47,270	$ 49,389
Accounts receivable (less allowance for doubtful accounts of $56 in 2002 and $28 in 2001)	3,856	1,308
Due from Novogyne	6,682	15,158
Inventories	3,910	4,324
Net deferred income tax asset	3,700	4,800
Prepaid and other current assets	478	304
	65,896	75,283
Property, plant and equipment, net	15,351	15,699
Other Assets:		
Investment in Novogyne	33,558	32,043
Net deferred income tax asset	10,895	10,150
Patent development costs, net	2,023	2,046
Deposits and other assets	905	1,007
	47,381	45,246
	$128,628	$ 136,228
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable	$ 8,261	$ 5,620
Notes payable current portion	7	252
Due to Aventis Pharmaceuticals		10,000
Accrued compensation and related liabilities	2,287	1,518
Other accrued liabilities	2,463	4,169
Deferred license revenue current portion	3,517	7,936
	16,535	29,495
Long-Term Liabilities:		
Notes payable	11	13
Deferred license revenue	28,497	24,822
	45,043	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 22,503,155 shares at March 31, 2002 and 22,481,977 at December 31, 2001	2	2

Additional paid-in capital	77,628	77,394
Retained earnings	5,955	4,502
	83,585	81,898
	$128,628	$ 136,228

The accompanying notes are an integral part of these statements.

Table of Contents

NOVEN PHARMACEUTICALS, INC.

Condensed Statements of Cash Flows
Three Months Ended March 31,
(in thousands)
(unaudited)

	2002	2001
Cash flows from operating activities:		
Net income	$ 1,453	$ 2,667
Adjustments to reconcile net income to net cash (used in) provided by operating activities:		
Depreciation and amortization	530	364
Amortization of patent costs	71	59
Amortization of non-competition agreement	100	
Deferred income tax provision	374	290
Recognition of deferred license revenue	(744)	(667)
Equity in earnings of Novogyne	(1,515)	(595)
(Increase) decrease in accounts receivable	(2,548)	1,934
(Increase) decrease in due from Novogyne	(1,524)	383
Decrease (increase) in inventories	414	(628)
(Increase) decrease in prepaid and other current assets	(174)	31
Decrease in deposits and other assets	2	51
Increase (decrease) in accounts payable	2,641	(1,147)
Increase (decrease) in accrued compensation and related liabilities	769	(607)
(Decrease) increase in other accrued liabilities	(1,674)	1,266
Increase in deferred license revenue		3,500
Cash flows (used in) provided by operating activities	(1,825)	6,901
Cash flows from investing activities:		
Purchase of property, plant and equipment, net	(182)	(268)
Investment in Novogyne		(12,250)
Distribution from Novogyne		10,200
Payments for patent development costs	(48)	(81)
Cash flows used in investing activities	(230)	(2,399)
Cash flows from financing activities:		
Issuance of common stock	183	849
Payments on notes payable	(247)	(92)
Cash flows (used in) provided by financing activities	(64)	757
Net (decrease) increase in cash and cash equivalents	(2,119)	5,259
Cash and cash equivalents, beginning of period	49,389	40,976
Cash and cash equivalents, end of period	$47,270	$ 46,235

The accompanying notes are an integral part of these statements.

5

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®. 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 financial statements of Noven contain all adjustments (consisting of only normal recurring adjustments) necessary to present fairly the financial position of Noven as of March 31, 2002, and the results of its operations for the three months ended March 31, 2002 and 2001. The results of operations and cash flows for the three months ended March 31, 2002 and 2001 are not 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 Annual Report on Form 10-K for the year ended December 31, 2001(Form 10-K).

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

Table of Contents

3. INVENTORIES:

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

	March 31, 2002	December 31, 2001
Finished goods	$ 65	$ 458
Work in process	1,232	1,140
Raw materials	2,613	2,726
Total	$3,910	$4,324

4. CASH FLOW INFORMATION:

Cash payments for income taxes were $1.7 million and $0.5 million for the three months ended March 31, 2002 and 2001, respectively. Cash payments for interest were $13,000 and $12,000 for the three months ended March 31, 2002 and 2001, respectively.

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

Noven recorded $51,000 and $0.7 million income tax benefits to additional paid-in capital for the three months ended March 31, 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:

Noven received a $5.0 million milestone payment from Novartis Pharma AG (Novartis AG) under the Estradot® license agreement in the fourth quarter of 2001 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 and will be recognized as license revenue through the fourth quarter of 2010 beginning in the first quarter of 2002.

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 months ended March 31, 2002 and 2001, Noven had the following transactions with Novogyne (in thousands):

	2002	2001
Revenue:		
Trade product	$5,117	$1,244
Sample product and other	1,260	18
Royalty	1,282	816
	$7,659	$2,078
Reimbursed Expenses:		
Services	$4,853	$2,954
Product specific marketing	2,829	625
	$7,682	$3,579

As of March 31, 2002, Noven had amounts due from Novogyne of $6.7 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 was satisfied in March 2002) 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 months ended March 31, 2002 and 2001 are as follows (in thousands):

	2002	2001
Revenues	$27,457	$13,868
Cost of sales	5,185	2,187
Selling, general and administrative expenses	11,228	4,799
Amortization of intangible assets	1,545	
Income from operations	9,499	6,882
Interest income	70	559
Net income	$ 9,569	$ 7,441

Subject to the approval of Novogyne s management committee, cash may be distributed to Novartis and Noven based upon a contractual formula. In March 2001, Noven received a distribution of $10.2 million from Novogyne. This amount was recorded as a reduction in the investment in Novogyne in the first quarter of 2001. In connection with the CombiPatch® transaction, Noven contributed $12.3 million to Novogyne in March 2001. This amount was recorded as an increase in the investment in Novogyne in the first quarter of 2001.

Table of Contents

7. COMMITMENTS:

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*. 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.

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 Form 10-K 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 and its licensees respective 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, could, should, will, woul These statements are based on Noven s current expectations and beliefs 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, 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, 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 commercialization of Noven s products, including CombiPatch®, MethyPatch® and Estalis®; uncertainties associated with the impact on the hormone replacement therapy market of published studies regarding the possible adverse health effects of hormone replacement therapy; 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; uncertainties associated with the projected growth of CombiPatch®, Vivelle® family, Estalis® and Estradot® prescriptions; 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; the limited ability of Noven to forecast accurately international product orders from Novartis AG; uncertainties concerning the timing and extent of Estradot® regulatory approvals and launch orders and Estalis® orders and commercialization efforts by Novartis AG; expected fluctuations in quarterly revenue and research and development expenses, including fluctuations in revenues resulting from factors not within 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 income before taxes was comprised of a non-cash item; the potential impact of MethyPatch® launch preparation expenses on Noven s financial results; the effect of changes in taxation; and economic, competitive, governmental and technological factors affecting Noven s operations, markets, products, prices and prospects.

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® is effective in the treatment of the symptoms of Attention Deficit Hyperactivity Disorder (ADHD). Noven is now preparing and expects to file a New Drug Application (NDA) with the United States Food and Drug Administration (FDA) in mid-2002. If Noven s

Table of Contents

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 in 2002 and 2003 as it prepares for the expected commercialization of the product in late 2003. No assurance can be given that Noven will be able to successfully complete and file the NDA in a timely manner, that the product will be approved by the FDA or that, if approved, it will be successfully marketed. 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® will be the first transdermal ADHD product submitted to FDA for approval, and there can be no assurance that the 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 months ended March 31, 2002 compared to three months ended March 31, 2001

Revenues:

Total revenues for the three months ended March 31, 2002 and 2001 are summarized as follows (dollar amounts in thousands):

	2002	2001	Percentage Change
Product sales	$11,991	$12,022	(0.3%)
License revenue	744	667	12%
Total revenue	$12,735	$12,689	0.4%
Gross profit (product sales less cost of products sold)	$ 6,091	$ 7,206	(15%)
Gross margin (as a percentage of product sales)	51%	60%	

The increase in total revenues for the three months ended March 31, 2002 over the same period in 2001 was primarily attributable to an increase in license revenue, which resulted from the license of CombiPatch® to Novogyne in the first quarter of 2001. Product sales were slightly lower in 2002 as a result of lower sales of Estalis® outside of the United States and, to a lesser extent, lower sales of CombiPatch® in the United States, mostly offset by an increase in sales of Vivelle-Dot® and Vivelle® to Novogyne and initial sales of Estradot® to Novartis AG. Noven recorded its first Estradot® sales in the first quarter of 2002.

Gross Margin:

Noven s gross margin was 51% (or gross profit of $6.1 million) for the three months ended March 31, 2002 versus 60% (or gross profit of $7.2 million) for the three months ended March 31, 2001. The decrease in gross margin was primarily due to timing differences in the receipt of a minimum fee payment from Novartis AG between 2002 and 2001. In 2001, Noven received a

Table of Contents

minimum fee payment and recorded the amount as revenue in the first quarter; in 2002, Noven received a minimum fee payment and recorded the amount as revenue in the second quarter. The timing difference was partially offset by higher royalty fee income in the first quarter of 2002.

Operating Expenses:

Operating expenses for the three months ended March 31, 2002 and 2001 are summarized as follows (dollar amounts in thousands):

	2002	2001	Percentage Change
Research and development	$3,369	$2,227	51%
Marketing, general and administrative	2,933	2,660	10%

Research and Development

The $1.1 million, or 51%, increase in research and development expenses for the three months ended March 31, 2002 over the same period in 2001 was primarily attributable to an increase in clinical study expenses for MethyPatch® due to the timing of Phase III clinical trials.

Marketing, General and Administrative Expenses

The $0.3 million, or 10%, increase in marketing, general and administrative expenses for the three months ended March 31, 2002 over the same period in 2001 was primarily attributable to an increase in pre-launch marketing expenses for MethyPatch®, and depreciation expense and other information management expenses related to Noven s enterprise resource planning system.

Interest Income:

Interest income, net, decreased approximately $0.4 million, or 67%, for the three months ended March 31, 2002 as compared to the same period in 2001, primarily due to lower interest rates.

Income Taxes:

Noven s effective tax rate decreased to 35.6% for the three months ended March 31, 2002 from 36.5% for the three months ended March 31, 2001. The provision for income taxes is based on the Federal statutory and state income tax rates. As of March 31, 2002, Noven had a net deferred tax asset of $14.6 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 months ended March 31, 2002 and 2001 are summarized as follows (dollar amounts in thousands):

	2002	2001	Percentage Change
Novogyne s Summary Results:			
Revenues	$27,457	$13,868	98%
Cost of sales	5,185	2,187	137%
Gross profit	22,272	11,681	91%
Gross margin percentage	81%	84%	
Selling, general and administrative expenses	11,228	4,799	134%
Amortization of intangible assets	1,545		100%
Income from operations	9,499	6,882	38%
Interest income	70	559	(88%)
Net income	$ 9,569	$ 7,441	29%
Noven s equity in earnings of Novogyne	$ 1,515	$ 595	155%

The increase in Novogyne s revenues of $13.6 million, or 98%, for the three months ended March 31, 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). Novogyne s gross margin was 81% (or gross profit of $22.3 million) for the three months ended March 31, 2002 versus 84% (or gross profit of $11.7 million) for the three months ended March 31, 2001. The decrease in gross margin is primarily attributable to the addition of CombiPatch® in March 2001. Novogyne s selling, general and administrative expenses increased to $11.2 million for the three months ended March 31, 2002 from $4.8 million in 2001, primarily due to expenses relating to the promotion of CombiPatch®, an approximate 20% increase in the size of the Novogyne sales force and higher sample expense. Novogyne amortized $1.5 million related to the CombiPatch® acquisition cost during the three months ended March 31, 2002.

Table of Contents

Liquidity and Capital Resources

As of March 31, 2002 and December 31, 2001, Noven had $47.3 million and $49.4 million in cash and cash equivalents, and working capital of $49.4 million and $45.8 million, respectively.

Cash provided by (used in) operating, investing and financing activities for the three months ended March 31, 2002 and 2001 is summarized as follows (amounts in thousands):

	2002	2001
Cash flows:		
Operating activities	$(1,825)	$ 6,901
Investing activities	(230)	(2,399)
Financing activities	(64)	757

Operating Activities:

Net cash used in operating activities for the three months ended March 31, 2002 primarily resulted from changes in working capital due to the timing of product shipments and payments for inventory and income taxes. A non-cash item (equity in earnings of Novogyne of $1.5 million) constituted approximately 67% of Noven s income before income taxes of $2.3 million.

Net cash provided by operating activities for the three months ended March 31, 2001 primarily resulted from 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.

Investing Activities:

Net cash used in investing activities for the three months ended March 31, 2002 was primarily attributable to the purchase of fixed assets and payments for patent developments costs.

Net cash used in investing activities for the three months ended March 31, 2001 was primarily attributable to a net contribution to Novogyne in the amount of $2.1 million in connection with the CombiPatch® transaction.

Financing Activities:

Net cash used in financing activities for the three months ended March 31, 2002 was primarily attributable to the payoff of all borrowings under a master lease facility in March 2002, partially offset by cash received in connection with the issuance of common stock from the exercise of stock options.

Net cash provided by financing activities for the three months ended March 31, 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.

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

Table of Contents

April 2003. The Credit Facility bears interest at LIBOR plus 1.50% (3.380% at March 31, 2002). At March 31, 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 borrowings under its Credit Facility. As discussed above, for the first quarter of 2002, approximately 67% of Noven s income before income taxes was comprised of a non-cash item, and, presently, Noven s short-term liquidity is largely dependent on sales of, and license royalties and fees related to sales of, a relatively small number of products. As a result, any decrease in the sales of those products by Noven or its licensees or the inability or failure of Novogyne to pay distributions could have a material adverse effect on Noven s short-term liquidity or 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, there can be no assurance that Novogyne will have sufficient profits to pay distributions or that Novogyne s Management Committee will authorize such distributions.

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 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. 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. 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.

Critical Accounting Policies

Noven s discussion and analysis of its financial condition and results of operations are based upon its financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these 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

Table of Contents

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 some 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 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.

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. 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. 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.

Table of Contents

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 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 March 31, 2002, Novogyne had a long-term asset of $55.6 million related to the acquisition of the marketing rights of CombiPatch®. Accounting principles generally accepted in the United States require that Novogyne record this asset at cost and that the asset be tested for impairment. Testing for impairment requires Novogyne to estimate the undiscounted future cash flows 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 less 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 generally accepted accounting principles in the United States, Novogyne determines the estimated fair value of the marketing rights of CombiPatch® utilizing a discounted cash flows analysis. Discounted cash flows 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.

Novogyne records its sales net of sales allowances for chargebacks, Medicaid rebates, managed healthcare rebates, cash discounts and other allowances. Novartis maintains the reserves associated with such sales allowances on behalf of Novogyne and pays all moneys 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 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

Table of Contents

additional allowance reserve 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 the amount of 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 principal factors that Noven expects could influence its 2002 financial results include:

The timing and magnitude of international product sales to Novartis AG;

Novogyne s ability to increase Vivelle® family and CombiPatch® sales;

Costs associated with new clinical studies for products in development; and

Costs associated with the continued development of MethyPatch® and related launch preparation.

The above list is not intended to be a comprehensive list of all of the factors that could affect Noven s 2002 financial results. A discussion of these and certain other factors that could impact Noven s 2002 financial results is provided under the caption Cautionary Factors that May Have an Impact on Future Results included in Item 7 of Noven s Form 10-K. In addition, other factors, trends, risks and uncertainties unknown to Noven could also influence Noven s 2002 financial results.

International Product Sales:

Noven receives firm orders from Novartis AG on a partial year basis, which limits Noven s ability to accurately forecast full year sales to Novartis AG. Novartis AG has advised Noven that it plans to seek approval of a second dosage strength of Estalis® in European countries where only one strength is presently approved but there can be no assurance that Novartis AG will seek or obtain such approval. Noven expects Estalis® sales to decline in 2002 compared to 2001, and, based upon the information received from Novartis AG, does not expect significant renewed growth in Estalis® sales unless a second dosage is commercialized in Europe, which may take several years.

Novartis began European launches of Estradot® in the first quarter of 2002, and expects to continue launches 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 those approvals will be received on a timely basis or at all, or that if they are received, that the product will be launched. Failure to receive those approvals on a timely basis could adversely affect Novartis AG s launch plans for Estradot®, which would adversely impact Noven s Estradot® sales during 2002. The timing of Novartis AG s receipt of regulatory approvals for Estradot® and of Novartis AG s product launches is outside the control of Noven.

Table of Contents

Vivelle® Family & CombiPatch®:

Prescription growth for the Vivelle® family of estrogen patches has historically increased from period-to-period. At some point the prescription growth of the Vivelle® family may make further gains by the product line more difficult as a result of market saturation. In addition, since the relaunch of CombiPatch® by Novogyne in May 2001, CombiPatch® monthly total prescriptions have not increased meaningfully. Novogyne has forecast growth in 2002 for both CombiPatch® and the Vivelle® family. If that expected growth is not realized, Novogyne would not meet its revenue and income targets, which would affect Noven s ability to meet its own financial targets for 2002.

MethyPatch® Launch Costs:

Noven has completed its MethyPatch® Phase III clinical trial and expects to file an NDA in mid-2002. Noven is incurring sales, marketing and other expenses in 2002 in anticipation of a MethyPatch® approval and launch in the second half of 2003. These planned expenses are expected to increase over the course of 2002, and to cause Noven s marketing, general and administrative expenses to increase 35% to 40% over 2001. Noven expects that these expenses will continue to increase in 2003 as launch approaches and a targeted ADHD sales force is established and trained. However, there can be no assurance that the MethyPatch® approval and launch will occur in this time frame or at all.

New Clinical Studies:

During 2002, Noven expects to initiate clinical trials for the development of as many as three new prescription transdermal therapies. These projects, together with continuing MethyPatch® research and development expenses, are expected to increase Noven s research and development expense up to 45% in 2002 as compared to 2001. The future level of research and development expenditures will depend on, among other things, the status of products under development and the outcome of clinical trials, strategic decisions by management, the consummation of new collaborative arrangements and Noven s liquidity. Noven s research and development expenses may vary significantly from quarter to quarter depending on product development cycles and the timing of clinical studies.

2002 Second Quarter and Full-Year:

Based on Novogyne and Novartis AG forecasts, Noven expects that product shipments in the 2002 second quarter will be higher than in any other 2002 quarter. Accordingly, Noven expects second quarter revenues of nearly $16 million, and diluted earnings per share to be $0.14 to $0.17, and expects that the second quarter will be the strongest quarter of the year in terms of revenues and net income.

For full-year 2002, based on information and forecasts provided by Novartis AG, Estradot® sales are expected to approximately offset an anticipated year-over-year decline in Estalis® sales. If Noven s 2002 sales targets are achieved, Noven would expect 2002 revenues to increase 15% to 20% over 2001 levels, and would expect diluted earnings per share to be $0.50 to $0.55. Noven expects gross margin for 2002 to be comparable to 2001 levels, subject to changes in product and country mix, higher than expected production costs, and unexpected changes in Novogyne s inventory. Novogyne s revenues are expected to increase 25% to 30% in 2002 compared to 2001, depending

Table of Contents

upon, among other things, Novogyne s ability to increase prescriptions of CombiPatch® and the Vivelle® family. Noven expects its equity in earnings of Novogyne to increase by a similar percentage as Novogyne s revenues. Noven expects its effective income tax rate for 2002 to be 34% to 37%.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Noven had no variable rate debt outstanding during the three months ended March 31, 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.

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.* 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.

Table of Contents

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

10.1	Amendment to Credit Agreement, dated March 19, 2002, between Noven and SunTrust Bank Miami, N.A.

(b) Reports on Form 8-K

No reports on Form 8-K were filed by the Registrant during the three months ended March 31, 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: May 9, 2002

By: /s/ James B. Messiry

James B. Messiry
Vice President and
Chief Financial Officer