

NOVEN PHARMACEUTICALS INC

Form 10-Q

August 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 June 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 ☒ 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 July 31, 2002

Common stock \$.0001 par value

22,545,981

NOVEN PHARMACEUTICALS, INC.

**INDEX**

|  | <b>Page<br/>No.</b> |
|--|---------------------|
| <b>PART I FINANCIAL INFORMATION</b>  |                     |
| Item 1. Unaudited Condensed Financial Statements   |                     |
| Condensed Statements of Operations for the Three and Six Months Ended June 30, 2002 and 2001 | 3                   |
| Condensed Balance Sheets as of June 30, 2002 and December 31, 2001                           | 4                   |
| Condensed Statements of Cash Flows for the Six Months Ended June 30, 2002 and 2001           | 5                   |

# Edgar Filing: NOVEN PHARMACEUTICALS INC - Form 10-Q

|   |    |
|---|----|
| Notes to Unaudited Condensed Financial Statements   | 6  |
| Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations | 10 |
| Item 3. Quantitative and Qualitative Disclosures About Market Risk                            | 22 |
| PART II OTHER INFORMATION   |    |
| Item 1. Legal Proceedings   | 22 |
| Item 4. Submission of Matters to a Vote of Security Holders                                   | 23 |
| Item 6. Exhibits and Reports on Form 8-K  | 23 |
| SIGNATURES  | 24 |

**TABLE OF CONTENTS**

**PART I. FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**Condensed Statements of Operations**

**Three and Six Months Ended June 30,**

**(in thousands, except per share amounts)**

**(unaudited)**

**Condensed Balance Sheets**

**(in thousands, except share data)**

**(unaudited)**

**Condensed Statements of Cash Flows**

**Six Months Ended June 30,**

**(in thousands)**

**(unaudited)**

**NOVEN PHARMACEUTICALS, INC.**

**Notes to Unaudited Condensed Financial Statements**

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

**Item 3. Quantitative and Qualitative Disclosure About Market Risk**

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

**Item 4. Submission of Matters to a Vote of Security Holders**

**Item 6. Exhibits and Reports on Form 8-K**

**Signatures**

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER**

**CERTIFICATION OF CHIEF FINANCIAL OFFICER**

---

**Table of Contents**

**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Financial Statements**

## NOVEN PHARMACEUTICALS, INC.

Condensed Statements of Operations  
Three and Six Months Ended June 30,  
(in thousands, except per share amounts)  
(unaudited)

|   | Three Months      |                   | Six Months        |                   |
|---|-------------------|-------------------|-------------------|-------------------|
|   | 2002              | 2001              | 2002              | 2001              |
| Revenues:   |                   |                   |                   |                   |
| Product sales   | \$ 15,277         | \$ 11,842         | \$ 27,268         | \$ 23,864         |
| License revenue                                       | 879               | 752               | 1,623             | 1,419             |
|   | <u>          </u> | <u>          </u> | <u>          </u> | <u>          </u> |
| Total revenues  | 16,156            | 12,594            | 28,891            | 25,283            |
| Expenses:   |                   |                   |                   |                   |
| Cost of products sold                                 | 6,021             | 5,894             | 11,921            | 10,710            |
| Research and development                              | 3,313             | 2,410             | 6,682             | 4,637             |
| Marketing, general and administrative                 | 3,679             | 3,176             | 6,612             | 5,836             |
|   | <u>          </u> | <u>          </u> | <u>          </u> | <u>          </u> |
| Total expenses  | 13,013            | 11,480            | 25,215            | 21,183            |
|   | <u>          </u> | <u>          </u> | <u>          </u> | <u>          </u> |
| Income from operations                                | 3,143             | 1,114             | 3,676             | 4,100             |
| Equity in earnings of Novogyne                        | 7,132             | 3,137             | 8,647             | 3,732             |
| Interest income, net                                  | 195               | 482               | 402               | 1,101             |
|   | <u>          </u> | <u>          </u> | <u>          </u> | <u>          </u> |
| Income before income taxes                            | 10,470            | 4,733             | 12,725            | 8,933             |
| Provision for income taxes                            | 3,827             | 1,510             | 4,629             | 3,043             |
|   | <u>          </u> | <u>          </u> | <u>          </u> | <u>          </u> |
| Net income  | \$ 6,643          | \$ 3,223          | \$ 8,096          | \$ 5,890          |
|   | <u>          </u> | <u>          </u> | <u>          </u> | <u>          </u> |
| Basic earnings per share                              | \$ 0.29           | \$ 0.14           | \$ 0.36           | \$ 0.26           |
|   | <u>          </u> | <u>          </u> | <u>          </u> | <u>          </u> |
| Diluted earnings per share                            | \$ 0.28           | \$ 0.14           | \$ 0.34           | \$ 0.25           |
|   | <u>          </u> | <u>          </u> | <u>          </u> | <u>          </u> |
| Weighted average number of common shares outstanding: |                   |                   |                   |                   |
| Basic   | 22,528            | 22,335            | 22,510            | 22,286            |
|   | <u>          </u> | <u>          </u> | <u>          </u> | <u>          </u> |
| Diluted   | 23,687            | 23,561            | 23,571            | 23,585            |
|   | <u>          </u> | <u>          </u> | <u>          </u> | <u>          </u> |

*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)

|   | <u>June 30, 2002</u> | <u>December 31, 2001</u> |
|---|----------------------|--------------------------|
| <b>Assets</b>   |                      |                          |
| Current Assets:   |                      |                          |
| Cash and cash equivalents   | \$ 53,401            | \$ 49,389                |
| Accounts receivable trade (less allowance for doubtful accounts of \$131 in 2002 and \$28 in 2001)  | 5,863                | 1,308                    |
| Accounts receivable Novogyne  | 9,481                | 15,158                   |
| Inventories   | 5,664                | 4,324                    |
| Net deferred income tax asset   | 3,700                | 4,800                    |
| Prepaid and other current assets  | 1,118                | 304                      |
|   | <u>79,227</u>        | <u>75,283</u>            |
| Property, plant and equipment, net  | 15,509               | 15,699                   |
| Other Assets:   |                      |                          |
| Investment in Novogyne  | 28,963               | 32,043                   |
| Net deferred income tax asset   | 9,438                | 10,150                   |
| Patent development costs, net   | 1,985                | 2,046                    |
| Deposits and other assets   | 781                  | 1,007                    |
|   | <u>\$ 135,903</u>    | <u>\$ 136,228</u>        |
| <b>Liabilities and Stockholders' Equity</b>   |                      |                          |
| Current Liabilities:  |                      |                          |
| Accounts payable  | \$ 7,222             | \$ 5,620                 |
| Notes payable current portion   | 7                    | 252                      |
| Due to Aventis Pharmaceuticals  |                      | 10,000                   |
| Accrued compensation and related liabilities  | 2,912                | 1,518                    |
| Other accrued liabilities   | 3,866                | 4,169                    |
| Deferred license revenue current portion  | 3,517                | 7,936                    |
|   | <u>17,524</u>        | <u>29,495</u>            |
| Long-Term Liabilities:  |                      |                          |
| Notes payable   | 9                    | 13                       |
| Deferred license revenue  | 27,618               | 24,822                   |
|   | <u>45,151</u>        | <u>54,330</u>            |
| 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 22,545,481 shares at June 30, 2002 and 22,481,977 at December 31, 2001 | 2                    | 2                        |
| Additional paid-in capital  | 78,152               | 77,394                   |
| Retained earnings   | 12,598               | 4,502                    |
|   | <u>90,752</u>        | <u>81,898</u>            |



---

\$ 135,903

---

---

\$ 136,228

---

*The accompanying notes are an integral part of these statements.*

**Table of Contents****NOVEN PHARMACEUTICALS, INC.**

Condensed Statements of Cash Flows  
Six Months Ended June 30,  
(in thousands)  
(unaudited)

|   | <b>2002</b>       | <b>2001</b>       |
|---|-------------------|-------------------|
| <b>Cash flows from operating activities:</b>  |                   |                   |
| Net income  | \$ 8,096          | \$ 5,890          |
| Adjustments to reconcile net income to net cash (used in) provided by operating activities: |                   |                   |
| Depreciation and amortization   | 1,063             | 738               |
| Amortization of patent costs  | 154               | 109               |
| Amortization of non-competition agreement   | 200               |                   |
| Deferred income tax provision   | 1,873             | 413               |
| Recognition of deferred license revenue   | (1,623)           | (1,419)           |
| Equity in earnings of Novogyne  | (8,647)           | (3,732)           |
| (Increase) decrease in accounts receivable trade  | (4,555)           | 681               |
| Increase in accounts receivable Novogyne  | (4,323)           | (1,873)           |
| (Increase) decrease in inventories  | (1,340)           | 484               |
| (Increase) decrease in prepaid and other current assets                                     | (814)             | 53                |
| Decrease (increase) in deposits and other assets  | 26                | (1,098)           |
| Increase (decrease) in accounts payable   | 1,602             | (2,397)           |
| Increase (decrease) in accrued compensation and related liabilities                         | 1,394             | (509)             |
| (Decrease) increase in other accrued liabilities  | (199)             | 2,284             |
| Increase in deferred license revenue  |                   | 3,500             |
|   | <u>          </u> | <u>          </u> |
| Cash flows (used in) provided by operating activities                                       | (7,093)           | 3,124             |
| <b>Cash flows from investing activities:</b>  |                   |                   |
| Purchase of property, plant and equipment, net  | (873)             | (1,547)           |
| Investment in Novogyne  |                   | (15,680)          |
| Distribution from Novogyne  | 11,727            | 13,080            |
| Payments for patent development costs   | (93)              | (130)             |
|   | <u>          </u> | <u>          </u> |
| Cash flows provided by (used in) investing activities                                       | 10,761            | (4,277)           |
| <b>Cash flows from financing activities:</b>  |                   |                   |
| Issuance of common stock  | 593               | 2,404             |
| Payments on notes payable   | (249)             | (167)             |
|   | <u>          </u> | <u>          </u> |
| Cash flows provided by financing activities   | 344               | 2,237             |
|   | <u>          </u> | <u>          </u> |
| Net increase in cash and cash equivalents   | 4,012             | 1,084             |
| Cash and cash equivalents, beginning of period  | 49,389            | 40,976            |
|   | <u>          </u> | <u>          </u> |
| Cash and cash equivalents, end of period  | \$ 53,401         | \$ 42,060         |
|   | <u>          </u> | <u>          </u> |

*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 the financial position of Noven as of June 30, 2002, and the results of its operations for the three and six months ended June 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 studies on the adverse health effects of certain forms of hormone replacement therapy (HRT) may have a material adverse impact on the HRT market and on Noven's liquidity, results of operations and business. Accordingly, the results of operations and cash flows for the three and six months ended June 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.

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):

|                 | <b>June 30, 2002</b> | <b>December 31, 2001</b> |
|-----------------|----------------------|--------------------------|
| Finished goods  | \$ 229               | \$ 458                   |
| Work in process | 1,733                | 1,140                    |
| Raw materials   | 3,702                | 2,726                    |
|                 | <hr/>                | <hr/>                    |
| Total           | \$5,664              | \$4,324                  |
|                 | <hr/>                | <hr/>                    |

**4. CASH FLOW INFORMATION:**

Cash payments for income taxes were \$2.6 million in 2002 and \$0.9 million in 2001. Cash payments for interest were \$14,000 in 2002 and \$21,000 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 \$1.1 million in income tax benefits to additional paid-in capital for the six months ended June 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 and will be 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 six months ended June 30, 2002 and 2001, Noven had the following transactions with Novogyne (in thousands):

|                            | Three Months    |                 | Six Months       |                 |
|----------------------------|-----------------|-----------------|------------------|-----------------|
|                            | 2002            | 2001            | 2002             | 2001            |
| Revenue:                   |                 |                 |                  |                 |
| Trade product              | \$ 5,487        | \$ 2,842        | \$ 10,604        | \$ 4,086        |
| Sample product and other   | 1,433           | 1,559           | 2,693            | 1,577           |
| Royalty                    | 1,500           | 950             | 2,782            | 1,766           |
|                            | <u>\$ 8,420</u> | <u>\$ 5,351</u> | <u>\$ 16,079</u> | <u>\$ 7,429</u> |
| Reimbursed expenses:       |                 |                 |                  |                 |
| Services                   | \$ 4,590        | \$ 4,000        | \$ 9,443         | \$ 6,954        |
| Product specific marketing | 1,356           | 1,214           | 4,185            | 1,839           |
|                            | <u>\$ 5,946</u> | <u>\$ 5,214</u> | <u>\$ 13,628</u> | <u>\$ 8,793</u> |

As of June 30, 2002, Noven had amounts due from Novogyne of \$9.5 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 six months ended June 30, 2002 and 2001 are as follows (in thousands):

|  | Three Months     |                 | Six Months       |                  |
|--|------------------|-----------------|------------------|------------------|
|  | 2002             | 2001            | 2002             | 2001             |
| Revenues                                     | \$ 32,972        | \$ 20,852       | \$ 60,429        | \$ 34,720        |
| Cost of sales                                | 6,269            | 3,887           | 11,454           | 6,074            |
| Selling, general and administrative expenses | 9,720            | 8,323           | 20,948           | 13,122           |
| Amortization of intangible assets            | 1,545            | 1,541           | 3,090            | 1,541            |
|  | <u>15,438</u>    | <u>7,101</u>    | <u>24,937</u>    | <u>13,983</u>    |
| Income from operations                       | 94               | 64              | 164              | 623              |
|  | <u>\$ 15,532</u> | <u>\$ 7,165</u> | <u>\$ 25,101</u> | <u>\$ 14,606</u> |

Subject to the approval of Novogyne's management committee, cash may be distributed to Novartis and Noven based upon a contractual formula. For the three and six months ended June 30, 2002, Noven received a distribution of \$11.7 million from Novogyne. For the three and six months ended June 30, 2001, Noven received distributions of \$2.9 million and \$13.1 million, respectively, from Novogyne. These amounts were recorded as reductions in the investment in Novogyne when received.

**Table of Contents**

In connection with the CombiPatch® transaction, for the three and six months ended June 30, 2001, Noven contributed \$3.4 million and \$15.7 million, respectively, to Novogyne. These amounts were recorded as increases 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.

## **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 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 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 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®; 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 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 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.



**Table of Contents**

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. Noven's transdermal HRT products differ from the products used in the WHI study and the primary products observed in the NCI study. There are, however, no head-to-head studies comparing the safety of Noven's products against other HRT therapies.

Although the range of consequences of these studies cannot be predicted, it is possible that these studies could result in a significant 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 both in the United States and abroad could, as a result of these findings, modify the permitted use of the products by mandatory product label changes, or remove the products from the market. Health care regulators could also 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 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.

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. In the first weeks following publication of the studies, United States prescriptions declined for substantially all HRT products, including Noven's products. 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 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.

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

**Table of Contents**

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 and six months ended June 30, 2002 compared to three and six months ended June 30, 2001*

**Revenues:**

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

|   | Three Months |           |                   | Six Months |           |                   |
|---|--------------|-----------|-------------------|------------|-----------|-------------------|
|   | 2002         | 2001      | Percentage Change | 2002       | 2001      | Percentage Change |
| Product sales   | \$ 15,277    | \$ 11,842 | 29%               | \$ 27,268  | \$ 23,864 | 14%               |
| License revenue   | 879          | 752       | 17%               | 1,623      | 1,419     | 14%               |
| Total revenue   | \$ 16,156    | \$ 12,594 | 28%               | \$ 28,891  | \$ 25,283 | 14%               |
| Gross profit (product sales less cost of products sold) | \$ 9,256     | \$ 5,948  | 56%               | \$ 15,347  | \$ 13,154 | 17%               |
| Gross margin (as a percentage of product sales)         | 61%          | 50%       |                   | 56%        | 55%       |                   |

The increase in total revenues for the three months ended June 30, 2002 over the same period in 2001 was primarily attributable to an increase in product sales. Product sales were higher in 2002 over 2001 as a result of sales of Estradot® to Novartis AG (which commenced in the first quarter of 2002) and an increase in sales of Vivelle-Dot® and Vivelle® to Novogyne, offset by lower sales of Estalis® outside of the United States. In 2002, Noven also received a minimum fee payment of approximately \$0.2 million related to the sales of Estalis® in certain countries in 2001.

The increase in total revenues for the six months ended June 30, 2002 over the same period in 2001 was primarily attributable to the same factors stated above, although sales of CombiPatch® to Novogyne were lower in the 2002 period. In addition, product sales for the six months ended June 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.

**Gross Margin:**

Noven's gross margin was 61% (or gross profit of \$9.3 million) for the three months ended June 30, 2002 versus 50% (or gross profit of \$5.9 million) for the three months ended June 30, 2001. The increase in gross margin was primarily due to increases in production volume resulting in more favorable overhead absorption, higher royalty income due to higher sales by Novogyne and favorable

**Table of Contents**

product mix as Noven sold more product in the United States, while sales outside of the United States (which carry a lower gross margin) declined.

Noven's gross margin was 56% (or gross profit of \$15.3 million) for the six months ended June 30, 2002 versus 55% (or gross profit of \$13.2 million) for the six months ended June 30, 2001. The increase in gross margin was primarily due to the same factors stated above offset by a lower minimum fee payment in the 2002 period.

***Operating Expenses:***

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

|                                       | Three Months |         |                   | Six Months |         |                   |
|---------------------------------------|--------------|---------|-------------------|------------|---------|-------------------|
|                                       | 2002         | 2001    | Percentage Change | 2002       | 2001    | Percentage Change |
| Research and development              | \$3,313      | \$2,410 | 37%               | \$6,682    | \$4,637 | 44%               |
| Marketing, general and administrative | 3,679        | 3,176   | 16%               | 6,612      | 5,836   | 13%               |

**Research and Development**

The \$0.9 million, or 37%, increase in research and development expenses for the three months ended June 30, 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 and the costs related to the filing of the NDA in June 2002. The \$2.0 million, or 44%, increase in research and development expenses for the six months ended June 30, 2002 over the same period in 2001 was primarily attributable to the same factors.

**Marketing, General and Administrative Expenses**

The \$0.5 million, or 16%, increase in marketing, general and administrative expenses for the three months ended June 30, 2002 over the same period in 2001 was primarily attributable to increases in pre-launch marketing expenses for MethyPatch®, increased insurance costs and depreciation expense and other information management expenses related to Noven's enterprise resource planning system, offset by lower outside consulting services. The \$0.8 million, or 13%, increase in marketing, general and administrative expenses for the six months ended June 30, 2002 over the same period in 2001 was primarily attributable to the same factors.

***Interest Income:***

Interest income, net, decreased approximately \$0.3 million and \$0.7 million, or 60% and 63%, for the three and six months ended June 30, 2002, respectively, compared to the same periods in 2001, primarily due to lower interest rates.

**Table of Contents*****Income Taxes:***

Noven's effective tax rate increased to 36.4% for the six months ended June 30, 2002 from 34.1% for the six months ended June 30, 2001, and to 36.6% for the three months ended June 30, 2002 from 31.9% for the three months ended June 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 June 30, 2002, Noven had a net deferred tax asset of \$13.1 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.

***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 six months ended June 30, 2002 and 2001 are summarized as follows (dollar amounts in thousands):

|  | Three Months |          |                   | Six Months |          |                   |
|--|--------------|----------|-------------------|------------|----------|-------------------|
|  | 2002         | 2001     | Percentage Change | 2002       | 2001     | Percentage Change |
| Novogyne's Summary Results:                  |              |          |                   |            |          |                   |
| Revenues                                     | \$32,972     | \$20,852 | 58%               | \$60,429   | \$34,720 | 74%               |
| Cost of sales                                | 6,269        | 3,887    | 61%               | 11,454     | 6,074    | 89%               |
| Gross profit                                 | 26,703       | 16,965   | 57%               | 48,975     | 28,646   | 71%               |
| Gross margin percentage                      | 81%          | 81%      |                   | 81%        | 83%      |                   |
| Selling, general and administrative expenses | 9,720        | 8,323    | 17%               | 20,948     | 13,122   | 60%               |
| Amortization of intangible assets            | 1,545        | 1,541    |                   | 3,090      | 1,541    | 101%              |
| Income from operations                       | 15,438       | 7,101    | 117%              | 24,937     | 13,983   | 78%               |
| Interest income                              | 94           | 64       | 47%               | 164        | 623      | (74%)             |
| Net income                                   | \$15,532     | \$7,165  | 117%              | \$25,101   | \$14,606 | 72%               |
| Noven's equity in earnings of Novogyne       | \$7,132      | \$3,137  | 127%              | \$8,647    | \$3,732  | 132%              |

The increase in Novogyne's revenues of \$12.1 million, or 58%, for the three months ended June 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). Revenues for the three months ended June 30, 2002 and 2001 are net of sales allowances and returns.

## **Table of Contents**

of \$5.8 million and \$3.6 million, respectively. The increase in sales allowances and returns is due primarily to increased sales of all products and higher returns of Vivelle®. The increase in Novogyne's revenues of \$25.7 million, or 74%, for the six months ended June 30, 2002 as compared to the same period in 2001 is primarily attributable to the same factors. Revenues for the six months ended June 30, 2002 and 2001 are net of sales allowances and returns of \$11.0 million and \$5.9 million, respectively. The increase in sales allowances and returns is primarily attributable to the same factors.

Novogyne's gross margin was 81% (or gross profit of \$26.7 million) for the three months ended June 30, 2002 versus 81% (or gross profit of \$17.0 million) for the three months ended June 30, 2001. Novogyne's gross margin was 81% (or gross profit of \$49.0 million) for the six months ended June 30, 2002 versus 83% (or gross profit of \$28.6 million) for the six months ended June 30, 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 \$9.7 million for the three months ended June 30, 2002 from \$8.3 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's selling, general and administrative expenses increased to \$20.9 million for the six months ended June 30, 2002 from \$13.1 million in 2001 primarily due to the same factors.

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

## **Liquidity and Capital Resources**

As of June 30, 2002 and December 31, 2001, Noven had \$53.4 million and \$49.4 million in cash and cash equivalents, and working capital of \$61.7 million and \$45.8 million, respectively.

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

|                      | <u>2002</u> | <u>2001</u> |
|----------------------|-------------|-------------|
| Cash flows:          |             |             |
| Operating activities | \$ (7,093)  | \$ 3,124    |
| Investing activities | 10,761      | (4,277)     |
| Financing activities | 344         | 2,237       |

### ***Operating Activities:***

Net cash used in operating activities for the six months ended June 30, 2002 primarily resulted from changes in working capital due to the timing and amount of product shipments and payments for inventory and income taxes. A non-cash item (equity in earnings of Novogyne of \$8.6 million) constituted approximately 68% of Noven's income before income taxes of \$12.7 million.

Net cash provided by operating activities for the six months ended June 30, 2001 primarily resulted from the receipt of a one-time license fee in the amount of \$3.5 million from Aventis

**Table of Contents**

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 provided by investing activities for the six months ended June 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 developments costs.

Net cash of approximately \$4.3 million was used in investing activities during the first six 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 \$1.5 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 six months ended June 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 six months ended June 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.

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% (3.336% at June 30, 2002). At June 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 six months ended June 30, 2002, approximately 68% of Noven's income before income taxes was comprised of a non-cash item, and, presently, Noven's short-term liquidity is almost entirely dependent on sales of, and license royalties and fees related to sales of, transdermal HRT products. As a result, any decrease in the sales of those products by Noven or its licensees (including any decreases resulting from the results of the WHI and NCI studies discussed above) or the inability or failure of Novogyne to pay distributions would 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.

**Table of Contents**

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 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 WHI and NCI 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.

**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

## **Table of Contents**

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.

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.

### ***Fair Value of Stock Options:***

Noven has elected to follow Accounting Principles Board Opinion No. 25, "Accounting for Stock Issues 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 six months ended June 30, 2002 and 2001 and for the years ended December 31, 2001, 2000 and 1999.



**Table of Contents**

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 among other things, 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 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 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.

## **Table of Contents**

As of June 30, 2002, Novogyne had a long-term asset of \$54.1 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 periodically 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 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 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. Neither Noven nor Novogyne is able to predict the effect of the results of the recent WHI and NCI studies on the short and long-term 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. Novartis maintains the reserves associated with such sales allowances 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 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 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.

## **Table of Contents**

### **Outlook**

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

#### ***HRT Market and Products:***

The recently published clinical study data regarding adverse health effects of HRT have raised considerable concerns regarding the use of HRT and have created uncertainty regarding the future of the HRT market. It is possible that these studies could result in a substantial decrease in the market for Noven's HRT products. Currently, Noven's liquidity, results of operations and business prospects are almost entirely dependent on HRT products. Any adverse change in the HRT market (including any change resulting from the foregoing studies) could have a material adverse impact on Noven's liquidity, results of operations and business prospects.

Until sufficient information becomes available, Noven is unable to predict what impact these study results will have on Noven's or Novogyne's revenues and earnings in the balance of 2002 or thereafter.

#### ***International Product Sales:***

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 that 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.

Noven cannot predict the impact, if any, that the recently published clinical study results involving HRT products may have on Novartis AG's global HRT strategy, development plans involving Noven's products, or the commercialization of Noven's international products. 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.

#### ***MethyPatch® Launch Costs:***

Noven filed an NDA for MethyPatch® on June 27, 2002. 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 increase over the course of 2002, and to cause Noven's marketing, general and administrative expenses for full year 2002 to increase up to 35% 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. There can be no assurance, however, that MethyPatch® will be approved or launched in this time frame or at all.

## **Table of Contents**

### ***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 in 2002 by up to 30% as compared to 2001. 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 six months ended June 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.

## **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; Evelyn 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.

**Table of Contents**

**Item 4. Submission of Matters to a Vote of Security Holders**

Annual Meeting of Stockholders held on May 15, 2002.

(i) Election of Directors

|                        | <b>For</b> | <b>Against</b> |
|------------------------|------------|----------------|
| Sidney Braginsky       | 21,335,107 | 60,792         |
| John G. Clarkson, M.D. | 21,334,107 | 61,792         |
| Lawrence J. DuBow      | 21,335,107 | 60,792         |
| Regina E. Herzlinger   | 21,334,457 | 61,442         |
| Robert C. Strauss      | 21,335,007 | 60,892         |
| Wayne P. Yetter        | 21,334,107 | 61,792         |

(ii) The ratification of the appointment of Deloitte & Touche LLP as Noven's independent certified public accountants for 2002 was approved by an affirmative vote of 21,141,156 shares to a negative vote of 239,101 shares, with 15,642 shares abstaining.

**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 June 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: August 9, 2002

By: /s/ James B. Messiry

---

James B. Messiry  
Vice President and Chief Financial Officer