NOVEN PHARMACEUTICALS INC
Form 10-K
March 09, 2004

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2003 **Commission File Number 0-17254**

NOVEN PHARMACEUTICALS, INC.

Incorporated under the laws of the State of Delaware	**I.R.S. Employer Identification Number 59-2767632**

11960 S.W. 144th Street, Miami, Florida 33186
305-253-5099

Securities registered pursuant to Section 12(b) of the Act:	None
Securities registered pursuant to Section 12(g) of the Act:	Common Stock, Par Value $.0001

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes x No o

As of March 1, 2004, there were 23,195,863 shares of Common Stock outstanding.

The aggregate market value of the voting stock held by non-affiliates of the registrant on March 1, 2004, was approximately $514 million.

The aggregate market value of such voting stock held by non-affiliates of the registrant was approximately $230 million (computed by reference to the price at which the voting stock was last sold on June 30, 2003, the last business day of the registrant s most recently completed second fiscal quarter).

DOCUMENTS INCORPORATED BY REFERENCE:

Part III: Portions of registrant s Proxy Statement for its 2004 Annual Meeting of Shareholders.

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NOVEN PHARMACEUTICALS, INC.

Annual Report on Form 10-K
for the year ended December 31, 2003

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PART I

Item 1. Business.

General

Noven Pharmaceuticals, Inc. is a leader in the development and manufacture of advanced transdermal drug delivery technologies and prescription transdermal products.

Our principal commercialized products are prescription transdermal drug delivery systems for use in menopausal hormone therapy (HT). Our first product was an estrogen patch for the treatment of menopausal symptoms marketed under the brand name Vivelle® in the United States and Canada and under the brand name Menorest® in Europe and certain other markets. In May 1999, our second generation estrogen patch, the smallest transdermal estrogen patch approved by the United States Food and Drug Administration (FDA), was launched in the United States under the brand name Vivelle-Dot®. This product has been launched in several foreign countries under the brand name Estradot®. We also developed a combination estrogen/progestin transdermal patch for the treatment of menopausal symptoms, which is marketed under the brand name CombiPatch® in the United States and under the brand name Estalis® in Europe and certain other markets.

As a component of our business strategy, we are seeking to diversify our product offerings beyond HT through strategic collaborations and new product development. In June 2002, we filed a New Drug Application (NDA) with the FDA for a once-daily transdermal methylphenidate delivery system for the treatment of Attention Deficit Hyperactivity Disorder (ADHD), which is intended to be marketed under the brand name MethyPatch®. We believe that this product, if approved by the FDA, will address several issues associated with existing therapies and compete in the United States market for ADHD therapies. In the first quarter of 2003, we signed an agreement to license the exclusive global rights to market MethyPatch® to Shire Pharmaceuticals Group plc (Shire) for payments of up to $150 million and ongoing manufacturing revenues. Noven and Shire are working to address a not approvable letter received from the FDA in April 2003 relating to our MethyPatch® NDA.

In July 2003, we submitted an Abbreviated New Drug Application (ANDA) to the FDA seeking approval to market a generic version of Duragesic® (fentanyl transdermal system). Duragesic® is a transdermal patch containing fentanyl, a Schedule II controlled substance opioid analgesic, and is indicated for the management of chronic pain. In February 2004, we licensed our fentanyl patch to Endo Pharmaceuticals Inc. (Endo). Based on the current patent and exclusivity status of Duragesic®, we believe that the earliest that our fentanyl patch could be commercialized is in January 2005. Endo and Noven have also agreed to seek to develop additional prescription patches.

In April 2003, we signed an agreement to develop new prescription transdermal delivery systems for P&G Pharmaceuticals, Inc. (P&GP), a subsidiary of The Procter & Gamble Company. The products under development explore follow-on product opportunities for Intrinsa®, P&GP s in-licensed investigational transdermal testosterone patch designed to help restore desire in menopausal women who have Hypoactive Sexual Desire Disorder. The first product in this collaboration is currently being studied in humans.

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We have an active research and development program investigating a broad range of products and therapeutic categories. Significant pre-clinical research is ongoing as we select new candidates for development. See Research and Development below for a more complete description of our product development program.

We were incorporated in Delaware in 1987, and our principal executive offices are located at 11960 S.W. 144th Street, Miami, Florida 33186; our telephone number is (305) 253-5099.

Novogyne Pharmaceuticals

Novogyne Pharmaceuticals (Novogyne) markets and sells our HT transdermal drug delivery systems in the United States. Novogyne is a joint venture that we formed with Novartis Pharmaceuticals Corporation (Novartis) in 1998 to market and sell women s prescription healthcare products. We own a 49% equity interest in the joint venture company and Novartis owns the remaining 51% equity interest. The joint venture company has been formed as a Delaware limited liability company under the name Vivelle Ventures LLC and does business under the Novogyne name. In 2003, our equity in earnings of Novogyne, a non-cash item, represented substantially all of our income before income taxes.

Novogyne presently markets our Vivelle®, Vivelle-Dot® and CombiPatch® products in the United States. Novogyne also co-promotes Novartis Famvir®, a product used to treat genital herpes. Novogyne s sales and marketing efforts have caused the Vivelle® family of products to become the most dispensed product family in the transdermal estrogen therapy (ET) category, with a greater than 40% share of monthly total prescriptions dispensed in the United States as of December 2003.

Under the terms of the joint venture agreements, we manufacture and supply Novogyne with Vivelle®, Vivelle-Dot® and CombiPatch®, perform marketing, sales and promotional activities, and receive royalties from Novogyne based on Novogyne s sales of the ET products. Novartis distributes Vivelle®, Vivelle-Dot® and CombiPatch® and provides certain other services to Novogyne, including contracting with the managed care sector, and regulatory, accounting and legal services.

Novogyne is managed by a committee of five members, three appointed by Novartis and two appointed by us. The President of Novogyne is Robert C. Strauss, who also serves as President, Chief Executive Officer and Chairman of the Board of Noven. Pursuant to the joint venture agreements, certain significant actions require a supermajority vote of the committee members, including approving or amending the annual operating and capital budgets of Novogyne, incurring debt or guaranties in excess of $1.0 million, entering into new supply or licensing arrangements, marketing new products and acquiring or disposing of material amounts of Novogyne assets. Novogyne s Management Committee has the authority to distribute cash to Novartis and us based upon a contractual formula. The joint venture agreements provide for an annual preferred return of $6.1 million to Novartis and then an allocation of income between Novartis and us depending upon sales levels attained. Our share of income increases as product sales increase, subject to a maximum of 49%.

The establishment of Novogyne modified a prior relationship in which we had licensed to Novartis the exclusive right to market Vivelle® in the United States and Canada and had received royalties from Novartis based upon Novartis sales. We initially invested $7.5 million in return for our 49% equity interest in Novogyne. Novartis contributed its rights to Vivelle® to Novogyne in return for its 51% equity interest.

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Novogyne acquired the exclusive United States marketing rights to our CombiPatch® product in March 2001 in a series of transactions involving Novogyne, Novartis, Aventis Pharmaceuticals, the U.S. pharmaceuticals business of Aventis Pharma AG (Aventis), and us. See Management s Discussion and Analysis Overview Novartis and Novogyne for a description of this transaction. In a related transaction, Novartis Pharma AG (Novartis Pharma) acquired from Aventis the development and marketing rights to future generations of our combination estrogen/progestin patch in all markets other than Japan. We are developing a next generation combination patch with Novartis Pharma. Novogyne may seek to sublicense the United States rights to these product improvements from Novartis Pharma, but we cannot assure that it will elect to do so or that Novartis Pharma will agree to sublicense any of these products on commercially reasonable terms. If future generation combination products are commercialized and sublicensed to Novogyne, Novogyne expects that it will pay a royalty to Novartis Pharma on the United States sales of such products. We manufacture and supply CombiPatch® to Novogyne, and expect to manufacture and supply any future combination products, to Novartis Pharma and to Novogyne, if licensed from Novartis Pharma.

Novartis has the right to dissolve the joint venture in the event of a change in control of Noven if the acquirer is one of the ten largest pharmaceutical companies (as measured by annual dollar sales). Upon dissolution, Novartis would reacquire the rights to market Vivelle® and Vivelle-Dot® subject to the terms of Novartis prior arrangement with us, and Novogyne s other assets would be liquidated and distributed to the parties in accordance with their capital account balances as determined pursuant to the joint venture operating agreement.

The joint venture operating agreement includes a buy/sell provision that either Noven or Novartis may trigger by notifying the other party of the price at which the triggering party would be willing to acquire 100% of the joint venture. Upon receipt of this notice, the non-triggering party has the option to either purchase the triggering party s interest in Novogyne or to sell its own interest in Novogyne to the triggering party at the price established by the triggering party. If Noven is the purchaser, then Noven must pay an additional amount equal to the net present value of Novartis preferred profit return. This amount is calculated by applying a specified discount rate and a period of 10 years to Novartis $6.1 million annual preferred return. Novartis is a larger company with greater financial resources, and therefore may be in a better position to be the purchaser if the provision is triggered. In addition, this buy/sell provision may have an anti-takeover effect on us since a potential acquirer of Noven will face the possibility that Novartis could trigger this provision at any time and thereby require any acquirer to either purchase Novartis interest in Novogyne or to sell its interest in Novogyne to Novartis.

Strategy

Our strategy for growth and profitability is to utilize our proprietary transdermal drug delivery technology to further our leadership position in this field. In pursuing this strategy, we intend to focus on developing products in a range of therapeutic areas, including hormone therapy and central nervous system conditions, such as ADHD, Hypoactive Sexual Desire Disorder and pain management. In general, we seek to develop and commercialize these products through agreements with strategic industry partners. On a long-term basis, we may seek to (i) expand our transdermal technology base through acquisitions, (ii) establish our own sales force to market certain independently developed products and to acquire products to market through our own sales force, and (iii) capitalize on the opportunity presented by our collaboration with Novartis through Novogyne by licensing certain of our women s health products to Novogyne and by expanding Novogyne s product range beyond transdermal products. No assurance can be given that we will implement all or part of our long-term strategy or that our strategy will be successful.

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Transdermal Drug Delivery

Transdermal patches utilize an adhesive patch containing medication that is administered through the skin and into the bloodstream over an extended period of time. Patches may offer significant advantages over conventional oral and parenteral dosage forms, including non-invasive administration, controlled delivery, improved patient compliance, flexible dose duration and avoidance of certain adverse side-effects.

Our most advanced patches utilize our patented DOT Matrix patch technology. DOT Matrix is a highly efficient class of diffusion-based drug-in-adhesive patch technology that can often deliver more drug through less patch area than competitive patches, without using irritating skin permeation enhancers and without compromising adhesion.

DOT Matrix patches, such as Vivelle-Dot®/Estradot®, CombiPatch®/Estalis® and MethyPatch®, utilize a patented blend of silicone, acrylic and drug. This blend causes microscopic pockets of concentrated drug to be formed and uniformly dispersed throughout the patch s drug/adhesive layer. The resulting high concentration gradient between each drug pocket and the skin works to enhance the diffusion of drug from the patch, through the skin and into the bloodstream. This inherent delivery efficiency reduces the need for skin permeation enhancers. Precise ratios of silicone, acrylic and drug regulate the rate of DOT Matrix drug delivery and help assure therapeutic blood levels over the intended course of therapy.

We believe that our technology enables us to develop patient-friendly transdermal systems that reduce skin irritation sometimes associated with patches, improve adhesion and minimize patch size. Our patches are capable of being modified to deliver a wide variety of chemical entities. Reduced patch size can have a beneficial effect on patient preference and provide a competitive advantage over patches that deliver similar compounds through a larger patch. DOT Matrix technology may also permit us to develop patient-friendly patches in cases where, due to the nature of the compound, competitors products could not deliver a proper dose without making the patch objectionably large.

Hormone Therapy Products

Overview

Our menopausal hormone therapy products consist of:

Vivelle®/Menorest®/Femiest® our first generation estrogen patch,

Vivelle-Dot®/Estradot® our second generation estrogen patch, and

CombiPatch®/Estalis® our combination estrogen/progestin patch.

We currently derive substantially all of our revenues from our HT products. Our total HT related revenues were $41.2 million, $54.5 million and $45.4 million for 2003, 2002 and 2001, respectively, which represented 96%, 98% and 99% of our revenues in these years, respectively. We estimate that, in 2003, worldwide sales of all HT products, including those delivered transdermally, were over $2.6 billion and that worldwide transdermal HT product sales were over $485 million.

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Our HT products are indicated for menopausal symptoms. Menopause begins when the ovaries cease to produce estrogen, or when both ovaries are removed surgically prior to natural menopause. The most common acute physical symptoms of natural or surgical menopause are hot flashes and night sweats, which can occur in up to 85% of menopausal women. Another common problem is vaginal dryness. This condition, which affects an estimated 25% of women, usually begins within five years after menopause. Moderate-to-severe menopausal symptoms can be treated by replacing the estrogen that the body can no longer produce. Estrogen therapy relieves hot flashes and night sweats effectively, and prevents drying and shrinking of the reproductive system. Our ET products are also indicated for the prevention of osteoporosis, a progressive deterioration of the skeletal system through the loss of bone mass. There are, however, other approved therapies for the prevention of osteoporosis and our labeling recently approved by the FDA will advise that ET should be used for this condition only in women who have a significant risk of osteoporosis and for whom non-estrogen therapies are inappropriate.

HT Studies

In July 2002, the National Institutes of Health (NIH) released data from its Women s Health Initiative (WHI) study on the risks and benefits associated with use of oral combination HT by healthy women. The NIH announced that it was discontinuing the arm of the study investigating the use of oral estrogen/progestin after an average follow-up period of 5.2 years because the oral combination HT 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 the orally delivered combined estrogen plus progestin product among healthy postmenopausal women. Also in July 2002, results of an observational study sponsored by the National Cancer Institute (NCI) on the effects of ET were announced. The main finding of the NCI study was that postmenopausal women who used ET for 10 or more years had a higher risk of developing ovarian cancer than women who never used HT. In June 2003, a further analysis of data from the discontinued combination therapy arm of the WHI study indicated that use of combination HT may also increase the frequency of abnormal mammograms beginning in the first year of therapy and/or may cause tumors to be more advanced at the time of diagnosis. In August 2003, further WHI data analysis suggested that the use of combination therapy increased the risk of heart disease beginning in the first year of therapy, and a large U.K. study suggested that the use of both estrogen-only and combination therapy increased the risk of breast cancer, and the risk of death from breast cancer, whether administered orally, transdermally or via implant. In December 2003, a Scandinavian study on the effects of HT on breast cancer survivors was discontinued after the study found a high risk of cancer recurrence. In March 2004, the NIH discontinued the estrogen-only arm of the WHI Study because of an increased risk of stroke and because, after nearly seven years of follow-up, the NIH determined that it had sufficient data to assess the risks and benefits of estrogen use in the trial. This arm of the WHI study also found that the use of an estrogen-only oral formulation appeared to decrease the risk of hip fracture, and did not appear to affect heart disease or to increase the risk of breast cancer. Researchers continue to analyze data from both arms of the WHI study and other studies. Other studies evaluating HT are currently underway or in the planning stages.

Since the July 2002 publication of the WHI and NCI study data, United States prescriptions have declined for substantially all HT products, including our products in the aggregate. For a discussion of the effects of these studies on our prescription rates and certain risks that we may face as a result of these studies, see Management s Discussion and Analysis of Financial Condition and Results of Operations Overview.

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As a result of these studies, in January 2003, the FDA announced that marketers of HT products, including Novogyne, are required to modify their HT product labels to include additional safety information and warnings. Among other things, the labels must indicate that HT should be used for short-term therapy only and that, in the absence of clinical studies demonstrating that HT products other than the oral product studied in the WHI study are safe, physicians should assume that all HT products carry the same risks. The FDA has approved revised labels for our ET products and we are awaiting approval for revised labels for our combination HT product. We expect that Noven, Novogyne and trade participants will be permitted to deplete product inventory bearing the old label concurrently with the introduction of product with revised labeling. We expect further revisions to HT product labels may be required by the FDA to include information from the Women s Health Initiative Memory Study, which reported an increased risk of dementia from use by women 65 and older of an oral combination estrogen with progestin product and possibly other studies. Regulatory authorities outside the United States have or are expected to require revised labeling as well.

First Generation Transdermal Estrogen Delivery System

Our first generation transdermal estrogen delivery system (marketed as Vivelle®, Menorest®, and Femiest®) is available by prescription and utilizes our adhesive matrix technology. This product delivers estradiol, the primary estrogen produced by the ovaries, through a patch that is applied twice weekly.

This product has been approved for marketing by the FDA, as well as by regulatory authorities in many foreign countries, for the treatment of menopausal symptoms and the prevention of osteoporosis. Marketing rights to this product are held by Novogyne in the United States, by Aventis in Japan, and by Novartis Pharma in all other territories. Novartis Pharma is selling this product under the brand name Menorest® in a number of foreign countries. Novogyne and Novartis Pharma s Canadian affiliate market this product under the brand name Vivelle® in the United States and Canada, respectively, and Aventis markets this product under the brand name Femiest® in Japan.

Pursuant to license and supply agreements with Novartis Pharma, Novogyne and Aventis, we manufacture Vivelle®, Menorest® and Femiest® for these parties and receive fees based on their sales of the products. The supply agreements for Menorest® and Femiest® are long-term agreements. The supply agreement for Vivelle® (and Vivelle-Dot®) expired in January 2003. Since the expiration of the Vivelle® supply agreement, the parties have continued to operate in accordance with the supply agreement s commercial terms. We cannot assure that we will enter into a new supply agreement on satisfactory terms or at all. Failure to extend the supply agreement could have a material adverse effect on our business, results of operations and financial position. Designation of a new supplier and approval of a new supply agreement would require the affirmative vote of four of the five members of Novogyne s Management Committee. Accordingly, both Novartis and Noven must agree on Novogyne s supplier. Due to our dependence on Novogyne, we may be unable to negotiate favorable business terms with Novartis or resolve any dispute that we may be involved in with them in a favorable manner.

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Second Generation Transdermal Estrogen Delivery System

Utilizing our proprietary DOT Matrix technology, our second generation transdermal estrogen delivery system (marketed as Vivelle-Dot® and Estradot®) is one-third the area of a Vivelle®/Menorest® system at any given dosage level, yet provides the same delivery of drug over the same period. This system is more flexible and comfortable to wear than the first generation product, with a lower potential for skin irritation. This product is bioequivalent to our first generation product and is available in the United States in five dosage strengths. The lowest dosage strength is approved only for osteoporosis, and in light of the HT studies described above and the expected label changes, many physicians may consider alternative treatments for the prevention of osteoporosis which would adversely affect the market for that dosage strength.

Novogyne markets Vivelle-Dot® in the United States and Aventis has marketing rights for Vivelle-Dot® in Japan. In November 2000, we entered into an exclusive license agreement with Novartis Pharma pursuant to which we granted Novartis Pharma the right to market Vivelle-Dot® under the name Estradot® in all countries other than the United States, Canada and Japan. The agreement also grants Novartis Pharma marketing rights in the same territories to any product improvements and future generations of estrogen patches developed by us.

Under the terms of the agreement, Novartis Pharma is responsible for seeking approval to market Estradot® in its territories. The product has been approved for marketing in over 30 foreign countries and the regulatory authorities of other countries are reviewing Novartis Pharma s registration applications. Novartis Pharma has launched the product in Germany, in Spain (without government reimbursement) and in a number of smaller European countries. However, Novartis Pharma has informed us that pricing, government reimbursement and labeling issues are adversely impacting its launch plans in many countries, including the United Kingdom, France, and Italy. Accordingly, there can be no assurance that Novartis Pharma will be successful in effecting additional registrations of Estradot® or that Novartis Pharma will launch Estradot® in any particular country. In some countries, including the United Kingdom and France, Novartis Pharma is seeking a marketing partner to launch the product but to date has been unsuccessful. We cannot assure that Novartis Pharma will be successful in securing a marketing partner or in launching Estradot® in those countries. The profitability of Estradot® and our other products sold in the European Union may also be negatively affected by parallel trade practices whereby a licensed importer may take advantage of price disparity between markets by purchasing our products in a market with a relatively lower price and then importing them into a country with a relatively higher price.

Novartis Pharma markets several other estrogen patches in addition to our products and Novartis Pharma may derive higher gross margins on the sale of its other products compared to ours. If pricing, government reimbursement and labeling issues are resolved, we expect that the growth of Estradot® sales will depend, in part, on Novartis Pharma s willingness and ability to convert sales of its existing patches to Estradot®. We cannot assure that Novartis Pharma will choose to actively convert sales of its existing patches to Estradot®.

Pursuant to license and supply agreements with Novartis Pharma and Novogyne, we manufacture the product for these parties and receive fees based on their sales of the product. The supply agreement for Estradot® is a long-term agreement. Vivelle-Dot® is supplied under the same agreement as Vivelle®. As discussed above, we cannot assure that the United States supply agreement will be extended on satisfactory terms or at all.

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Transdermal Combination Estrogen/Progestin Delivery System

We also developed the first combination transdermal therapy system approved for marketing by the FDA, a combination patch containing estradiol and norethindrone acetate, a progestin. Although benefits of estrogen therapy include menopausal symptom control and osteoporosis prevention, estrogen-only therapy has been associated with an increased risk of endometrial cancer for women who have an intact uterus (non-hysterectomized). To address this situation, a combination therapy of estrogen and progestin may be prescribed. Using both hormones together has been shown to reduce the risk of endometrial cancer while continuing to produce the menopausal symptom control benefits of estrogen therapy. Further, studies have shown that continuous use of both estrogen and low dose progestin may be effective for many women in eliminating the monthly menstrual cycle or irregular bleeding.

Novogyne acquired marketing rights to the product in March 2001 from Aventis (which was then our exclusive worldwide licensee for the product) and markets the product under the brand name CombiPatch® in two dosage strengths in the United States. Novogyne had been unable to increase CombiPatch® prescriptions after acquiring and relaunching the product, and since publication of the HT studies described above, CombiPatch® prescriptions and sales have declined significantly.

Novartis Pharma holds the right to market this product outside of the United States and Japan and is marketing this product under the brand name Estalis® in a number of foreign countries. In June 2001, we entered into a development agreement with Novartis Pharma relating to future generations of combination estrogen/progestin patch products.

Estalis® is presently approved in only one dosage strength in most European countries. Novartis Pharma has filed an application for approval of a second dosage strength in Sweden. Novartis Pharma, however, has determined that, in light of market changes since the publication of the HT studies, a dosage strength lower than the second dosage strength is necessary for the product to obtain market acceptance in Europe. As a consequence, Novartis Pharma has advised us that, in lieu of launching the second dosage strength of Estalis®, they will seek marketing approval and commercialization of a next generation combination estrogen/progestin patch product with a lower dosage strength when and if a next generation product is developed. No assurance can be given that we will complete development of a next generation combination estrogen/progestin patch or that approval will be obtained, and the timing of any launch of a next generation combination estrogen/progestin patch product cannot be predicted. We expect that growth in this market will be limited unless and until a next generation combination estrogen/progestin patch product is developed, approved and launched.

Pursuant to license and long-term supply agreements with Novartis Pharma and Novogyne, we manufacture the combination product for these parties and receive fees based on their sales of the product.

Our Additional Products

Transdermal Methylphenidate Delivery System

We have developed a once-daily transdermal methylphenidate patch for the treatment of ADHD. ADHD is the most commonly diagnosed and the most widely studied behavioral disorder in children in the United States. ADHD is characterized by developmentally inappropriate levels of attention, concentration, activity, distractibility and impulsivity symptoms. The disorder typically causes functional impairment that can limit success and create hardship in school, and in social and familial relationships. As children age, the symptoms can lead to serious conduct disorders, criminal behavior, substance abuse and accidental injuries. Methylphenidate is a stimulant and designated as a Schedule II controlled substance by the United States Drug Enforcement Administration (DEA).

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While prevalence rates can vary dramatically from study to study, it is widely reported that ADHD affects about 3% to 7% of school-aged children in the United States, over 2 million children nationwide. Stimulant therapies, including methylphenidate, are the most prescribed drug type for the treatment of ADHD. Presently, all ADHD medications approved in the United States are delivered orally. We believe that our patch will provide physicians with broad dosing flexibility, because dosing can be discontinued at any time during a day by simply removing the patch, and may offer other advantages as compared to certain oral ADHD medications.

In June 2002, we filed with the FDA an NDA for MethyPatch®. In the first quarter of 2003, we signed an agreement to license the exclusive global rights to market MethyPatch® to Shire for payments of up to $150 million and ongoing manufacturing revenues. Consideration for the transaction is as follows: (i) $25 million was paid upon closing of the transaction in April 2003; (ii) $50 million is payable upon receipt of final marketing approval for MethyPatch® by the FDA; and (iii) three installments of $25 million each are payable upon Shire s achievement of $25 million, $50 million and $75 million in annual net sales of MethyPatch®, respectively. Shire s annual net sales will be measured quarterly on a trailing 12-month basis, with each milestone payment due 45 days after the end of the first quarter during which trailing 12-month sales exceed the applicable threshold. Shire has agreed that it will not sell any other product containing methylphenidate as an active ingredient until the earlier of (i) five years from the closing date or (ii) payment of all of the sales milestones. On the closing date, we entered into a long-term supply agreement under which we expect to manufacture and supply MethyPatch® to Shire. The agreement gives Shire the right to qualify a second manufacturing source and purchase a portion of its requirements from the second source. If Shire were to exercise this right, Noven s revenues and profits from sales of MethyPatch® would be adversely affected. Pursuant to the agreement, under certain circumstances Shire has the right to require us to repurchase the product rights for $5 million.

In April 2003, we received a not approvable letter from the FDA relating to our MethyPatch® NDA. A not approvable letter is issued if the FDA does not consider the application approvable because one or more deficiencies in the application preclude the FDA from approving it. The letter cited clinical and other issues as the basis for non-approval. In October 2003, we submitted with Shire a jointly prepared, proposed study protocol for an additional clinical study for MethyPatch® to the FDA for review and comment. The purpose of this additional proposed study was to address clinical issues and risks raised in the FDA s not approvable letter. In November 2003, the FDA responded to our proposed study protocol and reported that the proposed study design did not address the clinical risk-benefit issues raised in the April 2003 not approvable letter. In its November 2003 response, the FDA provided specific recommendations regarding the proposed study design. Noven and Shire are working together to review and respond to the FDA s comments and recommendations with respect to the study design. We believe this study is necessary to amend the NDA and that other studies may also be required or advisable. Under a November 2003 agreement with Shire, if we agree with Shire on a study design, Shire will manage the new clinical study and we will fund it. Under our agreement with Shire, we are responsible for providing the clinical supplies for the study and we may incur certain additional expenses in pursuit of regulatory approval, including all or a portion of the cost of any other studies that we decide to conduct. At the conclusion of the trial, if Shire determines that submission of the study results to the FDA would not result in a commercially-viable product, Shire will have the right to terminate the original transaction agreement. If Shire exercises its termination right under these circumstances, however, Shire will forfeit its right to require us to repurchase the product rights, and the product rights will revert to us without payment to Shire. If Shire elects to proceed after reviewing the study results, we expect to cooperate with Shire in submitting the new study results to the FDA and continuing to seek regulatory approval of MethyPatch®. We cannot assure that any revised study design will be acceptable to the FDA or, even if accepted by the FDA, produce study results that will result in a commercially-viable product. If the parties are unable to reach agreement with each other or the FDA on a study design, the parties may not continue to pursue regulatory approval of MethyPatch®.

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Transdermal Fentanyl Delivery System

In July 2003, we submitted an ANDA to the FDA seeking approval to market a generic version of Duragesic® (fentanyl transdermal system). Duragesic® is a transdermal patch containing fentanyl, an opioid analgesic and a Schedule II controlled substance, and is indicated for the management of chronic pain. Our ANDA for this product was accepted for filing as of October 1, 2003. Acceptance for filing means that the FDA has made a threshold determination that the application is sufficiently complete to permit a substantive review.

In the first quarter of 2004, we entered into an exclusive license agreement with Endo pursuant to which we granted Endo the right to market our fentanyl patch in the United States and Canada. We retained all rights to the fentanyl patch outside of the U.S. and Canada, and we are exploring strategies to commercialize the product in other territories. We received an up-front payment of $8.0 million from Endo upon signing the agreement. The agreement provides that, upon Endo s first commercial sale of the fentanyl patch, we are entitled to receive an additional milestone payment ranging from $5.0 million to $10.0 million, depending on the timing of launch and the number of generic competitors in the market. Under a long-term supply agreement entered into between the parties, we will manufacture and supply the product at our cost and will share in Endo s profit generated from U.S. product sales.

Under the terms of the transaction, we remain responsible for securing final regulatory approval for our fentanyl transdermal system. The agreement provides that Endo may terminate the agreement, and its obligation to launch the product, if launch is delayed either (i) because of a delayed FDA approval or (ii) our failure to supply Endo with its launch requirements after approval, and if as a result of the delay additional generic competition beyond that currently expected by the parties. The earliest that this right could be triggered under the agreement is May 2005. In the event of such a termination, rights to the fentanyl patch would return to us.

The agreement provides that Endo is responsible for seeking regulatory approval to market the product in Canada. If such efforts are successful, we will supply product for sale in Canada on a cost-plus basis, with no royalty or profit sharing arrangement.

In addition to the fentanyl license, we have established a collaboration with Endo to seek to identify and develop new transdermal therapies. Of the $8.0 million received at signing, $1.5 million will be allocated to fund feasibility studies that we expect to undertake to seek to determine whether certain compounds identified by the parties can be delivered through our transdermal patch technology. Endo is expected to fund and manage clinical development of those compounds proceeding into clinical trials.

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Transmucosal Lidocaine Delivery System

Our first transmucosal delivery system, DentiPatch®, is a patented, proprietary technology consisting of a thin, solid state multi-laminate construction with a drug-bearing bio-adhesive that delivers lidocaine through the buccal mucosa over time. DentiPatch® was approved for marketing by the FDA in May 1996 and was the first FDA-approved oral transmucosal patch. We launched the product nationwide in April 1997. The product is indicated for the reduction of pain from oral injections and for the production of mild topical anesthesia prior to superficial dental procedures. It is the first topical anesthetic clinically proven to reduce pain when large needles are inserted to the bone. DentiPatch® is currently marketed in the United States through a network of independent distributors. Sales of DentiPatch® are not material to our results of operations.

Research and Development

Our research and development strategy is to identify drugs that can be delivered transdermally and which we believe have substantial market potential, as well as those that we believe can be improved by using our patented technologies. We typically seek to develop products that use approved drugs that currently are being delivered to patients through means other than transdermal delivery. In addition, we may seek to develop transdermal drug delivery systems utilizing proprietary compounds of other companies. For the years ended December 31, 2003, 2002 and 2001, we spent $8.1 million, $11.6 million and $11.0 million, respectively, for research and development activities. As part of our strategy, we seek to supplement our research and development efforts by entering into research and development agreements, joint ventures and other collaborative arrangements with other companies.

Our research and development expense may vary significantly from quarter to quarter depending on product development cycles, the timing of clinical studies and whether we or a third party are funding development. We intend to focus on long-term growth prospects, and, therefore, may incur higher than expected research and development expenses in a given period rather than delay clinical activities. These variations in research and development spending may not be accurately anticipated and may have a material effect on our results of operations.

The time necessary to complete clinical trials and the regulatory process to obtain marketing approval varies significantly. We cannot assure that we will have the financial resources necessary to complete products under development, that those projects to which we dedicate sufficient resources will be successfully completed, that we will be able to obtain regulatory approval for any such product, or that any approved product may be produced in commercial quantities, at reasonable costs, and be successfully marketed, either by us or by a licensing partner. Similarly, we cannot assure that our competitors, many of whom have greater resources than we do, will not develop and introduce products that will adversely affect our business and results of operations.

The following table summarizes as of March 1, 2004 the status of products marketed, approved and/or under development by us and is qualified by reference to the more detailed descriptions elsewhere in this Form 10-K. We have additional products under development that are not disclosed in the following table due to their early stage of development or for competitive reasons.

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Product	Indication	Regulatory Status	Marketing Rights
Transdermal HT			
Estrogen Vivelle®/Menorest®/ Femiest®	Menopausal Symptoms/ Osteoporosis	FDA-approved; Approved in over 15 foreign countries	Novogyne U.S. Aventis Japan Novartis Pharma all other territories
Second Generation Estrogen Vivelle-Dot®/ Estradot®	Menopausal Symptoms/ Osteoporosis	FDA-approved; Approved in over 45 foreign countries	Novogyne U.S. Aventis Japan Novartis Pharma all other territories
Combination Estrogen/Progestin CombiPatch®/Estalis®	Menopausal Symptoms/ Osteoporosis	FDA-approved; Approved in over 30 foreign countries	Novogyne U.S. Aventis Japan Novartis Pharma all other territories
Second Generation Combination Estrogen/Progestin	Menopausal Symptoms/ Osteoporosis	Phase I (sponsored by Novartis Pharma)	Aventis Japan Novartis Pharma all other territories
Other Transdermals			
Fentanyl	Pain Management	ANDA filed	Endo US and Canada Noven all other territories
Methylphenidate MethyPatch®	Attention Deficit Hyperactivity Disorder	NDA filed*	Shire worldwide
Undisclosed compounds	Hypoactive Sexual Desire Disorder	Early Clinicals	P&GP worldwide
Transmucosal			
Lidocaine/DentiPatch®	Dental pain associated with certain dental procedures	FDA-approved	Noven

* Noven and Shire are working to address a not approvable letter received from the FDA in late April 2003 relating to our MethyPatch® NDA. See -Our Additional Products Transdermal Methylphenidate Delivery System.

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Competition

The markets for our products are highly competitive. All drug delivery products being developed by us may face competition from conventional forms of drug delivery (i.e., oral and parenteral), from alternate forms of drug delivery, such as controlled release oral delivery, liposomes, implants, gels and creams and possibly from alternate non-drug therapies. In addition, some or all of the products being marketed or developed by us face, or will face, competition from other transdermal products that deliver the same drugs to treat the same indications.

Competition in drug delivery systems is generally based on a company s marketing strength, product performance characteristics (i.e., reliability, safety, patient convenience) and product price. As a general matter, transdermal drug delivery systems are more expensive to manufacture than oral formulations. Acceptance by physicians and other health care providers, including managed care groups, is also critical to the success of a product. The first product on the market in a particular therapeutic area typically is able to obtain and maintain a significant market share. In a highly competitive marketplace and with evolving technology, there can be no assurance that additional product introductions or medical developments by others will not render our products or technologies noncompetitive or obsolete. We also compete with other drug delivery companies in the establishment of business arrangements with large pharmaceutical companies to assist in the development or marketing of products.

In the market for HT products, Novogyne competes against Wyeth Pharmaceuticals, Watson Pharmaceuticals, Inc., Mylan Pharmaceuticals, Inc., Berlex Laboratories, Women First HealthCare, Inc., Novavax, Inc., Solvay Pharmaceuticals, Inc. and others, including Novartis, Novartis Pharma and their affiliates. We expect increased competition in the estrogen market as a result of the recent launches of a vaginal estrogen delivery system and a combination estrogen/progestin patch and the expected launches of estrogen cream and gel products, each of which is a new dosage form in this category, as well as the expected launch of an ultra-low dose estrogen patch. Most of our competitors are substantially larger and have greater resources than we do, as well as greater experience in developing and commercializing pharmaceutical products.

The market for ADHD drugs is also highly competitive, with a product mix that includes generic methylphenidate, long-acting formulations, other stimulant medications, medications not containing Schedule II controlled substances, and a variety of other drug types. Other products which may have improved safety and efficacy profiles are also in development. Shire currently markets non-methylphenidate products for the treatment of ADHD, and we cannot assure that Shire will market MethyPatch® aggressively or effectively if it is approved, or that MethyPatch® will compete effectively against extended release oral formulations of methylphenidate and/or other ADHD medications, especially those not involving controlled substances. Some of the companies marketing competitive products are substantially larger and have greater financial resources than Shire does. In particular, Johnson & Johnson markets Concerta®, the market-leading methylphenidate product, and Novartis and Eli Lilly & Company (Lilly) market competitive ADHD products. Strattera®, a non-stimulant, non-controlled substance therapy launched by Lilly in 2003, has gained significant market share in a short period of time. There is at least one clinical study underway comparing the efficacy of Strattera® to a long-acting methylphenidate product. If Strattera® or other therapies in development become recognized as therapeutically superior to stimulants, or are preferred by physicians, parents and/or patients, the market for stimulants, including MethyPatch®, would be adversely affected.

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Subject to FDA approval, we expect our fentanyl transdermal system will compete against other generic versions of Johnson & Johnson s Duragesic® patch. In the market for generics, the first products to be approved and available for sale typically achieve and maintain significant market share. As competing generic manufacturers receive regulatory approvals, market share, revenues and gross profit typically decline, in some cases dramatically. Accordingly, the level of market share, revenues and gross profit for a generic product is typically tied to the number of competitors in the market and the timing of that product s FDA approval and launch in relation to competing approvals and launches. In addition to other generic manufacturers, we expect to face competition from Johnson & Johnson, the manufacturer of Duragesic®, who may seek to compete in this market by collaborating with other generic pharmaceutical companies or by marketing their own generic equivalent of Duragesic®. Johnson & Johnson s patent and pediatric exclusivity for Duragesic® expire in January 2005, which is the earliest possible date that we could launch our fentanyl transdermal system, but we can not assure that we will obtain FDA approval or launch a product in this timeframe or at all. Mylan Laboratories has received final approval from the FDA for its generic fentanyl transdermal system and has announced its intention to launch this product in July 2004. We believe that other generic manufacturers have submitted or will submit ANDAs for fentanyl transdermal systems. To seek to be prepared for a timely launch, we expect to manufacture launch supplies prior to receipt of tentative FDA approval. If launch supplies are manufactured and approval is not ultimately received or is sufficiently delayed such that these supplies are not saleable, the license agreement provides that we will share the cost of manufacturing these supplies with Endo in accordance with a formula, but we would be unable to offset all of our up-front production costs with sales of the product. We expect that these costs could be significant.

Dependence on Licensees and Joint Venture

During 2003, 48% and 43% of our revenues were generated from sales to, and contract revenues, fees and royalties received from, Novogyne and Novartis Pharma, respectively, and substantially all of our income before income taxes was attributable to our equity in Novogyne s earnings, a non-cash item. Going forward, we expect to be dependent on sales to Novartis Pharma, Novogyne and possibly Shire and Endo, as well as fees, milestone payments, profit sharing and royalties generated from their sales of our transdermal delivery systems, for a significant portion of our expected revenues. No assurance can be given regarding the amount and timing of such revenues. Failure of these parties to successfully market our products would cause the quantity of products purchased from us and the amount of fees, milestone payments and royalties ultimately paid to us to be reduced and would therefore have a material adverse effect on our business and results of operations. We expect to be able to influence the marketing of Vivelle®, Vivelle-Dot® and CombiPatch® in the United States through our participation in the management of Novogyne, but the Management Committee of Novogyne is comprised of a majority of Novartis representatives, and we will not be able to control those matters. Our agreements with our marketing partners impose certain obligations on them, but there can be no assurance that such agreements will provide us with any meaningful level of protection or cause these companies to perform at a level that we deem satisfactory. Further, these companies and their affiliates sell competing products, both in the United States and abroad, and it is possible that they will promote their other competitive products at our expense. Any reduction in the level of support and promotion that these companies provide to our products, whether as a result of their focus on other products or otherwise, could have a material adverse effect on our business, results of operations, financial condition and prospects.

We expect that a significant portion of our earnings for at least the next several years will be generated through our interest in Novogyne, and no assurance can be given regarding Novogyne s future profitability. Novogyne s sales force is significantly smaller than the sales forces promoting several competitive products, and there can be no assurance that Novogyne s sales force will be successful. Prior to the publication of the HT study data described above, CombiPatch® prescription trends had not improved significantly since Novogyne acquired marketing rights in March 2001. Since the HT study data was published, CombiPatch® prescriptions have, like most HT products, declined, and we do not expect Novogyne to be able to grow CombiPatch® sales and sales may continue to decline. Failure of Novogyne to successfully market Vivelle®, Vivelle-Dot® or CombiPatch® would have a material adverse

effect on our business and results of operations.

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Manufacturing

We conduct our manufacturing operations in a facility comprised of two approximately 40,000 square foot buildings located on approximately 10 acres in Miami-Dade County, Florida. This facility has been inspected by the FDA and by the Medicines and Healthcare Products Regulatory Agency of the United Kingdom and found to be in compliance with applicable regulatory requirements. This facility has also been certified by the Drug Enforcement Administration to manufacture products containing controlled substances. The manufacturing area is being expanded to facilitate the manufacture and storage of commercial quantities of MethyPatch® and our transdermal fentanyl system. Our manufacturing capability is approximately 400 million patches per year. There is sufficient room for further development of facilities at this site that would significantly increase our manufacturing capacity to accommodate additional products under development. We anticipate that full development of this site, including possible new construction on the property, can accommodate our space requirements for the foreseeable future. No assurance can be given that we will have the financial resources necessary to adequately expand our manufacturing capacity if and when the need arises.

Raw materials essential to our business generally are readily available from multiple sources. Certain raw materials and components used in the manufacture of our products (including essential polymer adhesives and other critical components) are, however, available from limited sources, and in some cases, a single source. Our NDA for MethyPatch® includes only one supplier of the active pharmaceutical compound. This same supplier is also the only source of the active pharmaceutical compound for which we have sought approval under the ANDA for our transdermal fentanyl system. In addition, the DEA controls access to controlled substances (including methylphenidate, amphetamine and fentanyl), and we must receive authorization from the DEA to obtain these substances. Any curtailment in the availability of such raw materials could result in production or other delays, and, in the case of products for which only one raw material supplier exists, could result in a material loss of sales, with consequent adverse effects on our business and results of operations. In addition, because most raw material sources for transdermal patches must generally be approved by regulatory authorities, changes in raw material suppliers may result in production delays, higher raw material costs and loss of sales, customers and market share. Some raw materials used in our products are supplied by companies that restrict certain medical uses of their products. While our use is presently acceptable, there can be no assurance that such companies will not expand their restrictions to include our applications.

Marketing & Sales

Our business strategy generally is to seek to license a new product to a third party who we believe has the clinical and regulatory resources and expertise necessary to develop the product and the marketing and sales resources necessary to broadly commercialize the product. We seek to retain manufacturing rights for ourselves, in part to help safeguard our proprietary technology. Except for DentiPatch®, we have historically granted product marketing rights to our Novogyne joint venture and to other pharmaceutical companies.

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Our strategy, however, does not preclude the possibility that we may retain the rights to a particular new product and develop, market and sell it ourselves. A decision to retain rights to any product would be based upon an analysis of, among other things, our financial resources and capabilities at the time; the characteristics of the particular product and market; complementary products in our pipeline or available to us; and the estimated costs associated with clinical studies, sales, marketing and distribution.

Under the Novogyne joint venture agreements, we have responsibility for the day-to-day management of Novogyne s marketing efforts and sales force. In fulfilling this responsibility, we believe that we have established significant marketing and sales expertise. We believe this expertise has helped lead the Vivelle® family of products to become the most dispensed product family in the U.S. transdermal ET category. We also seek to use this expertise more broadly to help us identify and evaluate the commercial potential of new product development projects that may help advance our growth strategy.

Patents and Proprietary Rights

We seek to obtain patent protection on our delivery systems and manufacturing processes whenever possible. We have obtained over 30 United States patents and over 184 foreign patents relating to our transdermal and transmucosal delivery systems and manufacturing processes, and have over 137 pending patent applications worldwide.

As a result of changes in United States patent law under the General Agreement on Tariffs and Trade and the accompanying agreement on Trade-Related Aspects of Intellectual Property Law, which took effect in their entirety on January 1, 1996, the terms of some of our existing patents have been extended beyond the original term of seventeen years from the date of grant. Our patents filed after June 7, 1995 will have a term of twenty years computed from the effective filing date.

We are unaware of any challenge to the validity of our patents or of any third party claim of patent infringement with respect to any of our products, in either case that could have a material adverse effect on our business or prospects.

Although there is a statutory presumption as to a patent s validity, the issuance of a patent is not conclusive as to such validity, or as to the enforceable scope of the claims of the patent. We cannot assure that our patents or any future patents will prevent other companies from developing similar or functionally equivalent products. We cannot assure that we would have the resources to prosecute an action to enforce our patent rights against an alleged infringer or that we would be successful in any infringement action that we elect to bring. Likewise, we cannot assure that we would have the resources to defend an infringement action or that we would be successful in any such defense. Furthermore, we cannot assure that any of our future processes or products will be patentable, that any pending or additional patents will be issued in any or all appropriate jurisdictions or that our processes or products will not infringe upon the patents of third parties.

We also attempt to protect our proprietary information under trade secret and confidentiality agreements. Generally, our agreements with each employee, licensing partner, consultant, university, pharmaceutical company and agent contain provisions designed to protect the confidentiality of our proprietary information. There can be no assurance that these agreements will not be breached, that we will have adequate legal remedies as a result thereof, or that our trade secrets will not otherwise become known or be independently developed by others.

Trademarks

The trademarks for the products that we manufacture as well as for other products referred to in this Form 10-K are registered as follows:

MethyPatch®, DOT Matrix® and DentiPatch® are registered trademarks of Noven Pharmaceuticals, Inc.
Vivelle® is a registered trademark of Novartis Corporation
Vivelle Dot® and Estradot® are registered trademarks of Novartis AG
CombiPatch® is a registered trademark of Vivelle Ventures LLC
Estalis®, Femiest® and Menorest® are registered trademarks of Aventis Pharma S.A.
Duragesic® is a registered trademark of Johnson & Johnson
Concerta® is a registered trademark of Alza Corporation
Strattera® is a registered trademark of Eli Lilly and Company
Intrinsa is a trademark of Proctor & Gamble Pharmaceuticals, Inc.
Famvir® is a registered trademark of Novartis International Pharmaceutical Ltd.

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Government Regulation

Our operations are subject to extensive regulation by governmental authorities in the United States and other countries with respect to the testing, approval, manufacture, labeling, marketing and sale of pharmaceutical products. We devote significant time, effort and expense to address the extensive government regulations applicable to our business.

The marketing of pharmaceutical products requires the approval of the FDA in the United States. The FDA has established regulations, guidelines and safety standards, which apply to the pre-clinical evaluation, clinical testing, manufacturing and marketing of pharmaceutical products. The process of obtaining FDA approval for a new product may take several years or more and is likely to involve the expenditure of substantial resources. The steps required before a product can be produced and marketed for human use typically include: (i) pre-clinical studies; (ii) submission to the FDA of an Investigational New Drug Exemption (IND), which must become effective before human clinical trials may commence in the United States; (iii) adequate and well controlled human clinical trials; (iv) submission to the FDA of a New Drug Application (NDA); and (v) review and approval of the NDA by the FDA.

An NDA generally is required for products with new active ingredients, new indications, new routes of administration, new dosage forms or new strengths. An NDA requires that complete clinical studies of a product s safety and efficacy be submitted to the FDA, the cost of which is substantial. These costs can be reduced, however, for delivery systems which utilize approved drugs. In these cases, the company seeking approval may refer to safety and toxicity data reviewed by the FDA in its approval process for the innovator product. In addition, a supplemental NDA may be filed to add an indication to an already approved product.

An abbreviated approval process may be available for products that have the same active ingredient(s), indication, route of administration, dosage form and dosage strength as an existing FDA-approved product covered by an NDA, if clinical studies have demonstrated bio-equivalence of the new product to the FDA-approved product covered by an NDA. For this abbreviated process, an Abbreviated New Drug Application (ANDA) is submitted to the FDA instead of an NDA. Under FDA ANDA regulations, companies that seek to introduce an ANDA product must also certify that the product does not infringe on the approved product s patent listed with the FDA or that such patent has expired. If the applicant certifies that its product does not infringe on the approved product s patent or that such patent is invalid, the patent holder may institute legal action to determine the relative rights of the parties and the application of the patent. Under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), the FDA may not finally approve the ANDA until the later of thirty months from the date of the legal action or a final determination by a court that the applicable patent is invalid or would not be infringed by the applicant s product. We have filed an ANDA for our transdermal fentanyl system and we are developing other products for which we or a licensee intend to file an ANDA. There can be no assurance we will not be sued for patent infringement, that we would prevail in any litigation or that the costs of any such litigation would not be prohibitive.

The Hatch-Waxman Act further provides for a period of 180 days of generic marketing exclusivity for each ANDA applicant that is first to file an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed with respect to a reference drug product, commonly referred to as a Paragraph IV certification. During this exclusivity period, the FDA cannot grant final approval to any other generic equivalent. If an ANDA containing a Paragraph IV certification is successful, it generally results in higher market share, net revenues and gross margin for that applicant. Even if we obtain FDA approval for generic drug products, we may lose significant advantages to a competitor who was first to file an ANDA containing a Paragraph IV certification.

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Pre-clinical studies are conducted to obtain preliminary information on a product s safety. The results of these studies are submitted to the FDA as part of the IND and are reviewed by the FDA before human clinical trials begin. Human clinical trials may commence 30 days after receipt of the IND by the FDA, unless the FDA objects to the commencement of clinical trials.

Human clinical trials are typically conducted in three sequential phases, but the phases may overlap. Phase I trials consist of testing the product primarily for safety in healthy volunteers or a small number of patients at one or more doses. In Phase II trials, the safety and efficacy of the product are evaluated in a patient population somewhat larger than the Phase I trials. Phase III trials typically involve additional testing for safety and clinical efficacy in an expanded population at different clinical test sites. A clinical plan, or protocol, accompanied by information on the investigator(s) conducting the trials, must be submitted to the FDA prior to commencement of each phase of the clinical trials. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time.

The results of product development and pre-clinical and clinical studies are submitted to the FDA as an NDA or ANDA for approval. If an application is submitted, there can be no assurance that the FDA will review and approve the NDA or ANDA in a timely manner. The FDA may deny an NDA or ANDA if applicable regulatory criteria are not satisfied or it may require additional clinical testing. Even if such data is submitted, the FDA may ultimately deny approval of the product. Further, if there are any modifications to the drug, including changes in indication, manufacturing process, labeling, or a change in manufacturing facility, an NDA or ANDA supplement may be required to be submitted to the FDA. Product approvals may be withdrawn after the product reaches the market if compliance with regulatory standards is not maintained or if problems occur regarding the safety or efficacy of the product. The FDA may require testing and surveillance programs to monitor the effect of products which have been commercialized, and has the power to prevent or limit further marketing of these products based on the results of these post-marketing programs.

The approval procedures for the marketing of our products in foreign countries vary from country to country, and the time required for approval may be longer or shorter than that required for FDA approval. Even after foreign approvals are obtained, further delays may be encountered before products may be marketed. For example, many countries require additional governmental approval for price reimbursement under national health insurance systems. Additional studies may be required to obtain foreign regulatory approval. Further, some foreign regulatory agencies may require additional studies involving patients located in their countries.

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Manufacturing facilities are subject to periodic inspections for compliance with the FDA s good manufacturing practices regulations and each domestic drug manufacturing facility must be registered with the FDA. Foreign regulatory authorities may have similar regulations. In complying with standards set forth in these regulations, we must expend significant time, money and effort in the area of quality assurance to ensure full technical compliance. Facilities handling controlled substances, such as ours, also must be licensed by the DEA, and are subject to more extensive regulatory requirements than those facilities not licensed to handle controlled substances. We also require approval of the DEA to obtain and possess controlled substances, including methylphenidate, amphetamine and fentanyl. We produce transdermal drug delivery products in accordance with United States and international regulations for clinical trials, manufacturing process validation studies and commercial sale. FDA approval to manufacture a drug product is site specific. In the event our approved manufacturing facility becomes inoperable, obtaining the required FDA approval to manufacture such drug at a different manufacturing site could result in production delays, which could adversely affect our business and results of operations.

Failure to comply with governmental regulations may result in fines, warning letters, unanticipated compliance expenditures, interruptions or suspension of production and resulting loss of sales, product seizures or recalls, injunctions prohibiting further sales, withdrawal of previously approved marketing applications and criminal prosecution. In 2003, our product stability testing program revealed that certain lots of CombiPatch® and Vivelle-Dot® did not maintain required specifications throughout the products shelf lives, resulting in product recalls. Our 2003 revenues are net of approximately $1.4 million and $6.5 million in allowances for returns at Noven and Novogyne, respectively, related to the recalls. In addition, our marketing, selling and administrative expenses in 2003 include $850,000 in estimated costs associated with these recalls. See Management s Discussion and Analysis Recent Developments Production Issues.

The federal and state governments in the United States, as well as many foreign governments, from time to time explore ways to reduce medical care costs through health care reform. Due to uncertainties regarding the ultimate features of reform initiatives and their enactment and implementation, we cannot predict what impact any reform proposal ultimately adopted may have on the pharmaceutical industry or on our business or operating results.

Our activities are subject to various federal, state and local laws and regulations regarding occupational safety, laboratory practices, environmental protection and hazardous substance control, and may be subject to other present and possible future local, state, federal and foreign regulations. Under certain of these laws, we could be liable for substantial costs and penalties in the event that waste is disposed of improperly. While it is impossible to accurately predict the future costs associated with environmental compliance and potential remediation activities, compliance with environmental laws is not expected to require significant capital expenditures and has not had, and is not presently expected to have, a material adverse effect on our earnings or competitive position.

Employees

We employ approximately 305 people; approximately 189 are engaged in manufacturing, process development, quality assurance and quality control, 20 in research and development, 12 in clinical research and regulatory affairs, and 84 in marketing and administration. No employee is represented by a union and we have never experienced a labor-related work stoppage. We believe our employee relations are good. In addition to the employees employed directly by us, Novogyne has a contract sales force of approximately 120 individuals that we manage under the terms of the Novogyne joint venture agreements.

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Seasonality

There are no significant seasonal aspects to our existing HT business. We may face increased seasonality if our ADHD product, MethyPatch®, is approved by the FDA and successfully commercialized since ADHD products are generally prescribed and dispensed more frequently during the school year than in the summer months.

Available Information

Our Internet website address is www.noven.com. Our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports are available free of charge through its website, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. We also make available on our website the beneficial ownership reports (Form 3, Form 4 and Form 5) filed by Noven officers, directors and other reporting persons under Section 16 of the Securities Exchange Act of 1934. Our Internet website and the information contained therein or connected thereto are not incorporated into this Annual Report on Form 10-K.

Risk Factors

For a discussion of certain risk factors that could have a material adverse affect on our business, financial position and results of operations, see Management s Discussion and Analysis Cautionary Factors that May Impact Future Results.

Item 2. Properties.

Our headquarters and manufacturing facility is located on a 10 acre site in Miami, Florida. On this site, we own an approximately 20,000 square foot building, which is used for laboratory, office and administrative purposes. We also lease from Aventis, for $1.00 per year, two approximately 40,000 square foot buildings on this site, which we use for manufacturing, engineering, administrative and warehousing purposes. The facility has been certified by the DEA to manufacture products containing controlled substances. The lease expires upon the earlier of 2024 or the termination of our license agreement with Aventis. We have an option to purchase the leased facilities at any time during the term of the lease. Aventis may terminate the lease prior to the expiration of its term upon termination or expiration of our 1992 license agreement with Aventis. We expect that we will have sufficient cash to purchase the facility in this event. Nonetheless, if we are unable to purchase the facility, termination of the lease by Aventis could have a material adverse effect on our business and results of operations.

We also lease approximately 8,500 square feet of office space in a neighboring facility for certain administrative functions and an additional 5,600 square feet of industrial space used for warehousing. In addition, we own five acres of vacant land on a contiguous site that could accommodate new buildings for a variety of manufacturing, warehousing and developmental purposes. We believe that our facilities are in satisfactory condition, are suitable for their intended use and, in the aggregate, have capacities in excess of those necessary to meet our present needs.

Our sole manufacturing facility, our research and development activities, as well as our corporate headquarters and other critical business functions, are located in an area subject to hurricane casualty risk. Although we have certain limited protection afforded by insurance, our business, earnings and competitive position could be materially adversely affected in the event of a major windstorm or other casualty.

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Item 3. Legal Proceedings.

Miller Donovan v. Noven Pharmaceuticals, Inc., Robert C. Strauss, James B. Messiry, and Juan A. Mantelle, United States District Court, Southern District of Florida; August 7, 2003.

Plaintiff filed the above referenced action on behalf of a purported class of purchasers of Noven s common stock during the period from October 29, 2001 through April 28, 2003. The complaint alleges that, during the subject period, Noven and its officers named as defendants violated the Securities Exchange Act of 1934 by making false and misleading statements in its public disclosures regarding MethyPatch®. Following the filing of Plaintiff s complaint, five other substantially similar complaints were filed against Noven and its officers named as defendants in the above referenced action. In response to a joint motion, on or about January 6, 2004, the Court entered an order consolidating the six related actions. Pursuant to this order, plaintiffs must file a consolidated class action complaint not later than 60 days after the entry of an order appointing lead plaintiff and lead counsel. An order appointing lead plaintiff and lead counsel has not yet been entered. This development 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.

We are a party to other pending legal proceedings arising in the normal course of business, none of which we believe is material to our financial position or results of operations.

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

We did not submit any matters to a vote of stockholders during the quarter ended December 31, 2003.

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Executive Officers of the Registrant

Set forth below is a list of the names, ages, positions held and business experience of the persons serving as our executive officers as of March 1, 2004. Officers serve at the discretion of the Board of Directors. There is no family relationship between any of the executive officers or between any of the executive officers and any of our directors, and there is no arrangement or understanding between any executive officer and any other person pursuant to which the executive officer was selected.

Eduardo G. Abrao, M.D. Dr. Abrao, age 61, has been Vice President Clinical Development & Chief Medical Officer of Noven since September 2003. Prior to joining Noven, Dr. Abrao served as the Vice President, Regulatory Affairs and Drug Safety of Berlex Laboratories, Inc. from March 2002 to October 2002. From 1996 to 2002, Dr. Abrao served Otsuka America Pharmaceutical, Inc. in a variety of regulatory and operational positions, most recently as its President and Chief Operating Officer. From 1989 to 1996, Dr. Abrao was Vice President, International Medical Department with Marion Merrell Dow.

Diane M. Barrett. Ms. Barrett, age 43, has been with Noven since August 2000 and, since May 2003, has served as Vice President & Chief Financial Officer. From 1997 to 2000, Ms. Barrett served as Vice President and Chief Financial Officer of BioNumerik Pharmaceuticals, Inc. and, from 1990 to 1997, served Cordis Corporation in a variety of finance positions, most recently as Treasurer. Prior to joining Cordis, Ms. Barrett was a manager with Arthur Andersen & Co.

Jeffrey F. Eisenberg. Mr. Eisenberg, age 38, has been with Noven since November 1998 and, since November 2000, has served as Vice President Strategic Alliances, General Counsel & Corporate Secretary. From 1995 through 1998, Mr. Eisenberg served as Associate General Counsel and then as Acting General Counsel of IVAX Corporation. Prior to joining IVAX, he was a lawyer in the corporate securities department of the law firm of Steel Hector & Davis.

W. Neil Jones. Mr. Jones, age 51, has been with Noven since February 1997 and, since November 2000, has served as Vice President Marketing & Sales. From 1981 through 1997, he served Ciba-Geigy Corporation in a variety of sales and marketing positions, most recently as Executive Director of Marketing.

Juan A. Mantelle. Mr. Mantelle, age 45, has been with Noven since March 1990 and, since June 2000, has served as Vice President & Chief Technical Officer. From December 1986 to March 1990, he served Paco Research Corp. as Manager Product Development. From April 1983 to December 1986, he served Key Pharmaceuticals, Inc. as Senior Research Engineer.

Robert C. Strauss. Mr. Strauss, age 62, has been President, Chief Executive Officer & Chairman of the Board of Noven since June 2001. From December 1997 to September 2000, he served as President & Chief Executive Officer and as a Director of Noven, and from September 2000 to June 2001, he served as Co-Chairman of Noven. From March 1997 to July 1997, he served as President and Chief Operating Officer and a Director of IVAX Corporation. From 1983 to 1997, he served in various executive positions with Cordis Corporation, most recently as its Chairman of the Board, President and Chief Executive Officer. Mr. Strauss serves on the Board of Directors of CardioGenesis Corporation (medical devices), Columbia Laboratories, Inc. (pharmaceuticals), Percardia Inc. (medical devices) and TissueLink Medical, Inc. (surgical devices and procedures).

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PART II

Item 5. Market for Registrant s Common Equity and Related Stockholder Matters.

Our Common Stock is listed on the Nasdaq Stock Market and is traded under the symbol NOVN. As of March 1, 2004, we had 316 stockholders of record of our Common Stock. We have never paid a cash dividend on our Common Stock and do not anticipate paying cash dividends in the foreseeable future. The following table sets forth, for the periods indicated, the high and low sale prices for the Common Stock as reported on the Nasdaq Stock Market.

	High Price	Low Price
First Quarter, 2003	$14.69	$ 7.30
Second Quarter, 2003	14.98	8.10
Third Quarter, 2003	12.64	9.96
Fourth Quarter, 2003	15.80	9.69
First Quarter, 2002	$23.22	$16.01
Second Quarter, 2002	27.51	18.57
Third Quarter, 2002	25.37	8.91
Fourth Quarter, 2002	14.50	8.95

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Item 6. Selected Financial Data.

The selected financial data presented below is derived from our audited financial statements. The data set forth below should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and the Financial Statements and related notes appearing elsewhere in this Form 10-K. All amounts in thousands, except per share amounts.

	Years Ended December 31,				
Statement of Operations Data:	**2003**	**2002**	**2001**	**2000**	**1999**
Net revenues	$ 43,166	$ 55,372	$ 45,947	$ 42,924	$31,650
Expenses:					
Cost of products sold	19,482	22,973	20,376	19,219	12,721
Research and development	8,082	11,634	10,973	13,621	7,171
Marketing, general and administrative	15,858	14,257	11,554	8,737	7,860
Total expenses	43,422	48,864	42,903	41,577	27,752
(Loss) income from operations	(256)	6,508	3,044	1,347	3,898
Equity in earnings of Novogyne	17,094	14,368	14,013	9,294	1,487
Interest income, net	659	822	1,770	1,385	343
Income before income taxes	17,497	21,698	18,827	12,026	5,728
Income tax expense (benefit)	6,301	7,819	6,736	(7,608)	(4,732)
Net income	$ 11,196	$ 13,879	$ 12,091	$ 19,634	$10,460
Basic earnings per share	$ 0.50	$ 0.62	$ 0.54	$ 0.90	$ 0.49

Diluted earnings per share	$ 0.49	$ 0.60	$ 0.51	$ 0.84	$ 0.48
Balance Sheet Data:					
Cash and cash equivalents	$ 83,381	$ 58,684	$ 49,389	$ 40,976	$15,338
Total assets	169,484	137,702	136,228	104,031	56,888
Long-term notes payable		5	13	265	604
Deferred license revenue	50,005	29,445	32,758	27,109	8,028
Stockholders equity	108,823	96,741	81,898	65,277	39,393

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Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations.

The following section addresses material aspects of Noven s financial condition and results of operations. The contents of this section include:

An overview of Noven and:

our relationship with Novartis and our joint venture, Novogyne,

the production issues that we experienced in 2003, and

MethyPatch®, our methylphenidate patch for the treatment of ADHD;

An analysis of our results of operations and our liquidity and capital resources;

A discussion of recently issued accounting standards and the application of our critical accounting policies;

An outlook that includes our current financial guidance and certain factors that we believe may influence our financial results in 2004; and

A discussion of forward-looking statements used in this report and a review of cautionary factors that could have a material adverse affect on our business, financial condition and results of operations.

This discussion should be read in conjunction with Noven and Novogyne s 2003 financial statements and the related notes included in this Form 10-K.

Overview

We develop and manufacture advanced transdermal patches and presently derive substantially all of our revenues from sales of transdermal patches for use in menopausal hormone therapy. In the United States, our HT products are marketed and sold by Novogyne, the joint venture that we formed with Novartis in 1998. In all countries other than the United States, Canada and Japan, our HT products are marketed and sold by Novartis Pharma, an affiliate of Novartis. A detailed discussion of the Novogyne joint venture and our several licensing arrangements with Novartis and Novartis Pharma is included in this Overview section under Novartis and Novogyne.

The market for HT products, including our transdermal HT products, has contracted since the July 2002 publication of the WHI study results. Comparing the second quarter of 2002 (the quarter immediately preceeding the WHI study) to the fourth quarter of 2003, total prescriptions dispensed in the HT market in the United States declined by 42%. For the same period, aggregate prescriptions for Noven s United States products decreased 11%. The estrogen segment of the HT market in the United States declined 36%, while our Vivelle® family decreased 5%. Vivelle-Dot®, which represented 74% of our total United States prescriptions in the fourth quarter of 2003, increased 10% from the second quarter of 2002 to the fourth quarter of 2003. We believe Vivelle-Dot® prescriptions have benefited from patient conversions from original Vivelle®. At the end of 2003, the Vivelle® family held a 41% share of total estrogen patch prescriptions, compared to a 35% share at the end of the second quarter of 2002. In 2003, our Vivelle-Dot® estrogen patch became the most frequently dispensed estrogen patch in its market segment. We believe this is due in part to the beneficial wear characteristics made possible by our technology.

U.S. prescriptions for CombiPatch® (which represented approximately 16% of our total U.S. prescriptions in the fourth quarter of 2003) declined 36% from the second quarter of 2002 to the fourth quarter of 2003, while prescriptions for the total United States market for fixed combination hormone therapy declined 64%. WHI involved an oral combination estrogen/progestin product and, accordingly, that segment of the HT market has experienced the most significant decline. As noted above, prescriptions for our CombiPatch® combination estrogen/progestin patch, like most combination HT therapies, have declined significantly since WHI. Further declines for CombiPatch® could require Novogyne (which holds the CombiPatch® marketing rights) to record an impairment loss related to the CombiPatch® marketing rights, which would harm both our and Novogyne s results of operations. See Critical Accounting Policies Investment in Novogyne.

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Notwithstanding the decreased size of the HT market post-WHI studies, we remain committed to the HT business and it remains profitable for us. In 2003, we generated profits for the fifth consecutive year. We recognized net income of $11.2 million in 2003 compared to $13.9 million in 2002 and $12.1 million in 2001. Our revenues declined 22% in 2003 compared to 2002 due primarily to the lower prescription trends following the WHI study. Our revenues in 2003 were also adversely affected by an increased allowance for returns of $1.4 million related to the product recalls that we experienced in 2003. See Production Issues below for additional information on the product recalls.

An important part of our business strategy is to seek to diversify our product offerings beyond the HT market through strategic collaborations and new product developments. Since the beginning of 2003, we have entered into the following new collaborations:

Shire licensed our MethyPatch® product for ADHD;

P&GP engaged us to develop new prescription patches in the area of Hypoactive Sexual Desire Disorder; and

Endo licensed our developmental fentanyl patch.

Novartis and Novogyne

Our business, financial position and results of operations currently depend on the joint venture, Novogyne, that we formed with Novartis to market and sell women s prescription healthcare products in the United States. Novogyne markets our three principal HT products Vivelle®, Vivelle-Dot® and CombiPatch® in the United States. In all countries other than the United States, Canada and Japan, we have licensed the marketing rights to these products to Novartis Pharma, which is an affiliate of Novartis. In most of these markets, Vivelle® is marketed under the brand name Menorest®, Vivelle-Dot® is marketed under the brand name Estradot® and CombiPatch® is marketed under the brand name Estalis®.

We hold a 49% equity interest in Novogyne, and Novartis holds a 51% equity interest. Under the terms of the joint venture agreements, we manufacture and supply Vivelle®, Vivelle-Dot® and CombiPatch® to Novogyne, perform marketing, sales and promotional activities, and receive royalties from Novogyne based on Novogyne s sales of the ET products. Novartis distributes Vivelle®, Vivelle-Dot® and CombiPatch® and provides certain other services to Novogyne.

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Novartis is entitled to an annual $6.1 million preferred return, which has the effect of reducing our share of Novogyne s income in the first quarter of each year. After the annual preferred return to Novartis, our share of Novogyne s income increases as product sales increase, subject to a maximum of 49%. Our share of Novogyne s income was $17.1 million, $14.4 million and $14.0 million in 2003, 2002 and 2001, respectively. The income we recognize from Novogyne is a non-cash item. Any cash we receive from Novogyne is in the form of cash distributions declared by Novogyne s Management Committee. Accordingly, the amount of cash that we receive from Novogyne in any period may not be the same as the amount of income we recognize from Novogyne for that period. In 2003, 2002 and 2001, we received $21.7 million, $11.7 million and $13.1 million in distributions from Novogyne, which accounted for a substantial portion of our net cash flows provided by operating activities for these periods. We re-invested the distributions that we received in 2001 from Novogyne, plus an additional $2.6 million, in Novogyne to fund our portion of the payments associated with the CombiPatch® license transaction. We expect that a significant portion of our earnings and cash flow for the next several years will be generated through our interest in Novogyne, but we cannot assure that Novogyne will continue to be profitable or make cash distributions. Any failure by Novogyne to remain profitable or to continue to make distributions could have a material adverse effect on our results of operations and financial condition.

Novogyne acquired the exclusive United States marketing rights to CombiPatch® in March 2001 in a series of transactions involving Novogyne, Noven, Novartis and Aventis. In the transaction, Novogyne paid Aventis $25.0 million at closing, plus an additional $40.0 million, which was due in four quarterly installments of $10.0 million, with the final payment made in March 2002. As a consequence of the transaction and under the terms of our existing license agreement with Aventis, we received $3.5 million from Aventis, which amount was deferred and recognized as license revenues over ten years beginning in the first quarter of 2001. Since the publication of the HT studies, prescriptions for CombiPatch® have declined substantially. Novogyne recorded the acquisition of CombiPatch® marketing rights at cost and, at December 31, 2003, this asset had a net book value of $44.8 million. Novogyne tests this asset for impairment on a periodic basis. Any further adverse change in the market for HT products could have a material adverse impact on the ability of Novogyne to recover its investment in its CombiPatch® marketing rights, which could require Novogyne to record an impairment loss. Impairment of that asset would adversely affect Novogyne s, and consequently our, operating results and could, depending on the size of the impairment, result in a loss at both the Novogyne and Noven level for the period in which the impairment occurred.

Under the Novogyne joint venture, Novartis is responsible for providing Novogyne with financial, accounting, legal and regulatory services, including monitoring inventory levels. In late 2002, inventory levels at Novogyne exceeded then current and expected demand, which negatively affected our sales and results of operations in the first half of 2003 as Novogyne curtailed product shipments to its trade customers, and we reduced shipments to Novogyne based on demand.

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In November 2000, we entered into an exclusive license agreement with Novartis Pharma pursuant to which we granted Novartis Pharma the right to market Vivelle-Dot® under the name Estradot® in all countries other than the United States, Canada and Japan. We received a $20 million license payment upon execution of the agreement. For accounting purposes, the payment was deferred and is being recognized as license revenues over 10 years beginning in the fourth quarter of 2000. We subsequently received a $5.0 million milestone payment in the fourth quarter of 2001 that is being recognized as license revenues beginning in the first quarter of 2002 through the fourth quarter of 2010, which is the end of the estimated product life cycle. Under the terms of the agreement, Novartis Pharma is responsible for seeking approval to market Estradot® in its territories. The product has been approved for marketing in over 45 foreign countries and the regulatory authorities of other countries are reviewing Novartis registration applications. Novartis Pharma has launched the product in Germany, Spain (without government reimbursement) and a number of smaller countries. However, Novartis Pharma has informed us that pricing, government reimbursement and product labeling issues are adversely impacting its launch plans in many countries, including the United Kingdom, France and Italy. Accordingly, we cannot assure that Novartis Pharma will be successful in effecting additional registrations of Estradot® or that Novartis Pharma will launch Estradot® in any particular country. The profitability of Estradot® and our other products sold in the European Union may also be negatively affected by parallel trade practices whereby a licensed importer may take advantage of price disparity between markets by purchasing our products in a market with a relatively lower price and then importing them into a country with a relatively higher price. Novartis Pharma markets several other transdermal HT products in addition to our products, which may limit the efforts Novartis Pharma devotes to our products. In some countries, including the United Kingdom and France, Novartis Pharma is seeking a marketing partner to launch the product but to date has been unsuccessful. We cannot assure that Novartis Pharma will be successful in securing a marketing partner or in launching Estradot® in those countries. It can be expected that sales by Novartis Pharma of Menorest®, our first generation transdermal estrogen system, will be negatively affected if and as Novartis Pharma increases sales of Estradot®, our second generation transdermal estrogen system.

Novartis Pharma also holds the rights to market Estalis®, our combination estrogen/progestin patch product, outside of the United States and Japan. Estalis® is presently approved in only one dosage strength in most European countries. Novartis Pharma has filed an application for approval of a second dosage strength in Sweden. Novartis Pharma, however, believes that, in light of the market changes since the publication of the HT studies, the product will not be successful in Europe without a dosage strength lower than the second dosage strength. As a consequence, Novartis Pharma has advised us that, in lieu of launching the second dosage strength of Estalis®, they intend to seek marketing approval and commercialization of a next generation combination estrogen/progestin patch product with a lower dosage strength. No assurance can be given that approval will be obtained, and the timing of any launch of a next generation combination estrogen/progestin patch product cannot be predicted. We expect that growth in this market will be limited unless a next generation combination estrogen/progestin patch product is approved and launched, and we cannot assure that the product will be successful even if a lower dosage strength combination product is approved and launched.

For the reasons discussed above, we do not expect European sales of Estradot® or Estalis® to contribute growth in 2004.

Production Issues in 2003

In 2003, our product stability testing program revealed that certain lots of CombiPatch® and Vivelle-Dot® did not maintain required specifications throughout the products shelf lives, resulting in product recalls. Revenues for 2003 are net of approximately $1.4 million and $6.5 million in allowances for returns at Noven and Novogyne, respectively, related to the recalls. In addition, our marketing, selling and administrative expenses in 2003 include $850,000 in estimated costs associated with these recalls.

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The CombiPatch® issue resulted from a previously disclosed production issue related to a problematic raw material supplied by one vendor. This issue caused us to temporarily suspend shipments of CombiPatch® to Novogyne in the 2003 first quarter, and caused Novartis to recall one lot of CombiPatch® in July 2003. Since identifying the issue, we have been monitoring all lots of CombiPatch® product manufactured with the problematic material. Even though interim testing indicated that these additional lots were expected to maintain specifications throughout their shelf lives, we experienced an unexpected stability failure in one additional lot. In light of this event, Novartis initiated a recall of all lots of CombiPatch® product remaining in distribution that were potentially affected by this problematic raw material. After addressing the issues with the particular raw material, we continue to manufacture and ship CombiPatch® to Novogyne and there was no interruption of trade supplies.

We are working to identify the root cause of the Vivelle-Dot® issue, and in the interim have initiated more rigorous testing of Vivelle-Dot® and Estradot® product. In October 2003, a quantity of Vivelle-Dot® tested out of specification. In November 2003, an additional quantity tested out of specification. Novartis has announced a recall of the Vivelle-Dot® product that tested out of specification in October and November 2003. We have identified additional product that demonstrates adverse stability trends but remains within required specifications. Based on results of our testing and analysis to date, we do not believe that any additional Vivelle-Dot® product that is currently in distribution or in our inventory is unlikely to maintain required stability. We have established allowances for estimated sales returns for product that has been recalled as a result of testing out of specification. Novogyne has increased its allowance for sales returns in light of the same issue. If a root cause determination or additional testing indicates that the production issue affects more product than our current testing and analysis suggests, additional recalls may be required, our allowances may prove insufficient and/or we may be forced to suspend shipping. If we are unable to ship Vivelle-Dot® and/or Estradot®, Novogyne and/or Novartis would be unable to supply its customers, which would result in lost sales and potentially lost market share, and our results of operations and prospects would be materially adversely affected.

MethyPatch®

We have developed a once-daily transdermal methylphenidate delivery system for the treatment of ADHD, which is intended to be marketed under the trade name MethyPatch®. We filed an NDA with the FDA in June 2002.

In the first quarter of 2003, we signed an agreement to license the exclusive global rights to market MethyPatch® to Shire for payments of up to $150 million and ongoing manufacturing revenues. Consideration for the transaction is as follows: (i) $25 million was paid upon closing of the transaction in April 2003; (ii) $50 million is payable upon receipt of final marketing approval for MethyPatch® by the FDA; and (iii) three installments of $25 million each are payable upon Shire s achievement of $25 million, $50 million and $75 million in annual net sales of MethyPatch®, respectively. Shire s annual net sales will be measured quarterly on a trailing 12-month basis, with each milestone payment due 45 days after the end of the first quarter during which trailing 12-month sales exceed the applicable threshold. Shire has agreed that it will not sell any other product containing methylphenidate as an active ingredient until the earlier of (i) five years from the closing date or (ii) payment of all of the sales milestones. On the closing date, we entered into a long-term supply agreement under which we expect to manufacture and supply MethyPatch® to Shire. The agreement gives Shire the right to qualify a second manufacturing source and purchase a portion of its requirements from the second source. If Shire were to exercise this right, Noven s revenues from sales of MethyPatch® would be adversely affected. Pursuant to the agreement, under certain circumstances Shire has the right to require us to repurchase the product rights for $5 million.

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In April 2003, we received a not approvable letter from the FDA relating to our MethyPatch® NDA. A not approvable letter is issued if the FDA does not consider the application approvable because one or more deficiencies in the application preclude the FDA from approving it. The letter cited clinical and other issues as the basis for non-approval. In October 2003, we submitted with Shire a jointly prepared, proposed study protocol for an additional clinical study for MethyPatch® to the FDA for review and comment. The purpose of this additional proposed study was to address clinical issues and risks raised in the FDA s not approvable letter. In November 2003, the FDA responded to our proposed study protocol and reported that the proposed study design did not address the clinical risk-benefit issues raised in the April 2003 not approvable letter. In its November 2003 response, the FDA provided specific recommendations regarding the proposed study design. Noven and Shire are working together to review and respond to the FDA s comments and recommendations with respect to the study design. We believe this study is necessary to amend the NDA and that other studies may also be required or advisable. Under a November 2003 agreement with Shire, if we agree with Shire on a study design, Shire will manage the new clinical study and we will fund it. Under our agreement with Shire, we are responsible for providing the clinical supplies for the study and we may also incur certain additional expenses in pursuit of regulatory approval, including all or a portion of the cost of any other studies we decide to conduct. At the conclusion of the trial, if Shire determines that submission of the study results to the FDA would not result in a commercially-viable product, Shire will have the right to terminate the original transaction agreement. If Shire exercises its termination right under these circumstances, however, Shire will forfeit its right to require us to repurchase the product rights, and the product rights will revert to us without payment to Shire. If Shire elects to proceed after reviewing the study results, we expect to cooperate with Shire in submitting the new study results to the FDA and continuing to seek regulatory approval of MethyPatch®. We cannot assure that any revised study design will be acceptable to the FDA or, even if accepted by the FDA, produce study results that will result in a commercially-viable product. If the parties are unable to reach agreement with each other or the FDA on a study design, the parties may not continue to pursue regulatory approval of MethyPatch®.

Of the $25 million received from Shire at closing, $5 million has been deferred and is expected to be recognized as license revenues over time beginning when Shire s right to require us to repurchase MethyPatch® rights expires. A portion of the remaining $20 million was recognized as revenues in the 2003 second quarter using a 10-year amortization period, which is the estimated product life cycle. Beginning in the 2003 third quarter, we ceased amortization of the balance of the $20 million due to the planned initiation of an additional clinical trial and the significant costs expected to be incurred in pursuing MethyPatch® approval.

We are committed to continuing to seek regulatory approval for MethyPatch® for as long as it remains a commercially practicable strategy. We have determined that we cannot yet estimate the total cost of seeking MethyPatch® approval, but we do not expect the total cost to exceed the deferred revenue balance of $19.1 million as of December 31, 2003. We expect to defer direct expenses incurred in pursuit of MethyPatch® regulatory approval (including the cost of any clinical studies) against the deferred revenue balance. License revenues deferred under this arrangement will be recorded net of direct expenses incurred in pursuing regulatory approval. Once we can estimate our expected total cost in obtaining regulatory approval, we expect to recognize any unused portion of the deferred revenue balance over the remainder of the initial 10-year period. The accounting treatment of amounts received from Shire would be expected to change if Shire were to exercise its right to require us to repurchase the product rights or if MethyPatch® development were abandoned. In either of these scenarios, Noven would expect to recognize the remaining deferred license revenue immediately into income in the period of exercise or abandonment, net of the $5 million repurchase price.

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Results of Operations

Revenues:

Total revenues are summarized as follows (dollar amounts in thousands):

	2003	% Change	2002	% Change	2001
Product revenues Novogyne:					
Product sales	$15,932	(37%)	$25,394	52%	$16,689
Royalties	4,978	10%	4,505	12%	4,037
	20,910	(30%)	29,899	44%	20,726
Product revenues third parties:					
Product sales	16,078	(20%)	20,126	(5%)	21,182
Royalties	128	(26%)	174	35%	139
	16,206	(20%)	20,300	(5%)	21,321
Total product revenues	37,116	(26%)	50,199	19%	42,047
License and contract revenues:					
Contract	2,024	13%	1,787	70%	1,049
License	4,026	19%	3,386	19%	2,851
	6,050	17%	5,173	33%	3,900
Net revenues	$43,166	(22%)	$55,372	21%	$45,947

Net Revenues

As described in more detail below, the decline in 2003 revenues as compared to 2002 was primarily attributable to lower unit sales for both our U.S. and international products, as well as approximately $1.4 million in allowances for returns related to product recalls.

As described in more detail below, the increase in 2002 revenues as compared to 2001 was primarily attributable to an increase in unit sales to Novogyne for all products, increased unit sales of Estradot® to Novartis Pharma, and increased contract revenues. These increases were partially offset by lower unit sales of CombiPatch® to Aventis,

lower unit sales of Estalis® to Novartis Pharma and lower minimum fee payments related to sales of Menorest®.

Product revenues Novogyne

Product revenues Novogyne consists of our sales of Vivelle®, Vivelle-Dot®/Estradot® and CombiPatch® to Novogyne at a fixed price for resale primarily in the United States as well as the royalties we receive as a result of Novogyne s sales of Vivelle® and Vivelle-Dot®. For additional information on the components of product revenues Novogyne as well as our other sources of revenues, see Critical Accounting Policies Revenue Recognition.

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The decline in revenues from Novogyne for 2003 as compared to 2002 relates to volume declines of product sold to Novogyne, which reflect lower prescription trends following the publication of the WHI and other HT studies and the impact of inventory reduction initiatives intended to align inventories with post-WHI demand. An allowance for returns related to product recalls established in the third and fourth quarters also contributed to the decline. Price was not a factor contributing to this decline.

The increase in revenues from Novogyne for 2002 as compared to 2001 relates to volume increases of product sold to Novogyne in the first part of the year, which reflect pre-WHI prescription trends. Furthermore, Vivelle-Dot®/Estradot® Canada, which we sell to Novogyne, was fully launched in the first quarter of 2002. Price was not a significant factor contributing to this increase.

Product revenues third parties

Product revenues third parties substantially consists of sales of Menorest®, Estradot® and Estalis® to Novartis Pharma at a price based on a percentage of the licensee s net selling price (subject to certain minima) for resale primarily outside the United States and Japan, together with royalties generated from Novartis Pharma s sales of Vivelle® and Estradot® in Canada. In 2001, it also included sales of CombiPatch® to Aventis at a fixed price. As discussed above, CombiPatch® was licensed to Novogyne in March of 2001.

Revenues from third parties declined $4.1 million for 2003 as compared to 2002, of which $2.7 million related to volume declines of all products and $1.4 million related to price declines, primarily of Estalis®. Novartis Pharma has indicated that it has reduced orders for Menorest® in certain countries in anticipation of planned transitions to Estradot®. Also contributing to the decline in volume sales of all products are reduced orders as a result of declines in the HT market in Europe following the publication of WHI and the other HT studies.

Revenues from third parties declined $1.0 million for 2002 as compared to 2001, of which $700,000 related to volume declines of all products taken in the aggregate; only Estradot® experienced a volume increase. The remaining $300,000 related to price declines. The decline in volume sales of Estalis® relates primarily to several major country launches in 2001, which in the aggregate generated insufficient sales to support re-orders at comparable levels in 2002. In addition, there were fewer new country launches in 2002. The decline in volume sales of CombiPatch® sold to Aventis is related to the license of the product to Novogyne in March of 2001. The increase in sales of Estradot® relates to the commencement of sales to Novartis Pharma in the first quarter of 2002.

License and contract revenues

The increase in contract revenues for 2003 as compared to 2002 is primarily attributable to the attainment of certain product development milestones and the completion of certain product development contracts in 2003. The increase in license revenues for 2003 as compared to 2002 is due to the recognition of license revenues in connection with the Shire transaction. Beginning in the third quarter of 2003, we ceased amortization of the deferred balance of license revenues received in the Shire transaction due to the planned initiation of an additional clinical trial and the significant costs expected to be incurred in seeking MethyPatch® approval. In the fourth quarter, we began to defer direct expenses incurred in seeking MethyPatch® regulatory approval (including the cost of any clinical studies) against the deferred revenue balance, which amounted to $414,000 for the quarter and year ended December 31, 2003.

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The increase in contract revenues for 2002 as compared to 2001 is primarily attributable to the attainment of certain product development milestones and the completion of certain product development contracts in 2002. The increase in license revenues for 2002 as compared to 2001 is primarily attributable to an Estradot® product approval milestone earned in the first quarter of 2002.

Gross Margin:

Gross margin is summarized as follows (dollar amounts in thousands):

	2003	% Change	2002	% Change	2001
Total product revenues	$37,116	(26%)	$50,199	19%	$42,047
Gross profit (product revenues less cost of products sold)	17,634	(35%)	27,226	26%	21,671
Gross margin (gross profit as a percentage of product revenues)	48%		54%		52%

The declines in gross margin in 2003 as compared to 2002 were primarily due to lower overhead absorption due to lower production volumes, allowances for returns established in 2003 related to product recalls, which decreased product revenues without affecting cost of goods sold, and unfavorable product mix (as product revenues declined more in the United States where sales have a higher gross margin).

The increase in gross margin in 2002 as compared to 2001 resulted from a favorable product mix (we sold more product in the United States where sales have a higher gross margin) and to increases in production volume resulting in more favorable overhead absorption, partially offset by a lower minimum fee payment in 2002.

Operating Expenses:

Operating expenses are summarized as follows (dollar amounts in thousands):

	2003	% Change	2002	% Change	2001
Research and development	$ 8,082	(31%)	$11,634	6%	$10,973
Marketing, general and administrative	15,858	11%	14,257	23%	11,554

Research and Development

The $3.6 million decline for 2003 as compared to 2002 was primarily attributable to $2.9 million lower expenses for MethyPatch® due to the completion of a Phase III clinical trial in the prior year, $300,000 lower expenses for our fentanyl transdermal system due to the completion of significant bioequivalence studies in the prior year and $200,000 lower FDA fees due to the filing of the NDA for MethyPatch® in the prior year.

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The $700,000 increase for 2002 as compared to 2001 was primarily attributable to $2.2 million increases in purchases of materials and other expenses primarily associated with our fentanyl transdermal delivery system and $300,000 increased FDA fees due to the filing of the NDA for MethyPatch® in 2002, partially offset by a $1.8 million decrease in clinical study expenses for MethyPatch® due to most of the Phase III clinical studies occurring in 2001.

Marketing, General and Administrative Expenses

The $1.6 million increase in 2003 as compared to 2002 was primarily attributable to $900,000 in costs associated with product recalls, $700,000 increase in insurance costs, $400,000 increase in legal fees, primarily related to the Shire transaction, $400,000 increase in consulting and professional fees, and $300,000 increase in accounting and audit fees primarily related to new requirements resulting from Sarbanes-Oxley. This increase was partially offset by the elimination of $1.3 million in pre-launch marketing expenses for MethyPatch®, which ceased as a result of the Shire transaction.

The $2.7 million increase in 2002 as compared to 2001 was primarily attributable to a $1.7 million increase in MethyPatch® pre-launch marketing expenses, $1.2 million compensation costs primarily related to higher bonus payments under our formula incentive plan, $300,000 increase in insurance expense and $200,000 increase in relocation and recruitment expenses. These expenses were partially offset by $700,000 of lower outside consulting services related to the implementation of our enterprise resource planning system and $300,000 in depreciation and reserves for obsolete production equipment in 2001.

Other Income and Expenses:

Income Taxes

Our effective tax rate was 36.0% for 2003 and 2002, and 35.8% for 2001. The provision for income taxes is based on the Federal statutory and state income tax rates. 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 December 31, 2003, we had a net deferred tax asset of $18.7 million. Realization of this deferred tax asset depends upon the generation of sufficient future taxable income. Although realization is not assured, we believe 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

We share 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 each of 2003, 2002 and 2001 for us to recognize earnings from Novogyne under the formula. We report our share of Novogyne s earnings as Equity in earnings of Novogyne on our Statements of Operations.

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The financial results of Novogyne are summarized as follows (dollar amounts in thousands):

	2003	% Change	2002	% Change	2001
Gross revenues[1]	$120,278	(8%)	$130,359	25%	$104,146
Sales allowances	11,275	(17%)	13,602	55%	8,786
Sales returns allowances	7,926	(44%)	14,272	164%	5,402
Sales allowances and returns	19,201	(31%)	27,874	96%	14,188
Net revenues	101,077	(1%)	102,485	14%	89,958
Cost of sales	21,485	(18%)	26,136	25%	20,833
Gross profit	79,592	4%	76,349	10%	69,125
Gross margin percentage	79%		74%		77%
Selling, general and administrative expenses	30,673	(7%)	33,091	21%	27,347
Amortization of intangible asset	6,179	0%	6,179	33%	4,635
Income from operations	42,740	15%	37,079	(0%)	37,143
Interest income	182	(48%)	350	(52%)	734
Net income	$ 42,922	15%	$ 37,429	(1%)	$ 37,877
Noven s equity in earnings of Novogyne	$ 17,094	19%	$ 14,368	3%	$ 14,013

(1) Novogyne s gross revenues, which are calculated by adding sales allowances and sales returns allowances to net revenues, is discussed in this section because Noven s management believes it is a useful measure to evaluate and compare Novogyne s sales period to period in light of the significant historic fluctuations in Novogyne s sales allowances and returns.

Novogyne Net Revenues

Novogyne s gross revenues declined $10.1 million for 2003 as compared to 2002, comprising $21.8 million related to volume declines, primarily of Vivelle® and CombiPatch®, partially offset by volume increases in Vivelle-Dot®. The volume declines were partially offset by $11.7 million related to price increases, primarily for Vivelle-Dot®. The

decline in volume sales of Vivelle® for 2003 as compared to 2002 is partially attributable to Vivelle® being in a declining trend due to product maturity. The lower volume sales of CombiPatch® in 2003 were due to the continuing effect of the HT studies described above.

Sales allowances consist of chargebacks, Medicaid rebates, managed healthcare rebates, cash discounts and other allowances, which tend to fluctuate based on changes in gross revenues. These sales allowances were 9%, 10% and 8% of gross revenues for the year ended December 31, 2003, 2002 and 2001, respectively. The $6.3 million decline in sales returns allowances for expiring product for 2003 as compared to 2002 was primarily attributable to lower unit sales of Vivelle®, lower returns for the Vivelle® family, and lower overall trade inventory levels. These factors caused Novogyne to reduce its estimate of future returns and correspondingly reduce its reserve for sales returns allowances by $12.8 million for the year ended 2003. This decline was partially offset by a $6.5 million increase in allowances for sales returns established in the third and fourth quarters related to product recalls.

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Novogyne s gross revenues increased $26.2 million for 2002 as compared to 2001, of which $17.8 million related to volume increases, primarily of Vivelle-Dot®, and $8.4 million related to price increases for all products. The increase in volume sales of Vivelle-Dot® reflects increased prescription trends prior to WHI.

The $8.9 million increase in sales returns allowances for 2002 as compared to 2001 was primarily attributable to increased product sales for all products, higher returns for Vivelle®, and higher overall trade inventory levels. These factors caused Novogyne to increase its estimate of future returns and correspondingly increase its reserve for sales returns allowances for the year ended 2002.

Novogyne Gross Margin

The increase in gross margin for 2003 as compared to 2002 was primarily due to lower sales allowances and returns, which increased net revenues without affecting cost of goods sold, and lower inventory obsolescence reserves.

The decline in gross margin for 2002 as compared to 2001 was primarily attributable to higher sales allowances and returns and an increase in inventory obsolescence reserves for 2002.

Novogyne Selling, General and Administrative

Novogyne s selling, general and administrative expenses declined for 2003 as compared to 2002, due to lower advertising and promotion expenses, primarily related to CombiPatch®, and expense reductions associated with the co-promotion of Novartis Famvir product.

Novogyne s selling, general and administrative expenses increased $5.7 million for 2002 as compared to 2001, primarily due to a $2.4 million increase in advertising and promotion expenses, $1.3 million increase of sample expenses and $1.7 million increase of sales force expenses, primarily due to the launch of CombiPatch® in March 2001 and increased focus on our Vivelle® family of products.

Liquidity and Capital Resources:

As of December 31, 2003 and 2002, we had $83.4 million and $58.7 million in cash and cash equivalents and working capital of $76.7 million and $59.3 million, respectively.

Cash provided by (used in) operating, investing and financing activities is summarized as follows (amounts in thousands):

	2003	2002	2001
Cash flows:			
Operating activities	$29,104	$11,787	$ 24,683
Investing activities	(4,722)	(3,011)	(19,020)
Financing activities	315	519	2,750

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Operating Activities:

Net cash provided by operating activities in 2003 primarily resulted from the receipt of a $25.0 million license payment upon the closing of the Shire transaction in April 2003 and $21.7 million in distributions from Novogyne. The increase was partially offset by changes in working capital due to the timing and amount of product shipments, payment of Director s and Officer s insurance premiums and payment of income taxes.

Net cash provided by operating activities in 2002 primarily resulted from an $11.7 million distribution from Novogyne.

Net cash provided by operating activities in 2001 primarily resulted from distributions from Novogyne totaling $13.1 million, the receipt of a license fee in the amount of $3.5 million in connection with the CombiPatch® license transaction and a $5.0 million milestone payment in connection with the Estradot® license transaction. See Note 5, License and Contract Agreements, in the Notes to Financial Statements for more information. Changes in working capital accounted for most of the remaining change over 2000.

Investing Activities:

Net cash used in investing activities in 2003 and 2002 was primarily attributable to the purchase of fixed assets to expand production capacity for future products and payment of patent development costs.

Net cash used in investing activities in 2001 was primarily attributable to the implementation of an enterprise resource planning system and a $15.7 million investment in Novogyne related to the CombiPatch® acquisition.

Financing Activities:

Net cash provided by financing activities for 2003 was primarily attributable to cash received in connection with the issuance of common stock from the exercise of stock options, partially offset by the repurchase of 105,000 shares of our common stock.

Net cash provided by financing activities in 2002 and 2001 was attributable to cash received in connection with the issuance of common stock from the exercise of stock options, partially offset by payments made on notes payable.

Short-Term and Long-Term Liquidity:

Our principal sources of short-term liquidity are existing cash, cash generated from product sales, fees and royalties under development and license agreements and distributions from Novogyne. In April 2003, Shire paid us $25 million upon closing of the MethyPatch® transaction. For the year ended December 31, 2003, substantially all of our income before income taxes was comprised of equity in earnings of Novogyne, a non-cash item. Our short-term liquidity is dependent on sales, royalties and license fees associated with transdermal HT products. Any decrease in sales of those products by us or our licensees or any increase in returns of products to Novogyne (including any such changes resulting from the results of the recent or ongoing HT studies or the pending product label changes), the further decline of the transdermal HT market, or the inability or failure of Novogyne to pay distributions would have a material adverse effect on our short-term liquidity and require us to rely on our existing cash balances or on borrowings to support our operations and business. Although we expect to receive distributions from Novogyne, there can be no assurance that Novogyne will have sufficient profits or cash flow to pay distributions or that Novogyne s Management Committee will authorize such distributions. We also expect our funding obligation of an additional MethyPatch® clinical study/studies will have a negative impact on our short-term liquidity. We cannot assure that MethyPatch® will be approved by the FDA, particularly in light of the not approvable letter we received from the

FDA in April 2003, or that, even if approved, Shire will generate MethyPatch® sales at levels that would trigger our milestone payments; therefore, we cannot assure that we will receive any further payments from Shire. Our short-term liquidity may also be adversely affected during the period prior to the launch of a new product when we expect to incur new and potentially significant capital expenditures related to the manufacture of the new product as well as the cost for pre-launch inventories.

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In the first quarter of 2003, our Board of Directors authorized a share repurchase program under which we may acquire up to $25 million of our Common Stock. As of December 31, 2003, we had repurchased 105,000 shares of our common stock at an aggregate price of $1.3 million. Any repurchases of Common Stock under our share repurchase program could adversely affect our short-term liquidity.

We believe that we will have sufficient cash available to meet our operating needs and anticipated short-term capital requirements. For our long term operating needs, we intend to utilize funds derived from the above sources, as well as funds generated through sales of products under development or products that we may license or acquire from others. We expect that such funds will be comprised of payments received pursuant to future development and licensing arrangements, as well as direct sales of our own products. We expect that our cash requirements will continue to increase, primarily to fund clinical studies for products under development and for plant and equipment to expand production capacity. We cannot assure that we will successfully complete the development of such products, that we 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 we 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 we are unable to launch additional commercially-viable products that we develop or that we license or acquire from others, we 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 our long-term liquidity needs. Many factors that could impact our ability to develop or acquire and launch additional commercially-viable products are discussed under Cautionary Factors that May Impact Future Results.

We are unable to predict the effect of the results of the discontinued and ongoing HT studies discussed above on our long-term prospects for the HT market or for the market for our transdermal HT products. Accordingly, we are not able to predict the effect that those studies may have on our long-term liquidity, results of operations and business prospects.

To the extent that capital requirements exceed available capital, we will seek alternative sources of financing to fund our operations. No assurance can be given that alternative financing will be available, if at all, in a timely manner, or on favorable terms. If we are unable to obtain satisfactory alternative financing, we may be required to delay or reduce our proposed expenditures, including expenditures for research and development and plant and equipment, in order to meet our future cash requirements. See Cautionary Factors that May Impact Future Results for a description of certain matters that could affect our short or long-term liquidity.

Our credit facility for up to a maximum of $10 million expired in April 2003. We did not renew this credit facility because we had not used it and had no plans to use it.

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Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have, or, in the judgement of our management, are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Aggregate Contractual Obligations

The table below lists our significant contractual obligations as of December 31, 2003 (all amounts are in thousands):

	Total	Less Than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Operating Lease Obligations[1]	$ 716	$ 336	$338	$32	$ 10
Purchase obligations[2]	4,606	4,333	264	9	
Total[3]	$5,322	$4,669	$602	$41	$ 10

(1) During the ordinary course of business, we enter into operating leases for machinery, equipment, warehouse and office space. Total rental expense for operating leases was $309,000, $343,000 and $293,000 for the years ended December 31, 2003, 2002 and 2001, respectively.

(2) In the ordinary course of business, we enter into non-cancelable purchase obligations to vendors to which we have submitted purchase orders, but have not yet received the goods or services.

(3) The amounts that may be paid by Noven to fund the clinical trials for MethyPatch® are not included in the foregoing table because total costs cannot be determined at this time. Furthermore, the $5 million we may have to pay Shire in the case Shire would exercise its right to require us to repurchase the product rights of MethyPatch® is also not included. See Business Our Additional Products Transdermal Methylphenidate Delivery System.

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New Accounting Standards

In December 2003, the FASB issued Interpretation No. 46R, *Consolidation of Variable Interest Entities* (FIN 46). This Interpretation of Accounting Research Bulletin 51, *Consolidated Financial Statements*, addresses consolidation by business enterprises of variable interest entities which have one or both of the following characteristics: (i) the equity investment at risk is not sufficient to permit the entity to finance its activities without additional subordinated financial support from other parties, which is provided through other interests that will absorb some or all of the expected losses of the entity, and (ii) the equity investors lack one or more of the characteristics of a controlling financial interest. This interpretation applies immediately to variable interest entities created after January 31, 2003, and to variable interest entities in which an enterprise obtains an interest after that date. It applies no later than the first reporting period ending after March 15, 2004 to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. Our investment in Novogyne is not considered a variable interest in a Variable Interest Entity (VIE) under the provisions of FIN 46. Therefore, the consolidation and disclosure rules of FIN 46 are not applicable to us and we do not expect any impact on our financial statements from adopting this interpretation. These conclusions are based on currently available information and require us to assess our investment interest and ownership rights in Novogyne. If our conclusions or our underlying assumptions of factual information concerning our investment in Novogyne were to change, Novogyne may be considered a VIE and our investment in Novogyne could become subject to the consolidation and disclosure rules of FIN 46. In that case, a determination would have to be made as to the primary beneficiary of Novogyne s interest. The primary beneficiary would then consolidate Novogyne. We believe that even if a determination were made that Novogyne was a VIE at December 31, 2003, Novartis is the primary beneficiary due to its preferred return and 51% equity interest in Novogyne and would continue to consolidate Novogyne.

In April 2003, the FASB issued Statement No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities*. This statement amends and clarifies financial reporting for derivative instruments and for hedging activities accounted for under Statement 133 and is effective for contracts entered into or modified, and for hedges designated, after June 30, 2003. We have not experienced, and do not anticipate, a significant impact on our financial statements from adopting this statement.

In May 2003, the FASB issued Statement No. 150, *Accounting for Certain Instruments with Characteristics of Both Liabilities and Equity.* This statement establishes how an issuer classifies and measures certain freestanding financial instruments with characteristics of liabilities and equity and requires that such instruments be classified as liabilities. This statement is effective for financial instruments entered into or modified after May 31, 2003 and is otherwise effective at the beginning of the first interim period beginning after December 15, 2003. We do not anticipate a significant impact on our financial statements from adopting this statement.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us 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, we evaluate our estimates, including those related to revenue recognition, the fair value of employee stock options, the determination of the net realizable value of the net deferred tax asset, estimates related to allowance for returns related to product recalls, accrued liabilities, income and other tax accruals, revenue recognition and contingencies and litigation. We base our estimates on historical experience and on various other assumptions that we believe 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 our critical accounting policies are those which we believe 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. Using different assumptions could result in materially different results. A discussion of our 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:

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Revenue Recognition:

Substantially all of our product revenues were for sales to our licensees, Novogyne, Novartis Pharma and its affiliates and Aventis Pharma AG. Revenues from product sales are recognized at the time of shipment when both title and the risks and rewards of ownership have been transferred to the buyer. Certain of our license agreements provide that the ultimate supply price is based on a percentage of the licensee s net selling price. Each of those agreements also establishes a fixed minimum supply price per unit that represents the lowest price we are entitled to receive on sales to the licensee. We receive the minimum price at the time of shipment with the possibility of an upward adjustment later when the licensee s net selling price is known. Revenues under these agreements are recorded at the minimum price at the time of shipment. We record any upward adjustments to revenues at the time that the information necessary to make the determination is received from the licensee. If the upward adjustments are not determinable, we record the adjustments (which historically have not been significant) on a cash basis. These amounts are included in product revenues.

Royalty revenues consist of royalties payable by Novogyne and Novartis Pharma from sales of Vivelle® and Vivelle-Dot®/Estradot® in the United States and Canada. We accrue royalties from Novogyne s and Novartis Pharma s product sales each quarter based on Novogyne s and Novartis Pharma s net sales for that quarter. Royalties are included in product revenues.

License revenues consist of up-front, milestone and similar payments under license agreements and are not recognized until earned under the terms of the applicable agreements. In most cases, license revenues are deferred and recognized over the estimated product life cycle or the length of relevant patents, whichever is shorter. Estimates of product life cycles are inherently uncertain. Any change to the actual or estimated product life could require us to change the recognition period.

Contract revenues consist of contract payments related to research and development projects performed for third parties. The work performed by us includes feasibility studies to determine if a specific drug is amenable to transdermal drug delivery, the actual formulation of a specific drug into a transdermal drug delivery system, studies to address the ongoing stability of the drug in a transdermal drug delivery system and manufacturing of batches of product that can be used in human clinical trials. We receive contract payments for the work we perform in the following forms:

nonrefundable up-front payments prior to commencing the work (or certain phases of the work);

additional payments upon completion of additional phases; and

in some cases, success milestone payments based on achievement of specified performance criteria.

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As prescribed by EITF 00-21 Accounting for Revenue Arrangements with Multiple Deliverables , we analyze each contract in order to separate each deliverable into separate units of accounting and then recognize revenues for those separated units at their fair value, as delivered, based on the proportionate share of the work performed by us as we perform under the contract. If each deliverable does not qualify as a separate unit of accounting, the deliverables are combined and the amounts under the contract are allocated to the combined deliverables. The appropriate recognition of revenue is then determined for the combined deliverables as a single unit of accounting. The difference between the amount of the payments received and the amount recognized is recorded as deferred revenues until that amount is earned in accordance with SEC Staff Accounting Bulletin 101, Revenue Recognition in Financial Statements (SAB 101). The analysis prescribed by EITF 00-21 requires us to make a number of significant assumptions and judgments, including those related to sales price, unit costs, and work performed.

Milestone payments are recorded when the specified performance criteria are achieved, as determined by the customer. Each contract may have different payment terms. Therefore, the timing of revenue recognition may vary from contract to contract.

Revenues are net of an allowance for returns. We establish allowances for returns for product that has been recalled or that we believe is probable of being recalled. The methodology used by us to estimate product recall returns is based on the distribution and expiration dates of the affected product and overall trade inventory levels. These estimates are based on currently available information, and the ultimate outcome may be significantly different than the amounts estimated given the subjective nature of the assumptions and complexities inherent in this area and in the pharmaceutical industry. For example, during 2003 Novartis initiated recalls of certain lots of CombiPatch® and Vivelle-Dot® due to production issues. Our revenues for 2003 are net of approximately $1.4 million and $6.5 million in allowances for returns at Noven and Novogyne, respectively. If our estimate concerning the amount of the product returns is incorrect or if Novartis should initiate further unexpected recalls, then our results of operations could be materially different.

Fair Value of Stock Options:

We have elected to follow Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees and related Interpretations in accounting for our employee stock options as allowed pursuant to SFAS 123, as amended by SFAS 148. Accordingly, no compensation expense has been recognized for the years ended December 31, 2003, 2002 and 2001.

Our accounting for 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 us to include the fair value of employee stock options in our compensation expense. Congress, the Securities and Exchange Commission and the accounting profession are reevaluating 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 be adopted, or, if such a policy is adopted, what its requirements may be. However, it is possible that we may in the future be required under accounting principles generally accepted in the United States to include the fair value of our employee stock options in our compensation expense.

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Had compensation cost for our stock option plans been determined on the basis of fair value at the grant date for awards under those plans, consistent with SFAS 123, and as amended by SFAS 148, and our existing valuation method for our employee stock options, the Black-Scholes option pricing model, we estimate that our net income for the years ended December 31, 2003, 2002 and 2001 would have been reduced by 32%, 32% and 41%, respectively. However, SFAS 123 requires the use of option valuation models that use 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 SFAS 123 has not been adopted. Because our 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 our employee stock options. In addition, the effect of applying the fair value method of accounting for stock options on reported net income for 2003, 2002 and 2001 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 we not record a valuation allowance against our net deferred tax asset if it is more likely than not that we will be able to generate sufficient future taxable income to utilize our net deferred tax asset. Although realization is not assured, we believe it is more likely than not that the net deferred income tax asset will be realized based upon our estimated future income 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 our provision for income taxes to vary significantly from period to period.

Investment in Novogyne:

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

As of December 31, 2003, Novogyne had a long-term intangible asset of $44.8 million related to the acquisition of the marketing rights to CombiPatch®. Accounting principles generally accepted in the United States require that Novogyne record this asset at cost and that the asset be tested for recoverability whenever events or changes in circumstances indicate that its carrying amount may not be recoverable. Testing for impairment requires Novogyne to estimate the undiscounted future cash flow of the asset and compare that amount to the carrying value of the asset. If this 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 would involve 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, if Novogyne would be required to estimate the fair value of the marketing rights, it would utilize a discounted cash flow analysis. A discounted cash flow analysis values an asset on the basis of the net present value of the cash expected to be generated by that asset over its estimated useful life. This analysis requires Novogyne to make a number of significant assumptions and judgments. For example, estimates need to be made regarding prescription trends, sales price, unit cost and product life cycle among many other factors including the discount rate to be applied to the estimated cash generated by sales of the product. A material change in any of these assumptions may require Novogyne to record an impairment loss, which would adversely affect Novogyne s operating results in the period in which the determination or allowance were made. This would reduce our earnings attributable to our investment in Novogyne for that period and the amount of our investment in Novogyne and could, depending on the size of the

impairment, result in a loss at both the Novogyne and Noven level for the period in which the impairment occurred. Neither Novogyne nor we are able to predict the effect of the recently discontinued and currently ongoing HT studies, the pending product label changes, or the expected 2004 launch of a competitive combination HT patch, on the prospects for the HT market or the market for CombiPatch®. Any adverse change in the market for HT products could have a material adverse impact on the ability of Novogyne to recover its investment in CombiPatch® which could require Novogyne to record an impairment loss for that asset.

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Novogyne records sales net of sales allowances for chargebacks, Medicaid rebates, managed healthcare rebates, cash discounts, product returns and other allowances. The returns portion of the sales allowance related to expiration dating is based in part on Novartis returned goods policy. The methodology used by Novogyne to estimate product returns is based on (i) the historical experience of actual product returns and (ii) the estimated lag time between when an actual sale takes place in relation to when the products are physically returned by a customer. The historical actual returns rate is then applied to product sales during the estimated lag period to develop the returns estimate. However, because Novogyne s return history includes periods of higher and lower trade inventory levels and varying levels of demand, in making its final estimations of expected product return, Novogyne also considers trends and expectations for future demand and trade inventory levels. Novogyne does not accept returns due to short-dating until the product has less than a certain amount of shelf-life remaining. Also, Novogyne does not accept returns due to expiration later than a certain period after the product has expired. These policies cause a significant lag time between when a product is sold and the latest date on which a return could occur. Novogyne believes this is a reasonable basis on which to estimate returns exposure and incorporates the key factors that contribute to returns. In addition, Novogyne establishes sales returns allowances for product that has been recalled or that they believe is probable of being recalled. The methodology used to estimate product returns is based on the distribution and expiration dates of the affected product and overall trade inventory levels. These estimates are based on currently available information, and the ultimate outcome may be significantly different than the amounts estimated given the subjective nature and complexities inherent in this area and in the pharmaceutical industry.

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

The critical accounting policies discussed herein are not intended to be a comprehensive list of all of our 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.

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Outlook

A summary of our initial 2004 financial guidance is provided below. This financial guidance assumes that there are no acquisitions, unusual transactions, changes in accounting, or material changes in the demand for our HT products or in our business relationships/collaborations. We cannot assure that we will achieve results consistent with this guidance, and refer you to the risks, uncertainties and cautionary factors discussed below and under the caption Cautionary Factors that May Impact Future Results in Item 7 of this Form 10-K that could impact our ability to achieve such results.

2004 Financial Guidance:

For full-year 2004, we currently expect net revenues to approximate 2003 results, research and development spending in 2004 to increase compared to 2003, and fully diluted earnings per share to be in the $0.40 to $0.45 range.

Novogyne s 2004 net revenues and net income are expected to approximate 2003 results. Operating results are expected to fluctuate by quarter in part due to the timing of orders placed by trade customers. Novogyne s first quarter contribution to Noven s profit is expected to be lower than in subsequent quarters due to satisfaction of a $6.1 million preferred distribution to Novartis under the joint venture agreements. In addition, Noven expects that Novogyne s 2004 first quarter sales may be lower than sales in the 2003 fourth quarter due to the timing of orders placed by trade customers.

Endo:

On February 25, 2004, we licensed our developmental generic fentanyl patch to Endo. Our fentanyl patch is intended to be the generic equivalent of Johnson & Johnson s Duragesic® (fentanyl transdermal system), which had branded U.S. sales of over $1.3 billion in 2003.

We received an $8.0 million up-front payment from Endo on signing. Upon Endo s first commercial sale of the fentanyl patch, we are entitled to receive an additional payment ranging from $5.0 million to $10.0 million, depending on the timing of launch and the number of generic fentanyl competitors in the market. We will manufacture and supply the product at our cost and will share in Endo s profit from product sales.

Based on the current patent and exclusivity status of Duragesic®, we believe that the earliest our generic fentanyl patch could be launched is January 2005, assuming FDA approval is received by that time, but we cannot assure that we will receive FDA approval by that time or at all. Noven and Endo may elect to manufacture launch supplies prior to receipt of tentative FDA approval. If launch supplies are manufactured and approval is not ultimately received or is delayed, the agreement provides that Noven and Endo will share the cost of manufacturing product that cannot be sold by Endo in accordance with an agreed-upon formula, but we would be unable to offset all of our up-front production costs with sales of the product. If the product has not been approved or we have not supplied Endo s launch requirements by May 2005, Endo may have the right to terminate the license, depending on the number of generic competitors in the market.

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In addition to the fentanyl license, we have established a collaboration with Endo to seek to identify and develop new transdermal therapies. Of the $8.0 million up-front payment, $1.5 million will be allocated to fund feasibility studies that we expect to undertake to seek to determine whether certain compounds identified by the parties can be delivered using our transdermal technology. Endo is expected to fund and manage clinical development of those compounds proceeding into clinical trials.

The $8.0 million received by Noven at signing is expected to be recognized as revenues over a period of years.

P&G Pharmaceuticals:

In April 2003, we established a collaboration with P&GP for the development of new prescription patches. The products under development explore follow-on product opportunities for Intrinsa®, P&GP s in-licensed investigational transdermal testosterone patch designed to help restore desire in menopausal women who have Hypoactive Sexual Desire Disorder. P&GP has initiated studies of the first product in humans. Potential development milestones totaling $4.8 million remain to be received under the P&GP collaboration, a portion of which is expected to be received in the remainder of 2004.

Shire:

In April 2003, we received a not approvable letter from the FDA relating to our MethyPatch® New Drug Application. During 2004, Noven and Shire expect to undertake additional MethyPatch® clinical studies. Noven has committed to fund the additional studies. Our direct costs incurred in pursuit of approval are expected to be deferred against a portion of the $25 million deferred revenue previously received from Shire, and therefore such expenses are not expected to impact our research and development expenses in 2004. In light of the not approvable letter, it is possible that development will not be completed and/or that MethyPatch® will not be approved or launched, and that we may not receive additional milestone payments or manufacturing revenues from Shire.

Cautionary Factors that May Impact Future Results

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 our and our strategic partners 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, seeks, will, would and similar words. These statements a current expectations and beliefs concerning future events but are subject to risks and uncertainties, including but not limited to economic, competitive, governmental and technological factors affecting our operations, results of operations, markets, products, prices and prospects, and other factors discussed below and elsewhere in this report and the other documents filed by us with the Securities and Exchange Commission (SEC). These factors may cause our results to differ materially from the statements made in this report or otherwise made by or on behalf of us. The following is a summary of some of the risk factors, which are not listed in order of priority, that could adversely affect our results. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operation. We do 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.

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The market for HT products, including our line of transdermal HT products, has been negatively affected by studies indicating adverse health risks associated with HT products. Additional HT studies may cause the market for HT products to further decline.

We currently derive substantially all of our revenues from the sale of our line of HT transdermal products. The market for HT products has been negatively affected by the WHI study and other studies that have found that the overall health risks from the use of certain oral HT products exceed the benefits from the use of those products among healthy postmenopausal women. For example, total prescriptions dispensed in the HT market in the United States declined by 42% from the second quarter of 2002 (the quarter immediately preceding the WHI study) to the fourth quarter of 2003.

Other studies evaluating HT are currently underway or in the planning stages. The market for HT products, including ours, both in the United States and abroad, could be further adversely impacted if these studies are halted or otherwise find unacceptable risks from HT use. Currently, our liquidity, results of operations and business prospects are almost entirely dependent on sales, license royalties and fees associated with transdermal HT products. Accordingly, any further adverse change in the market for HT products could have a material adverse impact on our business, financial position and results of operations.

Our future success depends on our ability to develop, license or acquire new products and to bring these new products to market on a timely basis. Our failure to do so could negatively affect our financial position and results of operations and could cause the price of our common stock to decline.

Our long-term strategy is dependent upon the successful development of new products, such as MethyPatch® and our transdermal fentanyl system for chronic pain, and their successful commercialization. There can be no assurance that we will be able to identify commercially promising products or technologies. The length of time necessary to complete clinical trials and obtain marketing approval from regulatory authorities may be considerable. No assurance can be given that we will have the financial resources necessary to complete products under development, that those projects to which we dedicate resources will be successfully completed, that we will be able to obtain regulatory approval for any such product, or that any approved product can be produced in commercial quantities, at reasonable costs, and be successfully marketed, either by us or by a licensing partner. A project can fail or be delayed at any stage of development, even if each prior stage was completed successfully, which could jeopardize our ability to recover our investment in the product. Some of our development projects will not be completed successfully or on schedule. Many of the factors which may cause a product in development to fail or be delayed, such as difficulty in enrolling patients in clinical trials, the failure of clinical trials, lack of sufficient supplies or raw materials, inability to apply the subject product or technology on a commercial scale on an economical basis and changes in regulations, are beyond our control.

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From time to time we may need to acquire licenses to patents and other intellectual property of third parties to develop, manufacture and commercialize our products. There can be no assurance that we will be able to acquire such licenses on commercially reasonable terms. The failure to obtain such a license could negatively affect our ability to develop, manufacture and commercialize certain products. In some cases, we have begun and, in the future, may begin development of a product that we do not intend to independently develop through clinical trials and market, with the expectation that a licensee will be identified to assist in development and/or marketing. There can be no assurance that we will attract a business partner for any particular product or will be able to negotiate an agreement on commercially reasonable terms. If an agreement is not reached, our initial development investment in any such product may not be recovered.

We depend on partners to obtain regulatory approval for, and to market and sell, certain of our products. Our marketing partners sell products that compete with our products.

We depend upon collaborative agreements with other pharmaceutical companies to obtain regulatory approval for and to market and sell certain of our products. Under the terms of the Novogyne joint venture, Novartis is responsible for the distribution of Novogyne s products, including Vivelle®, and for selling Novogyne s products to its trade customers. For MethyPatch®, we have granted the exclusive marketing rights to Shire and we are working jointly with Shire to obtain FDA approval of MethyPatch®. For our transdermal fentanyl patch, we have granted the exclusive marketing rights to Endo. Failure of Novartis and our other marketing partners to market our products successfully would cause the quantity of products purchased from us and the amount of fees and royalties ultimately paid to us to be reduced and would therefore have a material adverse effect on our business and operations. Our partners may have different and, sometimes, competing priorities. Some of our partners, including Novartis and Shire, market and sell products competitive with ours. The marketing organizations of our partners may be unsuccessful, or those partners may assign a lower level of priority to the marketing of our products. If one or more partners fails to pursue the marketing of our products as planned, or if marketing of any of those products is otherwise delayed, our business, financial position and results of operations may be negatively affected. Absent these marketing partners, we do not presently have a significant direct marketing channel to health care providers for our drug delivery technologies.

We do not control Novogyne and we may face additional risks because Novartis, our joint venture partner, has significantly greater resources than we do.

Our equity in earnings of Novogyne contributed substantially all of our income before income taxes in 2003, and Novogyne s results will likely continue to be material to us in the future. Because, among other things, we are vastly different in size from Novartis, and because Novartis and its affiliates sell competing products outside of Novogyne, our interests may not always be aligned. This may result in potential conflicts between Novartis and us on matters relating to Novogyne which we may not be able to resolve on favorable terms or at all. Novartis has the right to dissolve Novogyne under certain circumstances. Novogyne s Management Committee is comprised of a majority of representatives from Novartis. While certain significant corporate actions require the supermajority vote of the committee members, we do not control Novogyne. In addition, the joint venture operating agreement has a buy/sell provision that either Noven or Novartis may trigger by notifying the other party of the price at which the triggering party would be willing to acquire 100% of the joint venture. Upon receipt of this notice, the non-triggering party has the option to either purchase the triggering party s interest in Novogyne or to sell its own interest in Novogyne to the triggering party at the price established by the triggering party. If Noven is the purchaser, then Noven must pay an additional amount equal to the net present value of Novartis preferred profit return. This amount is calculated by applying a specified discount rate and a period of 10 years to Novartis $6.1 million annual preferred return. Novartis is a larger company with greater financial resources, and therefore may be in a better position to be the purchaser if the provision is triggered. If the provision is triggered and Novartis is the purchaser, there can be no assurance that we would be able to reinvest the proceeds of the sale in a manner that would result in sufficient earnings to offset the loss

of earnings from Novogyne. If the provision is triggered and we are the purchaser, there can be no assurance that we would not be adversely affected by the changes in capital and/or debt structure that likely would be required to finance the purchase transaction.

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We depend on Novartis to perform financial, accounting, inventory, sales deductions and other functions for Novogyne.

Under the Novogyne joint venture, Novartis is responsible for providing Novogyne with certain financial, accounting, legal and regulatory services, including monitoring inventory levels. In late 2002, inventory levels at Novogyne exceeded then current and expected demand, which negatively affected our sales and results of operations in the first half of 2003 as Novogyne curtailed product shipments to its trade customers, and we deferred product shipments to Novogyne. Novartis is also responsible for estimating and recording sales allowances for Novogyne (including reserves and allowances related to product returns). As a consequence, we may have limited ability to accurately forecast the amount of such sales allowances in any period. If Novartis materially changes the assumptions it uses in allocating reserves or in the actual determination of the gross reserve, Novogyne may be required to record an additional reserve allowance on its financial statements, which would adversely affect Novogyne s operating results during the period in which the determination or reserve were made, and would, consequently also reduce our earnings attributable to our investment in Novogyne for that period. Failure by Novartis to perform its obligations under the joint venture could negatively affect the financial position and results of operations of Novogyne and us.

We may be unable to obtain marketing approval for our new products, including MethyPatch® and our fentanyl patch.

We are not able to market our products (including generic drug products) in the United States or in another jurisdiction without first obtaining marketing approval from the FDA or an equivalent foreign agency. In April 2003, we received a not approvable letter from the FDA relating to our MethyPatch® NDA. A not approvable letter is issued if the FDA does not consider the application approvable because one or more deficiencies in the application preclude the FDA from approving it. The letter cited clinical and other issues as the basis for non-approval. In October 2003, we submitted with Shire a jointly prepared study protocol for an additional clinical study for MethyPatch® to the FDA for review and comment. In November 2003, the FDA responded to our draft protocol and reported that the proposed study design did not address the clinical risk-benefit issues raised in the April 2003 not approvable letter. In its November 2003 response, the FDA provided specific recommendations regarding the proposed study design. Noven and Shire are working together to review and respond to the FDA s comments with respect to the study design. We believe this study is necessary to amend the NDA and that other studies may also be required or advisable. Under our November 2003 agreement with Shire, if we agree with Shire on a study design, Shire will manage the new clinical study and we will fund it. Under our agreement with Shire, we are responsible for providing the clinical supplies for the study and we may also incur certain additional expenses in pursuit of regulatory approval. At the conclusion of the trial, if Shire determines that submission of the study results to the FDA would not result in a commercially-viable product, Shire will have the right to terminate the original transaction agreement. If Shire exercises its termination right under these circumstances, however, Shire will forfeit its right to require us to repurchase the product rights, and the product rights will revert to us without payment to Shire. We can not assure that any revised study design will be acceptable to the FDA, or even if acceptable, will produce study results that will result in a commercially-viable product.

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In addition to MethyPatch®, we are currently seeking regulatory approval for our fentanyl transdermal system for chronic pain and our partners are currently seeking regulatory approval for other products, including a next generation transdermal combination estrogen/progestin patch. We can not assure that we will obtain the necessary regulatory approval for these products or any other products we may seek to commercialize or that any such approval will be free from unduly burdensome conditions or limitations. In light of the WHI and other HT studies, it is possible that healthcare regulators could delay the approval of HT products or require that any new HT products be subject to more extensive or more rigorous study and testing prior to being approved, or could receive approval subject to more extensive conditions or limitations.

Our approved products may not achieve the expected level of market acceptance.

Even if we are able to obtain regulatory approval for our new products, the success of our products will depend on their market acceptance. Substantially all of our revenues are generated through sales of transdermal delivery systems, which generally are more expensive than oral formations. Our products are marketed primarily to physicians, some of whom are reluctant to prescribe a transdermal delivery system when an alternative delivery system is available. We and our licensees must demonstrate to prescribing physicians the benefits of transdermal delivery, especially with respect to products such as MethyPatch® for which there is presently no transdermal system on the market. The commercial success of our products is also based in part on patient preference, and difficulties in obtaining patient acceptance of our transdermal delivery systems may similarly impact our ability to market our products.

Even if we obtain FDA approval for MethyPatch®, the market for this product may be negatively affected by the ongoing public debate in the United States regarding the appropriateness of using methylphenidate and other medications to treat children with ADHD. We expect that this debate will continue for the foreseeable future. The outcome of this debate is uncertain, and we cannot predict what impact, if any, the increased public attention will have on the market for products indicated for ADHD or on MethyPatch®. Because at least part of the stigma results from the fact that most of the current products are Schedule II controlled substances, the non-stimulant product sold by Eli Lilly may benefit from this controversy at the expense of the methylphenidate and amphetamine-based products on the market. See Business Competition.

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Failure to comply with our supply agreements or otherwise adequately supply our products to our licensees could negatively affect our financial position and results of operations.

Our supply agreements with our licensees impose strict obligations on us with respect to the manufacture and supply of our products. We devote significant time, effort and expense complying with these requirements. Failure to comply with the terms of these supply agreements may result in our being unable to supply product to our licensees, resulting in lost revenues by us and potential responsibility for damages and losses suffered by our licensees.

Our supply agreement for Vivelle® and Vivelle-Dot® has expired. Since the expiration of the Vivelle® supply agreement, the parties have continued to operate in accordance with the supply agreement s commercial terms. We cannot assure that we will enter into a new supply agreement on satisfactory terms or at all. It is not clear that the non-commercial terms of the supply agreement would be enforceable with respect to post-expiration events or occurrences. Due to our dependence on Novogyne, we may be unable to negotiate favorable business terms with them or resolve any dispute that we may be involved in with them in a favorable manner. Failure to extend the supply agreement could have a material adverse effect on our business, results of operations and financial position. Designation of a new supplier and approval of a new supply agreement would require the affirmative vote of four of the five members of Novogyne s Management Committee. Accordingly, both Novartis and Noven must agree on Novogyne s supplier.

MethyPatch® and our fentanyl transdermal system are new products that we have never manufactured on a commercial scale. The terms of the Shire transaction will permit Shire to qualify a second manufacturing source and purchase a portion of its MethyPatch® requirements from the second source. Endo will have the same right under certain circumstances for our fentanyl patch. Failure to meet either party s requirements would affect our revenues and could affect the success of our new product launches and may result in Shire or Endo relying more heavily on second sources, reducing the manufacturing revenues that we would otherwise realize. It may also jeopardize our ability to obtain milestone payments under the Shire and Endo transactions. In addition, the active ingredients in MethyPatch® and our fentanyl patch are more expensive than the active ingredients in our HT patch products. If we experience manufacturing difficulties such as quality problems, yield deficiencies or similar issues, our overall manufacturing costs may be higher than anticipated.

If we fail to maintain satisfactory compliance with FDA regulations and other governmental agencies, we may be forced to recall products and we could be subject to civil or criminal penalties.

Our operations are subject to extensive regulation by governmental authorities in the United States and other countries with respect to the testing, approval, manufacture, labeling, marketing and sale of pharmaceutical products. These regulations are wide-ranging and govern, among other things: adverse drug experience reporting, product promotion, product pricing and discounting, drug sample accountability, drug product stability, product manufacturing, including good manufacturing practices, and product changes or modifications. Our facilities handle controlled substances, resulting in additional extensive regulatory requirements and oversight. We devote significant time, effort and expense addressing the extensive government regulations applicable to our business. Even if a product is approved by a regulatory authority, product approvals may be withdrawn after the product reaches the market if compliance with regulatory standards is not maintained or if problems occur regarding the safety or efficacy of the product. Failure to comply with governmental regulations may result in fines, warning letters, unanticipated compliance expenditures, interruptions or suspension of production and resulting loss of sales, product seizures or recalls, injunctions prohibiting further sales, withdrawal of previously approved marketing applications, and criminal prosecution. Under the terms of the Novogyne joint venture, Novartis is responsible for providing regulatory services. While we believe that Novartis provides these services adequately, there can be no assurance that a violation of any of these regulations will not have an adverse effect on us.

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New labeling requirements may negatively affect sales of our HT products.

In January 2003, the FDA announced that marketers of HT products, including Novogyne, are required to modify their HT product labels to include additional safety information and warnings. Among other things, the labels must indicate that HT should be used for short-term therapy only and that, in the absence of clinical studies demonstrating that HT products other than the oral product studied in the WHI study are safe, physicians should assume that all HT products carry the same risks. We expect further revisions to HT product labels may be required by the FDA to include information from the Women s Health Initiative Memory Study, which reported an increased risk of dementia from use by women 65 and older of an oral combination estrogen with progestin product.

We rely on a single supplier or a limited number of suppliers for certain raw materials and compounds used in our products.

Certain raw materials and components used in the manufacture of our products, including essential polymer adhesives, are available from limited sources, and, in some cases, a single source. In addition, regulatory authorities must generally approve raw material sources for transdermal products. Our NDA for MethyPatch®, for example, includes only one supplier of the active pharmaceutical compound. This same supplier is also the only source of the active pharmaceutical compound for which we have sought approval under the ANDA for our transdermal fentanyl system. Any curtailment in the availability of such raw materials could be accompanied by production or other delays, and, in the case of products for which only one raw material supplier exists, could result in a material loss of sales. In the case of controlled substances, the DEA sets quotas for controlled substances, including methylphenidate, fentanyl and amphetamine, and we must receive authorization from the DEA to handle these substances. We cannot assure that we will be granted sufficient DEA quota to meet production requirements for controlled substances. Without adequate approved supplies of raw materials or packaging supplies, our manufacturing operations could be interrupted until another supplier is identified, our products approved and trading terms with it negotiated. We may not be able to identify an alternative supplier and any supplier that we do identify may not be able to obtain the requisite regulatory approvals in a timely manner, or at all. Furthermore, we may not be able to negotiate favorable terms with an alternative supplier. Any disruptions in our manufacturing operations from the loss of an approved supplier may cause us to incur increased costs and lose revenues and may have an adverse effect on our relationships with our partners and customers, any of which could have adverse effects on our business and results of operations. Some raw materials used in our products are supplied by companies that restrict certain medical uses of their products. While our use is presently acceptable, there can be no assurance that such companies will not expand their restrictions to include our applications. Our business also faces the risk that third party suppliers may supply us with raw materials that do not meet required specifications, which, if undetected by us, could cause our products to test out of specification and require us to recall the affected product.

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We face significant competition, which may result in others discovering, developing or commercializing products before, or more successfully, than we do.

We face competition from a number of companies in the development of transdermal drug delivery products, and competition is expected to intensify as more companies enter the field. Some of these companies are substantially larger than we are and have greater resources than we do, as well as greater experience in developing and commercializing pharmaceutical products. As a result, they may succeed before us in developing competing technologies or obtaining governmental approvals for products. Our products compete with other transdermal products as well as alternative dosage forms of the same or comparable chemical entities, as well as non-drug therapies. For example, we expect increased competition in the estrogen market as a result of the 2003 launch of a vaginal estrogen delivery system, the 2004 launch of a combination estrogen/progestin patch and the expected launches of estrogen cream and gel products, each of which is a new dosage form in this category, as well as the expected launch of an ultra-low dose estrogen patch. The ADHD market is very competitive and our receipt of the sales-based milestones under the Shire agreement depends on the MethyPatch® sales levels achieved by Shire which already markets non-methylphenidate ADHD products. Other competitors marketing or developing ADHD products include Johnson & Johnson, Novartis, Glaxo-Smithkline, Bristol-Myers Squibb, Abbott Laboratories, Celltech plc, Cephalon, Inc. and Eli Lilly. Johnson & Johnson markets Concerta®, the market-leading methylphenidate product, and Novartis and Eli Lilly & Company (Lilly) market competitive ADHD products. Strattera®, a non-stimulant, non-controlled substance therapy launched by Lilly in 2003, has gained significant market share in a short period of time. There is at least one clinical study underway comparing the efficacy of Strattera® to a long-acting methylphenidate product. If Strattera® or other therapies in development by other companies become recognized as therapeutically superior to stimulants, or are preferred by physicians, parents and/or patients, the market for MethyPatch® would be adversely affected. These competitive products, especially those already marketed by Shire and those not designated as controlled substances, may negatively impact Shire s ability to gain market share for MethyPatch® and therefore may decrease the likelihood that we will receive the sales-based milestone payments. Subject to FDA approval, we expect our fentanyl transdermal system will compete against other generic equivalents of Johnson & Johnson s Duragesic® patch. In the market for generic equivalents, the first products to be approved and available for sale typically are able to achieve and maintain significant market share. As competing generic manufacturers receive regulatory approvals, market share, revenues and gross profit typically decline, in some cases dramatically. Accordingly, the level of market share, revenues and gross profit for a generic product is typically tied to the number of competitors in the market and the timing of that product s FDA approval and launch in relation to competing approvals and launches. In addition to other generic manufacturers, we expect to face competition from Johnson & Johnson, the manufacturer of Duragesic®, who may seek to compete in this market by collaborating with other generic pharmaceutical companies or by marketing their own generic equivalent of Duragesic®. Johnson & Johnson s patent and pediatric exclusivity for Duragesic® expire in January 2005, which is the earliest possible date that we could launch our fentanyl transdermal system, but we cannot assure that we will obtain FDA approval or launch a product in that time-frame or at all. Mylan Laboratories has received final approval from the FDA for its generic fentanyl transdermal system and has announced its intention to launch this product in July 2004. We believe that other generic manufactures have submitted or will submit ANDAs for fentanyl transdermal systems. To seek to be prepared for a timely launch, we expect to manufacture launch supplies prior to receipt of tentative FDA approval. If launch supplies are manufactured and approval is not ultimately received or is sufficiently delayed such that these supplies are not saleable, the license agreement provides that we will share the cost of manufacturing these supplies with Endo in accordance with a formula, but we would be unable to offset all of our up-front production costs with sales of the product. We expect that these costs could be significant. We cannot assure that our products will compete successfully against competitive products or that developments by others will not render our products obsolete or uncompetitive. If we cannot maintain competitive products and technologies, our current and potential strategic partners may choose to adopt the drug delivery technologies of our competitors or their own internally developed technologies.

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Competitors may use legal, regulatory and legislative strategies to prevent or delay our launch of generic products such as our developmental transdermal fentanyl system.

The Hatch-Waxman Act provides for a period of 180 days of generic marketing exclusivity for each ANDA applicant that is first to file an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed with respect to a reference drug product, commonly referred to as a Paragraph IV certification. During this exclusivity period, the FDA cannot grant final approval to any other generic equivalent. If an ANDA containing a Paragraph IV certification is successful, it generally results in higher market share, net revenues and gross margin for that applicant. Even if we obtain FDA approval for generic drug products, we may lose significant advantages to a competitor who was first to file an ANDA containing a Paragraph IV certification.

Competitors may also pursue legislative and other regulatory strategies to prevent or delay our launch of a generic product such as our developmental transdermal fentanyl system. These strategies include, but are not limited to: seeking to obtain new patents on drugs for which patent protection is about to expire, filing a citizen petition with the FDA, pursuing state legislative efforts to limit the substitution of generic versions of brand pharmaceuticals, filing patent infringement lawsuits that automatically delay FDA approval of many generic products, introducing a second generation product prior to the expiration of market exclusivity for the first generation product which may reduce demand for a generic first generation product, and obtaining market exclusivity extensions by conducting pediatric trials of brand drugs.

The European market may be limited due to pricing pressures and other matters.

Pharmaceutical prices, including prices for our products, in Europe and certain other countries are significantly lower than in the United States. Because our agreements with Novartis Pharma provide for us to receive a percentage of Novartis Pharma s net selling price (subject to a minimum price), our gross margins are generally much lower for product sold to Novartis Pharma for resale outside of the United States than for product sold to Novogyne for sale in the United States. In addition, the lower prices restrict Novartis Pharma s gross margin realized from selling our products. Because our products compete for sales and marketing resources with other Novartis Pharma products, including competitive HT products, there can be no assurance that the relatively low gross margins generated from selling our products will not cause Novartis Pharma to focus its resources on other products or even not launch our products in certain countries. Novartis Pharma has informed us that pricing, government reimbursement and labeling issues are adversely impacting its launch plans for Estradot® in many countries, including the United Kingdom, France, Spain and Italy. Novartis Pharma is seeking a marketing partner to launch Estradot® in the United Kingdom and France, but to date has been unsuccessful. The profitability of sales in Europe may also be negatively affected by parallel trade practices in the European Union whereby a licensed importer may take advantage of price disparity between markets by purchasing our products in a market with a relatively lower price and then importing them into a country with relatively higher price. In addition, Novartis Pharma has determined that, in light of marketing changes since publication of the HT studies, a dosage strength of Estalis® lower than the second dosage strength is necessary for the product to obtain market acceptance in Europe.

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Our quarterly operating results are subject to significant fluctuations, and we may not be able to adjust our operations to effectively address changes we do not anticipate.

We expect that revenues from product sales to our licensees will fluctuate from quarter to quarter and year to year depending upon various factors not in our control, including the marketing efforts of each licensee, the inventory requirements of each licensee, the impact of competitive products, the timing and scope of Estalis® and Estradot® launches and commercialization efforts by Novartis Pharma, CombiPatch® prescription trends in the United States, the impact of the HT studies on prescriptions for our hormone replacement products, the product pricing of each licensee, the timing of certain royalty reconciliations and payments under our license agreements, the timing of FDA approval of MethyPatch® or our fentanyl patch, if any, and any subsequent product launch of these products, and the success of Shire s and Endo s commercialization efforts. Our earnings may fluctuate because of, among other things, fluctuations in research and development spending resulting from the timing of clinical trials involving products in development. Novartis is entitled to an annual $6.1 million preferred return, which has the effect of reducing our share of Novogyne s income in the first quarter of each year.

Our results of operations will be adversely affected if Novogyne or we fail to realize the full value of our intangible assets.

Accounting principles generally accepted in the United States require Noven and Novogyne to test the recoverability of their respective long-lived assets and certain identifiable intangible assets whenever events or changes in circumstances indicate that its carrying amount may not be recoverable. If the fair value is less than the carrying amount of the asset, a loss is recognized for the difference. Novogyne recorded the acquisition of CombiPatch® marketing rights at cost and tests this asset for impairment on a periodic basis. Any further adverse change in the market for HT products could have a material adverse impact on the ability of Novogyne to recover its investment in its CombiPatch® marketing rights, which could require Novogyne to revalue that asset. Impairment of that asset would adversely affect Novogyne s, and consequently our, operating results.

We cannot be certain of the protection or confidentiality of our patents and proprietary rights.

Our success will depend, in part, on our ability to obtain or license patents for our products, processes and technologies. If we do not do so, our competitors may exploit our innovations and deprive us of the ability to realize revenues from those innovations. There is no assurance that we will be issued patents for any of our patent applications, that any existing or future patents that we receive or license will provide competitive advantages for our products, or that we will be able to enforce successfully our patent rights. Additionally, there can be no assurance that our patents or any future patents will prevent other companies from developing similar or functionally equivalent products, or challenging, invalidating or avoiding our patent applications or any existing or future patents that we receive or license. Many of our patents are formulation patents and would not preclude others from developing and marketing products that deliver drugs transdermally through non-infringing formulations. Furthermore, there is no assurance that any of our future processes or products will be patentable, that any pending or additional patents will be issued in any or all appropriate jurisdictions or that our processes or products will not infringe upon the patents of third parties.

We also rely on trade secrets, unpatented proprietary know-how and continuing technological innovation. We use confidentiality agreements with licensees, suppliers, employees and consultants to protect our trade secrets, unpatented proprietary know-how and continuing technological innovation, but there can be no assurance that these parties will not breach their agreements with us. We also cannot be certain that we will have adequate remedies for any breach. Disputes may arise concerning the ownership of intellectual property or the applicability of confidentiality agreements. Furthermore, we cannot be sure that our trade secrets and proprietary technology will not otherwise become known or that our competitors will not independently develop our trade secrets and proprietary technology.

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Third parties may claim that we infringe their proprietary rights, forcing us to expend substantial resources in resulting litigation, the outcome of which is uncertain. Any unfavorable outcome could negatively affect our financial position and results of operations.

Our success will also depend, in part, on our ability to operate without infringing the proprietary rights of others, and there can be no assurance that our products and processes will not infringe upon the patents of others. Third parties may also institute patent litigation against us for competitive reasons unrelated to any infringement by us. If a third party asserts a claim of infringement, we may have to seek licenses, defend infringement actions or challenge the validity of those third-party patents in court. If we cannot obtain the required licenses, or are found liable for infringement or are not able to have these patents declared invalid, we may be liable for significant monetary damages, encounter significant delays in bringing products to market or be precluded from participating in the manufacture, use or sale of products or methods of drug delivery covered by the patents of others. There can be no assurance that we have identified, or that in the future we will be able to identify, all U.S. and foreign patents that may pose a risk of potential infringement claims.

We may experience reductions in the levels of reimbursement for our products by governmental authorities, private health insurers and managed care organizations.

Our ability and our marketing partners ability to commercialize our products, including MethyPatch®, is dependent in part on obtaining reimbursement from government health authorities, private health insurers and managed care organizations. The trend toward managed healthcare in the United States and the prominence of health maintenance organizations (HMOs) and similar entities could significantly influence the purchase of our products, resulting in lower prices and lower demand. This is particularly true in a market that includes generic alternatives, such as the ADHD market. There can be no assurance that Shire will obtain acceptable reimbursement status for MethyPatch®. Additionally, if Strattera®, a non-stimulant ADHD treatment, becomes recognized as therapeutically superior to stimulant-based treatments such as MethyPatch®, the reimbursement status of MethyPatch® may be adversely affected. There can also be no assurance that managed care agreement established by Novartis will not adversely affect Novogyne s financial results. In Europe, Novartis Pharma has informed us that Estradot® has been launched in Spain (without government reimbursement) and that reimbursement and pricing issues are adversely affecting its launch plans in several European markets.

Health care reform or other changes in government regulation could harm our business.

The federal and state governments in the United States, as well as many foreign governments, from time to time explore ways to reduce medical care costs through health care reform. In the United States, these proposals include government programs involving prescription drug reimbursement benefits for seniors. Due to the diverse range of proposals put forth from country to country and the uncertainty of any proposal s adoption, we cannot predict what impact any reform proposal ultimately adopted may have on the pharmaceutical industry or on our business, financial position or results of operations.

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We may be exposed to product liability claims.

Like all pharmaceutical companies, the testing, manufacturing and marketing of our products may expose us to potential product liability and other claims resulting from their use. The publication of the HT study data described above may increase the likelihood of product liability claims against us. We are aware that claims have been brought against Wyeth Pharmaceuticals with respect to their oral HT product that was the particular subject of the HT study. If any such claims against us are successful, we may be required to make significant compensation payments and suffer the associated adverse publicity. We maintain product liability insurance, but there can be no assurance that our insurance will cover all future claims or that we will be able to maintain existing coverage or obtain additional coverage at reasonable rates. The trend in the pharmaceutical insurance market is toward narrower coverage and higher premiums, with certain pharmaceutical compounds specifically excluded from coverage. If a claim is not covered or if our coverage is insufficient, we may incur significant liability payments that would negatively affect our business, financial position or results of operations.

All of our products are manufactured at one location. An interruption of production at this facility could negatively affect our business, financial position and results of operations.

All of our products are manufactured at a single facility in Miami, Florida. An interruption of manufacturing resulting from regulatory issues, technical problems, casualty loss (including hurricane) or other factors could result in our inability to meet production requirements, which may cause us to lose revenues and which could have an adverse effect on our relationships with our partners and customers, any of which could have a material adverse effect on our business, financial position or results of operations. Without our existing production facility, we would have no other means of manufacturing our products until we were able to restore the manufacturing capability at our facility or develop an alternative manufacturing facility. Although we carry business interruption insurance to cover lost revenues and profits resulting from casualty losses, this insurance does not cover all possible situations and there can be no assurance that any event of casualty to our facility would be covered by such insurance. In addition, our business interruption insurance would not compensate us for the loss of opportunity and potential adverse impact on relations with our existing partners and customers resulting from our inability to produce products for them.

Our insurance coverage may not be adequate and rising insurance premiums could negatively affect our profitability.

We rely on insurance to protect us from many business risks, including product liability, business interruption, property and casualty loss, employment practices liability and directors and officers liability. An increase in the number of securities class action suits, an increase in damages and/or settlements paid in connection with certain of these class actions, an increase in the number of product liability claims and the resulting damages and settlements, including those resulting from the HT studies discussed above, and other factors we have experienced, and expect to continue to experience, could result in difficulty in obtaining adequate coverage at historical rates. The recent corporate and accounting scandals involving large public companies have also served to increase the cost of insurance to all businesses. In most cases, as is the trend in the pharmaceutical industry, as insurance policies expire, we may be required to procure policies with narrower coverage, more exclusions and higher premiums. In some cases, coverage may not be available at any price. There can be no assurance that the insurance that we maintain and intend to maintain will be adequate, or that the cost of insurance and limitations in coverage will not adversely affect our business, financial position or results of operations.

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We enter into agreements that include provisions that require us to indemnify the other party. Our financial position and results of operations could be harmed if we are required to perform under these indemnification provisions.

In the normal course of business, we enter into license, supply, employment and other agreements that include indemnification provisions. While insurance coverage may mitigate some of our obligations under these indemnification provisions, our business, financial position and results of operations could be harmed if we are required to perform under these indemnification provisions and there is no or insufficient insurance coverage.

Our success depends on attracting and retaining our key employees.

Our success depends on our ability to attract and retain qualified, experienced personnel. We face significant competition in recruiting competent personnel. In the past, our location in an area with relatively few pharmaceutical companies has made recruitment more difficult, as many candidates prefer to work in places with a broad pharmaceutical industry presence. The loss of key personnel, or the inability to attract and retain additional, competent employees, could adversely affect our business, financial position or results of operations.

Our stockholders rights plan, our charter documents, Delaware law and our joint venture with Novartis may have an anti-takeover effect.

Our stockholders rights plan, our corporate charter documents, Delaware law and our joint venture operating agreement with Novartis each include provisions that may discourage or prevent parties from attempting to acquire us. These provisions may have the effect of depriving our stockholders of the opportunity to sell their stock at a price in excess of prevailing market prices in an acquisition of Noven. We have a stockholders rights plan, commonly referred to as a poison pill, which is intended to cause substantial dilution to a person or group who attempts to acquire us on terms that our Board of Directors has not approved. The existence of the stockholders rights plan could make it more difficult for a third party to acquire a majority of our common stock without the consent of our Board of Directors. Certain provisions of our certificate of incorporation and bylaws could have the effect of making it more difficult for a third party to acquire a majority of our outstanding voting common stock. These include provisions that limit the ability of stockholders to bring matters before an annual meeting of stockholders, call special meetings or nominate candidates to serve on our Board of Directors.

We are also subject to the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. For purposes of Section 203, a business combination includes a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and an interested stockholder is a person who, either alone or together with affiliates and associates, owns (or within the past three years, did own) 15% or more of the corporation s voting stock.

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In addition, the operating agreement for our joint venture with Novartis has a buy/sell provision that either party may trigger by notifying the other party of the price at which the triggering party would be willing to acquire the joint venture. In response to this notice, the non-triggering party has the option to either purchase the triggering party s interest in Novogyne or to sell its own interest in Novogyne to the triggering party at the price established by the triggering party. In addition, if Novartis is the seller, then Novartis is entitled to an additional amount equal to the net present value of Novartis preferred profit return. This amount is calculated by applying a specified discount rate and a period of 10 years to Novartis $6.1 million annual preferred return. As a result of the buy/sell provision, any potential acquirer of Noven faces the possibility that Novartis could trigger this provision at any time and thereby require the acquirer to either purchase for cash Novartis interest in Novogyne or to sell its interest in Novogyne to Novartis. The existence of the buy/sell provision and the uncertainty it may create could discourage an acquisition of Noven by a third party, which could have an adverse effect on the market price for our common stock.

The market price for our common stock is volatile.

The market price of our common stock is volatile. From January 1, 2003 to March 1, 2004, our common stock traded as low as $7.30 per share and as high as $24.83 per share. Any number of factors, including some over which we have no control and some unrelated to our business or financial results, may have a significant impact on the market price of our common stock, including: announcements by us or our competitors of technological innovations or new commercial products, changes in governmental regulation, receipt by us or one of our competitors of regulatory approvals or adverse regulatory determinations, developments relating to our patents or proprietary rights of one of our competitors, publicity regarding actual or potential medical results or risks for products that we or one of our competitors market or has under development; and period-to-period changes in financial results and the economy generally. We, like any other company with a volatile stock price, may be subject to further securities litigation, which could have a material adverse effect on our business and financial results.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 8. Financial Statements and Supplementary Data.

See Index to Financial Statements at page 71 of this report.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

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Item 9A. Controls and Procedures.

Within 90 days prior to the date of this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective in timely alerting them to material information relating to Noven required to be included in our periodic Securities and Exchange Commission filings. However, that conclusion should be considered in light of the various limitations described below on the effectiveness of those controls and procedures, some of which pertain to most if not all business enterprises, and some of which arise as a result of the nature of our business. Our management, including the Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures will prevent all error and all improper conduct. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of improper conduct, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Further, the design of any system of controls also is based in part upon assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. Furthermore, our level of historical and current equity participation in Novogyne may substantially impact the effectiveness of our disclosure controls and procedures. Because we do not control Novogyne, and Novogyne s financial, accounting, inventory and sales deductions functions are performed by Novartis, our disclosure controls and procedures with respect to Novogyne are necessarily more limited than those we maintain with respect to ourselves. No significant changes were made in our internal controls or in other factors that could significantly affect these controls subsequent to the date of the Chief Executive Officer s and Chief Financial Officer s evaluation.

PART III

Item 10. Directors and Executive Officers of the Registrant.

The information concerning directors required by item 10 is incorporated by reference to our Proxy Statement for our 2003 Annual Meeting of Shareholders. The information concerning executive officers required by item 10 is contained in the discussion entitled Executive Officers of the Registrant in Part I hereof.

Item 11. Executive Compensation.

The information required by item 11 is incorporated by reference to our Proxy Statement for our 2004 Annual Meeting of Shareholders.

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Item 12. Security Ownership of Certain Beneficial Owners and Management.

The information required by item 12 is incorporated by reference to our Proxy Statement for our 2004 Annual Meeting of Shareholders.

Item 13. Certain Relationships and Related Transactions.

The information required by item 13 is incorporated by reference to our Proxy Statement for our 2004 Annual Meeting of Shareholders.

Item 14. Principal Accounting Fees and Services.

The information required by item 14 is incorporated by reference to our Proxy Statement for our 2004 Annual Meeting of Shareholders.

PART IV

Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K.

(a)(1) Financial Statements

See Index to Financial Statements at page 71 of this report.

(a)(2) Financial Statement Schedules

All schedules have been omitted because the required information is not applicable or the information is included in the financial statements or the notes thereto.

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(a)(3) Exhibits

Exhibit Number	Description	Method of Filing
3.1	Noven s Restated Certificate of Incorporation.	Incorporated by reference to Exhibit 3.1 of Noven s Form 10-K for the year ended December 31, 1998 (File No. 0-17254).
3.2	Noven s Certificate of Amendment of Certificate of Incorporation dated June 5, 2001.	Incorporated by reference to Exhibit 3.1 of Noven s Form 10-Q for the quarter ended June 30, 2001 (File No. 0-17254).
3.3	Certificate of Designations of Series A Junior Participating Preferred Stock of Noven Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 3.3 of Noven s Form 10-K for the year ended December 31, 2001 (File No. 0-17254)
3.4	Noven s Bylaws, as amended and restated as of February 8, 2001.	Incorporated by reference to Exhibit 3.2 of Noven s Form 10-K for the year ended December 31, 2000 (File No. 0-17254).
4.1	Rights Agreement by and between Noven and American Stock Transfer & Trust Company dated November 6, 2001.	Incorporated by reference to Exhibit 4.1 of Noven s Form 8-K dated November 6, 2001 (File No. 0-17254).
10.1	Noven Pharmaceuticals, Inc. Amended and Restated Stock Option Plan.*	Incorporated by reference to Noven s Form 10-K for the year ended December 31, 1990 (File No. 0-17254), as further amended on June 23, 1992 and incorporated

		by reference to the definitive Proxy Statement dated May 11, 1992, for the Annual Meeting of Shareholders held on June 23, 1992.
10.2	Amendment to Noven Pharmaceuticals, Inc. Amended and Restated Stock Option Plan.*	Incorporated by reference to Noven s Form 10-Q for the quarter ended June 30, 1999 (File No. 0-17254).
10.3	Noven Pharmaceuticals, Inc. 1997 Stock Option Plan.*	Incorporated by reference to Noven s definitive Proxy Statement dated May 1, 1997, for the Annual Meeting of Shareholders held on June 3, 1997.

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Exhibit Number	Description	Method of Filing
10.4	Amendment to Noven Pharmaceuticals, Inc. 1997 Stock Option Plan.*	Incorporated by reference to Noven s Form 10-Q for the quarter ended June 30, 1999 (File No. 0-17254).
10.5	Noven Pharmaceuticals, Inc. 1999 Long-Term Incentive Plan.*	Incorporated by reference to Noven s definitive Proxy Statement dated April 19, 1999, for the Annual Meeting of Shareholders held on June 8, 1999.
10.6	Amended and Restated Employment Agreement between Noven and Robert C. Strauss dated as of November 5, 2003*	Incorporated by reference to Exhibit 10.2 of Noven s Form 10-Q for the quarter ended September 30, 2003 (File No. 0-17254).
10.7	Form of Employment Agreement (Change in Control), between Noven and each of Eduardo G. Abrao, Diane M. Barrett, Jeffrey F. Eisenberg, W. Neil Jones and Juan A. Mantelle.*	Incorporated by reference to the Form of Employment Agreement (Change in Control) filed as Exhibit 10.7 of Noven s Form 10-K for the year ended December 31, 1999 (File No. 0-17254).
10.8	Form of Indemnification Agreement for Directors and Officers.	Incorporated by reference to Exhibit 10.4 of Noven s Form 10-K for the year ended December 31, 1998 (File No. 0-17254).
10.9	License Agreement between Noven and Ciba-Geigy Corporation dated November 15, 1991 (with certain provisions omitted pursuant to Rule 406).	Incorporated by reference to

		Exhibit 10.9 of Amendment No. 1 to Noven s Registration Statement on Form S-2 (File No. 33-45784).
10.10	Industrial Lease between Rhône-Poulenc Rorer Pharmaceuticals Inc. and Noven dated March 23, 1993 and effective February 16, 1993 (with certain provisions omitted pursuant to Rule 24b-2).	Incorporated by reference to Exhibit 10.20 of Noven s Form 10-K for the year ended December 31, 1993 (File No. 0-17254).
10.11	Operating Agreement of Vivelle Ventures LLC (a Delaware limited liability company) dated as of May 1, 1998.	Incorporated by reference to Exhibit 10.33 to Noven s Form 10-Q for the quarter ended March 31, 1998 (File No. 0-17254).
10.12	Amendment to Operating Agreement between Novartis Pharmaceuticals Corporation and Noven dated March 29, 2001.	Incorporated by reference to Exhibit 10.7 to Noven s Form 10-Q for the quarter ended March 31, 2001 (File No. 0-17254).

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Exhibit Number	Description	Method of Filing
10.13	Marketing and Promotional Services Agreement by and between Noven and Vivelle Ventures LLC dated as of May 1, 1998.	Incorporated by reference to Exhibit 10.4 to Noven s Form 10-Q for the quarter ended March 31, 1998 (File No. 0-17254).
10.14	First Amendment to Marketing and Promotional Services Agreement between Vivelle Ventures LLC and Noven dated March 29, 2001.	Incorporated by reference to Exhibit 10.6 to Noven s Form 10-Q for the quarter ended March 31, 2001 (File No. 0-17254).
10.15	Sublicense Agreement by and among Novartis Pharmaceuticals Corporation, Noven and Vivelle Ventures LLC dated as of May 1, 1998.	Incorporated by reference to Exhibit 10.35 to Noven s Form 10-Q for the quarter ended March 31, 1998 (File No. 0-17254).
10.16	Amended and Restated License Agreement between Noven and Rhône-Poulenc Rorer, Inc. dated September 30, 1999 (with certain provisions omitted pursuant to Rule 24b-2).	Incorporated by reference to Exhibit 10.1 of Noven s Form 10-Q for the quarter ended September 30, 1999 (File No. 0-17254).
10.17	Amended and Restated License Agreement between Noven and Rhône-Poulenc Rorer, Inc. dated September 30, 1999 (with certain provisions omitted pursuant to Rule 24b-2).	Incorporated by reference to Exhibit 10.2 of Noven s Form 10-Q for the quarter ended September 30, 1999 (File No. 0-17254).
10.18	Amendment No. 2 to Amended and Restated License Agreement between Rorer Pharmaceutical Products, Inc. and Noven Pharmaceuticals, Inc. dated March 29, 2001 (with certain provisions omitted pursuant to Rule 24b-2).	Incorporated by reference to Exhibit 10.2 of Noven s Form 10-Q for the quarter ended

		March 31, 2001 (File No. 0-17254).
10.19	License Agreement between Noven and Novartis Pharma AG dated as of November 3, 2000 (with certain provisions omitted pursuant to Rule 24b-2).	Incorporated by reference to Exhibit 10.2 of Noven s Form 10-Q for the quarter ended September 30, 2000 (File No. 0-17254).
10.20	License Agreement between Noven and Vivelle Ventures LLC dated March 29, 2001 (with certain provisions omitted pursuant to Rule 24b-2).	Incorporated by reference to Exhibit 10.1 of Noven s Form 10-Q for the quarter ended March 31, 2001 (File No. 0-17254).

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Exhibit Number	Description	Method of Filing
10.21	Sublicense Agreement among Rorer Pharmaceutical Products, Inc., Rhône -Poulenc Rorer Inc., Aventis Pharmaceuticals Products Inc., Rhône -Poulenc Rorer International Holdings Inc., Novartis Pharma AG and Noven dated March 29, 2001 (with certain provisions omitted pursuant to Rule 24b-2).	Incorporated by reference to Exhibit 10.3 of Noven s Form 10-Q for the quarter ended March 31, 2001 (File No. 0-17254).
10.22	Purchase Agreement among Rorer Pharmaceutical Products, Inc., Aventis Pharmaceuticals Products Inc. and Vivelle Ventures LLC dated March 29, 2001 (with certain provisions omitted pursuant to Rule 24b-2).	Incorporated by reference to Exhibit 10.4 of Noven s Form 10-Q for the quarter ended March 31, 2001 (File No. 0-17254).
10.23	Supply Agreement between Vivelle Ventures LLC and Noven dated March 29, 2001 (with certain provisions omitted pursuant to Rule 24b-2).	Incorporated by reference to Exhibit 10.5 of Noven s Form 10-Q for the quarter ended March 31, 2001 (File No. 0-17254).
10.24	Development Agreement between Novartis Pharma AG and Noven dated June 1, 2001.	Incorporated by reference to Exhibit 10.1 of Noven s Form 10-Q for the quarter ended June 30, 2001 (File No. 0-17254).
10.25	Transaction Agreement among Shire US Inc., Shire Pharmaceuticals Group PLC and Noven dated February 26, 2003 (with certain provisions omitted pursuant to Rule 24b-2)**.	Incorporated by reference to Exhibit 10.25 of Noven s Form 10-K for the year ended December 31, 2002 (File No. 0-17254).
10.26	License Agreement among Shire US Inc., Shire Pharmaceuticals Group PLC and Noven dated as April 7, 2003 (with certain provisions omitted pursuant to Rule 24b-2)**.	Incorporated by reference to Exhibit 10.25 of Noven s Form 10-K for the year ended

		December 31, 2002 (File No. 0-17254).
10.27	Toll Conversion and Supply Agreement among Shire US Inc., Shire Pharmaceuticals Group PLC and Noven dated as April 7, 2003 (with certain provisions omitted pursuant to Rule 24b-2)**.	Incorporated by reference to Exhibit 10.25 of Noven s Form 10-K for the year ended December 31, 2002 (File No. 0-17254).
10.28	Agreement between Shire US, Inc. and Noven dated November 5, 2003**.	Incorporated by reference to Exhibit 10.1 of Noven s Form 10-Q for the quarter ended September 30, 2003 (File No. 0-17254).

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Exhibit Number	Description	Method of Filing
10.29	Agreement between Noven and P&G Pharmaceuticals, Inc. dated April 28, 2003 (with certain provisions omitted pursuant to Rule 24b-2)**.	Filed herewith.
10.30	License Agreement between Noven and Endo Pharmaceuticals, Inc. dated February 25, 2004 (with certain provisions omitted pursuant to Rule 24b-2)**.	Filed herewith.
10.31	Supply Agreement between Noven and Endo Pharmaceuticals, Inc. dated February 25, 2004 (with certain provisions omitted pursuant to Rule 24b-2)**.	Filed herewith.
11	Computation of Earnings per Share.	Filed herewith.
21	Subsidiaries of the Registrant.	Filed herewith.
23.1	Consent of Deloitte & Touche LLP.	Filed herewith.
23.2	Consent of PricewaterhouseCoopers LLP.	Filed herewith.
31.1	Certification of Robert C. Strauss, President, Chief Executive Officer and Chairman of the Board, pursuant to Securities Exchange Act Rules 13a-15(c) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
31.2	Certification of Diane M. Barrett, Vice President and Chief Financial Officer, pursuant to Securities Exchange Act Rules 13a-15(c) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith.

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Exhibit Number	Description	Method of Filing
32.1	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.	Filed herewith.
32.2	Certification of Diane M. Barrett, 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.	Filed herewith.

* Compensation Plan or Agreement.

** Certain exhibits and schedules to this document have not been filed. The Registrant agrees to furnish a copy of any omitted schedule or exhibit to the Securities and Exchange Commission upon request.

(b) **Reports on Form 8-K.**
We did not file any Current Reports on Form 8-K during the three months ended December 31, 2003.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

Date: March 9, 2004

NOVEN PHARMACEUTICALS, INC.

By: /s/ Robert C. Strauss
Robert C. Strauss
President, Chief Executive Officer and
Chairman of the Board

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
By: /s/ Robert C. Strauss Robert C. Strauss (President, CEO and Chairman of the Board)	Principal Executive Officer and Chairman of the Board	March 9, 2004
By: /s/ Diane M. Barrett Diane M. Barrett (Vice President and Chief Financial Officer)	Principal Financial and Accounting Officer	March 9, 2004
By: /s/ Sidney Braginsky Sidney Braginsky	Director	March 9, 2004
By: /s/ John G. Clarkson, M.D. John G. Clarkson, M.D.	Director	March 9, 2004
By: /s/ Donald A. Denkhaus Donald A. Denkhaus	Director	March 9, 2004
By: /s/ Lawrence J. DuBow	Director	March 9, 2004

Lawrence J. DuBow		
By: /s/ Regina E. Herzlinger	Director	March 9, 2004
Regina E. Herzlinger		
By: /s/ Robert G. Savage	Director	March 9, 2004
Robert G. Savage		
By: /s/ Wayne P. Yetter	Director	March 9, 2004
Wayne P. Yetter		

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INDEX TO FINANCIAL STATEMENTS

NOVEN PHARMACEUTICALS, INC.

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INDEPENDENT AUDITORS REPORT

To the Board of Directors and Stockholders
of Noven Pharmaceuticals, Inc.:

We have audited the accompanying balance sheets of Noven Pharmaceuticals, Inc. (Noven) as of December 31, 2003 and 2002, and the related statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2003. These financial statements are the responsibility of Noven s management. Our responsibility is to express an opinion on these financial statements based on our audits. We did not audit the financial statements of Vivelle Ventures LLC (d/b/a Novogyne Pharmaceuticals), Noven s investment in which is accounted for by use of the equity method, for the years ended December 31, 2003, 2002 and 2001. Noven s equity in Vivelle Ventures LLC of $28,368,000 and $34,684,000 at December 31, 2003 and 2002, respectively, and Noven s share of that joint venture s income of $17,094,000, $14,368,000, and $14,013,000 for the years ended December 31, 2003, 2002 and 2001, respectively, are included in the accompanying financial statements. Such financial statements of Vivelle Ventures LLC were audited by other auditors whose report has been furnished to us, and our opinion, insofar as it relates to the amounts included for such joint venture for 2003, 2002 and 2001, is based solely on the report of such other auditors.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits and the reports of other auditors provide a reasonable basis for our opinion.

In our opinion based on our audits and the reports of other auditors, such financial statements present fairly, in all material respects, the financial position of Noven Pharmaceuticals, Inc. as of December 31, 2003 and 2002, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States of America.

Deloitte & Touche LLP
Certified Public Accountants

Miami, Florida
February 26, 2004

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NOVEN PHARMACEUTICALS, INC.

Balance Sheets
December 31, 2003 and 2002
(in thousands, except share data)

	2003	2002
Assets		
Current Assets:		
Cash and cash equivalents	$ 83,381	$ 58,684
Accounts receivable trade (less allowance for doubtful accounts of $84 in 2003 and $79 in 2002)	3,809	4,359
Accounts receivable Novogyne, net	6,320	2,581
Inventories	5,200	5,613
Net deferred income tax asset, current portion	6,500	2,600
Prepaid income taxes and other current assets	3,219	541
	108,429	74,378
Property, plant and equipment, net	18,354	16,232
Other Assets:		
Investment in Novogyne	28,368	34,684
Net deferred income tax asset	12,175	9,831
Patent development costs, net	1,977	1,996
Deposits and other assets	181	581
	42,701	47,092
	$169,484	$137,702
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable	$ 4,060	$ 5,062
Notes payable current portion		8
Accrued compensation and related liabilities	3,734	3,549
Other accrued liabilities	2,090	2,063
Deferred contract revenues	772	829
Deferred license revenues current portion	21,112	3,525
	31,768	15,036

Long-Term Liabilities:		
Notes payable		5
Deferred license revenues	28,893	25,920
	60,661	40,961
Commitments and Contingencies (Note 14)		
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 22,722,060 in 2003 and 22,579,112 in 2002	2	2
Additional paid-in capital	79,244	78,358
Retained earnings	29,577	18,381
	108,823	96,741
	$169,484	$137,702

The accompanying notes are an integral part of these statements.

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NOVEN PHARMACEUTICALS, INC.

Statements of Operations
Years Ended December 31, 2003, 2002 and 2001
(in thousands, except per share amounts)

	2003	2002	2001
Revenues:			
Product revenues Novogyne:			
Product sales	$15,932	$25,394	$16,689
Royalties	4,978	4,505	4,037
Product revenues Novogyne	20,910	29,899	20,726
Product revenues third parties	16,206	20,300	21,321
Total product revenues	37,116	50,199	42,047
License and contract revenues	6,050	5,173	3,900
Net revenues	43,166	55,372	45,947
Expenses:			
Cost of products sold	19,482	22,973	20,376
Research and development	8,082	11,634	10,973
Marketing, general and administrative	15,858	14,257	11,554
Total expenses	43,422	48,864	42,903
(Loss) income from operations	(256)	6,508	3,044
Equity in earnings of Novogyne	17,094	14,368	14,013
Interest income, net	659	822	1,770
Income before income taxes	17,497	21,698	18,827
Provision for income taxes	6,301	7,819	6,736

Net income	$11,196	$13,879	$12,091
Basic earnings per share	$ 0.50	$ 0.62	$ 0.54
Diluted earnings per share	$ 0.49	$ 0.60	$ 0.51
Weighted average number of common shares outstanding:			
Basic	22,544	22,532	22,367
Diluted	22,989	23,321	23,511

The accompanying notes are an integral part of these statements.

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NOVEN PHARMACEUTICALS, INC.

Statements of Stockholders Equity
Years Ended December 31, 2003, 2002 and 2001
(in thousands)

	Common Stock		Additional Paid-in Capital	Retained Earnings/ (Accumulated Deficit)	Total
	Shares	Amount			
Balance at December 31, 2000	22,178	$ 2	$72,864	$ (7,589)	$ 65,277
Issuance of shares pursuant to stock option plan, net	304		3,090		3,090
Tax benefit from exercise of stock options			1,385		1,385
Issuance of options to charitable organization			55		55
Net income				12,091	12,091
Balance at December 31, 2001	22,482	2	77,394	4,502	81,898
Issuance of shares pursuant to stock option plan, net	97		771		771
Tax benefit from exercise of stock options			153		153
Issuance of options to charitable organization			40		40
Net income				13,879	13,879
Balance at December 31, 2002	22,579	2	78,358	18,381	96,741
Issuance of shares pursuant to stock option plan, net	245		1,617		1,617
Issuance of stock to outside directors	3		31		31
Tax benefit from exercise of stock options			527		527
Purchase and retirement of common stock	(105)		(1,289)		(1,289)
Net income				11,196	11,196
Balance at December 31, 2003	22,722	$ 2	$79,244	$ 29,577	$108,823

The accompanying notes are an integral part of these statements.

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NOVEN PHARMACEUTICALS, INC.

Statements of Cash Flows
Years Ended December 31, 2003, 2002 and 2001
(in thousands)

	2003	2002	2001
Cash flows from operating activities:			
Net income	$ 11,196	$ 13,879	$ 12,091
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	2,278	2,216	2,488
Amortization of patent costs	341	312	233
Amortization of non-competition agreement	400	400	233
Deferred income tax (benefit) expense	(6,244)	2,586	709
Expense related to issuance of shares of stock to outside directors and options to charitable organization	31	40	55
Recognition of deferred contract revenues	(2,024)	(1,787)	(1,049)
Recognition of deferred license revenues	(4,026)	(3,386)	(2,851)
Equity in earnings of Novogyne	(17,094)	(14,368)	(14,013)
Distributions from Novogyne	21,739	11,727	13,081
Changes in operating assets and liabilities:			
Decrease (increase) in accounts receivable trade, net	550	(3,051)	4,369
(Increase) decrease in accounts receivable Novogyne, net	(3,739)	2,577	(2,241)
Decrease (increase) in inventories	413	(1,289)	1,774
(Increase) decrease in prepaid income taxes and other current assets	(480)	(237)	191
Decrease (increase) in deposits and other assets		26	(1,129)
Decrease in accounts payable	(1,002)	(558)	(177)
Increase (decrease) in accrued compensation and related liabilities	185	2,031	(986)
Increase (decrease) in other accrued liabilities	27	(603)	1,775
Increase in deferred contract revenue	1,967	1,199	1,630
Increase in deferred license revenue	25,000	73	8,500
Direct expenses incurred in pursuit of MethyPatch® regulatory approval	(414)		
Cash flows provided by operating activities	29,104	11,787	24,683
Cash flows from investing activities:			
Purchases of property, plant and equipment, net	(4,400)	(2,749)	(3,033)
Contributions to Novogyne			(15,680)
Payments for patent development costs	(322)	(262)	(307)
Cash flows used in investing activities	(4,722)	(3,011)	(19,020)

Cash flows from financing activities:			
Issuance of common stock	1,617	771	3,090
Purchase and retirement of common stock	(1,289)		
Repayments of notes payable	(13)	(252)	(340)
Cash flows provided by financing activities	315	519	2,750
Net increase in cash and cash equivalents	24,697	9,295	8,413
Cash and cash equivalents, beginning of year	58,684	49,389	40,976
Cash and cash equivalents, end of year	$ 83,381	$ 58,684	$ 49,389

The accompanying notes are an integral part of these statements.

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NOVEN PHARMACEUTICALS, INC.

NOTES TO 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 advanced transdermal drug delivery technologies and prescription transdermal 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 to third party customers.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

USE OF ESTIMATES:

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

The most significant estimates made by management include: (i) revenue recognition of certain license agreements containing price adjustment provisions, minimum fee payments and/or milestone and similar payments that are dependent on licensee supporting data or estimated product life cycles or length of patents, (ii) contract revenues consisting of development fees and milestone payments that require estimates of proportional performance of work completed, (iii) determination of the fair value of employee stock options to determine compensation expense for disclosure purposes, (iv) determination of the net realizable value of the net deferred tax asset, (v) reviewing Novogyne s testing for impairment of the long-term intangible asset related to the acquisition of the marketing rights to CombiPatch®, (vi) reviewing Novogyne s estimates related to sales allowances and returns at Novogyne and (vii) estimates related to allowance for returns related to product recalls at Noven, accrued liabilities, income and other tax accruals and contingencies and litigation.

CASH AND CASH EQUIVALENTS:

Cash and cash equivalents includes all highly liquid investments with an original maturity of three months or less at the date of purchase.

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INVENTORIES:

Inventories are stated at the lower of cost (first-in, first-out method) or market. Inventory costs include material, labor and manufacturing overhead. The following are the major classes of inventories as of December 31 (in thousands):

	2003	2002
Finished goods	$ 806	$ 830
Work in process	1,722	1,390
Raw materials	2,672	3,393
Total	$5,200	$5,613

Inventories at December 31, 2003 and 2002 relate to Noven s marketed products. As appropriate, provisions are made to reduce inventories to net realizable value. To date, Noven has not experienced any difficulty acquiring materials necessary to manufacture its products. Given that certain materials and compounds, including essential polymers used by Noven, are available from limited sources and, in some cases, a single supplier, no assurance can be given that Noven will not experience difficulty in the future. Noven s policy is to immediately recognize as expense all inventory purchased for research and development purposes.

PROPERTY, PLANT AND EQUIPMENT:

Property, plant and equipment are recorded at cost. Depreciation is provided using the straight-line method over the estimated useful lives of the assets ranging up to 31 years. Leasehold improvements are amortized over the life of the lease or the service life of the improvements, whichever is shorter. Major renewals and betterments are capitalized, while maintenance repairs and minor renewals are expensed as incurred.

SOFTWARE AND DEVELOPMENT COSTS:

Noven capitalizes purchased software which is ready for service and development costs for marketable software incurred from the time the preliminary project stage is completed until the software is ready for use. Under the provisions of SOP 98-1, Accounting for the Costs of Computer Software Developed or Obtained for Internal Use , Noven capitalizes costs associated with software developed or obtained for internal use when the preliminary project stage is completed. Capitalized costs include only (i) external direct costs of materials and services consumed in developing or obtaining internal-use software, and (ii) payroll and payroll-related costs for employees who are directly associated with and who devote time to the internal-use software project. Capitalization of such costs ceases no later than the point at which the project is substantially complete and ready for its intended purpose. For the years ended December 31, 2003 and 2002, approximately $200,000 and $400,000, respectively, of these costs were capitalized.

Computer software maintenance costs related to software development are expensed as incurred. Software development costs are amortized using the straight-line method over three years, but not exceeding the expected life of the product.

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IMPAIRMENT OF LONG LIVED ASSETS:

Long-lived assets and certain identifiable intangibles are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. If the fair value is less than the carrying amount of the asset, a loss is recognized for the difference. Fair value is determined based on market quotes, if available, or is based on valuation techniques.

PATENT DEVELOPMENT COSTS:

Costs related to the development of patents, principally legal fees, are capitalized and amortized over the lesser of their estimated economic useful lives or their remaining legal lives.

INCOME TAXES:

Noven accounts for income taxes in accordance with the provisions of Statement of Financial Accounting Standards (SFAS) No. 109, Accounting for Income Taxes . SFAS 109 provides that income taxes are accounted for using an asset and liability method which requires the recognition of deferred income tax assets and liabilities for expected future tax consequences of temporary differences between tax bases and financial reporting carrying values of assets and liabilities (see Note 8).

REVENUE RECOGNITION:

Substantially all of Noven s product revenues were for sales to its licensees, Novogyne, Novartis Pharma AG and its affiliates (Novartis Pharma) and Aventis Pharma AG (see Notes 5 and 6). Revenues from product sales are recognized at the time of shipment when both title and the risks and rewards of ownership have been transferred to the buyer. Certain of Noven s license agreements provide that the ultimate supply price is based on a percentage of the licensee s net selling price. Each of those agreements also establishes a fixed minimum supply price per unit that represents the lowest price Noven is entitled to receive on sales to the licensee. Noven receives the minimum price at the time of shipment with the possibility of an upward adjustment later when the licensee s net selling price is known. Revenues under these agreements are recorded at the minimum price at the time of shipment. Noven records any upward adjustments to revenues at the time that the information necessary to make the determination is received from the licensee. If the upward adjustments are not determinable, Noven records the adjustments (which historically have not been significant) on a cash basis. These amounts are included in product revenues.

Royalty revenues consist of royalties payable by Novogyne and Novartis Pharma from sales of Vivelle® and Vivelle-Dot®/Estradot® in the United States and Canada. Noven accrues royalties from Novogyne s and Novartis Pharma s product sales each quarter based on Novogyne s and Novartis Pharma s net sales for that quarter. Royalties are included in product revenues.

License revenues consist of up-front, milestone and similar payments under license agreements and are not recognized until earned under the terms of the applicable agreements. In most cases, license revenues are deferred and recognized over the estimated product life cycle or the length of relevant patents, whichever is shorter.

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Contract revenues consist of contract payments related to research and development projects performed for third parties. The work performed by Noven includes feasibility studies to determine if a specific drug is amenable to transdermal drug delivery, the actual formulation of a specific drug into a transdermal drug delivery system, studies to address the ongoing stability of the drug in a transdermal drug delivery system and manufacturing of batches of product that can be used in human clinical trials. Noven receives contract payments for the work it performs in the following forms:

nonrefundable up-front payments prior to commencing the work (or certain phases of the work);

additional payments upon completion of additional phases; and

in some cases, success milestone payments based on achievement of specified performance criteria.

As prescribed by EITF 00-21 Accounting for Revenue Arrangements with Multiple Deliverables , Noven analyzes each contract in order to separate each deliverable into separate units of accounting and then recognizes revenues for those separated units at their fair value, as delivered, based on the proportionate share of the work performed by Noven as it performs under the contract. If each deliverable does not qualify as a separate unit of accounting, the deliverables are combined and the amounts under the contract are allocated to the combined deliverables. The appropriate recognition of revenue is then determined for the combined deliverables as a single unit of accounting. The difference between the amount of the payments received and the amount recognized is recorded as deferred revenues until that amount is earned in accordance with SEC Staff Accounting Bulletin 101, Revenue Recognition in Financial Statements (SAB 101).

Milestone payments are recorded when the specified performance criteria are achieved, as determined by the customer. Each contract may have different payment terms. Therefore, the timing of revenue recognition may vary from contract to contract.

Revenues are net of an allowance for returns. Noven establishes allowances for returns for product that has been recalled or that it believes is probable of being recalled. The methodology used by Noven to estimate product recall returns is based on the distribution and expiration dates of the affected product and overall trade inventory levels. These estimates are based on currently available information, and the ultimate outcome may be significantly different than the amounts estimated given the subjective nature and complexities inherent in this area and in the pharmaceutical industry. During 2003, Novartis initiated recalls of certain lots of CombiPatch® and Vivelle-Dot® due to production issues. Revenues for 2003 are net of approximately $1.4 million and $6.5 million in allowances for returns at Noven and Novogyne, respectively. If Noven s estimate concerning the scope of, or amount of, the product returns is incorrect or if Novartis should initiate further unexpected recalls, then Noven s results of operations could be materially different.

Noven s revenue recognition policy is in compliance with the requirements of SAB 101.

COST OF PRODUCTS SOLD:

Direct and indirect costs of manufacturing are included in cost of products sold.

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RESEARCH AND DEVELOPMENT COSTS:

Research and development costs include costs of internally generated research and development activities and costs associated with work performed under agreements with third parties. Research and development costs include direct and allocated expenses and are expensed as incurred.

EARNINGS PER SHARE:

Noven computes its Earnings Per Share in accordance with Statement of Financial Accounting Standards No. 128, Earnings Per Share . Basic earnings per share excludes all dilution. It is based on income attributable to common stockholders and the weighted average number of common shares outstanding during the period. Diluted earnings per share reflects the potential dilution that would occur if securities or other contracts to issue common stock were exercised or converted into common stock. Common stock equivalents are not included in the diluted earnings per share calculation if the effect of their inclusion would be antidilutive. The total number of common stock equivalents not included in the diluted earnings per share calculation as of December 31, 2003 was 2,107,959 shares which represents out-of-the-money stock options.

COMPREHENSIVE INCOME:

For the years ended December 31, 2003, 2002 and 2001, total comprehensive income was equal to net income.

EMPLOYEE STOCK PLANS:

In accordance with the provisions of Statement of Financial Accounting Standards No. 123 (SFAS 123), Accounting for Stock-Based Compensation , as amended by Statement of Financial Accounting Standards No. 148 (SFAS 148), Accounting for Stock-Based Compensation Transition and Disclosure , Noven may elect to continue to apply the provisions of the Accounting Principles Board s Opinion No. 25 (APB 25, Accounting for Stock Issued to Employees) and related interpretations in accounting for its employee stock option plans, or adopt the fair value method of accounting prescribed by SFAS 123. Noven has elected to continue to account for its stock plans using APB 25, and therefore no stock-based employee compensation cost is reflected in net income, as all options granted under those plans had an exercise price equal to the market value of the underlying common stock on the date of grant.

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The following table illustrates the effect on net income and earnings per share if the company had applied the fair value recognition provisions of SFAS 123, as amended by SFAS 148:

	2003	2002	2001
Net income:			
As reported	$11,196	$13,879	$12,091
Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(3,596)	(4,443)	(4,916)
Pro forma	$ 7,600	$ 9,436	$ 7,175
Basic earnings per share:			
As reported	$ 0.50	$ 0.62	$ 0.54
Pro forma	$ 0.34	$ 0.42	$ 0.32
Diluted earnings per share:			
As reported	$ 0.49	$ 0.60	$ 0.51
Pro forma	$ 0.33	$ 0.40	$ 0.31

SFAS 123 requires the use of option valuation models that require the input of highly subjective assumptions, including expected stock price volatility. 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.

The effect of applying the fair value method of accounting for stock options on reported net income and earnings per share for 2003, 2002 and 2001 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.

The fair value of each option granted during 2003, 2002 and 2001 is estimated as $10.60, $9.65 and $12.80, respectively, on the date of the grant using the Black Scholes option-pricing model with the assumptions listed below:

	2003	2002	2001
Volatility	80.0%	85.0%	92.0%
Risk free interest rate	3.22%	3.22%	4.11%
Expected life (years)	5	6	6

SEGMENT INFORMATION:

Noven is engaged principally in one line of business, the development and commercialization of advanced transdermal drug delivery products and technologies and prescription transdermal products. See Note 12 for disclosures about geographic areas and major customers in accordance with Statement of Financial Accounting Standards No. 131 (SFAS 131), Disclosure about Segments of an Enterprise and Related Information .

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FAIR VALUE OF FINANCIAL INSTRUMENTS:

The carrying amounts of financial instruments such as cash and cash equivalents, accounts receivable, accounts payable and accrued expenses reasonably approximate fair value because of the short maturity of these items.

CONCENTRATIONS OF CREDIT RISK:

Noven s customers consist of Novogyne, Novartis Pharma and a limited number of pharmaceutical companies with worldwide operations. Noven performs ongoing credit evaluations of its customers financial condition and generally requires no collateral to secure accounts receivable. Noven maintains an allowance for doubtful accounts based on an assessment of the collectability of such accounts. Noven maintains all its cash and cash equivalents in one money-market fund.

RECLASSIFICATION:

Certain reclassifications have been made to the prior financial statements to conform to the current year s presentation.

RECENT ACCOUNTING PRONOUNCEMENTS:

In December 2003, the FASB issued Interpretation No. 46R, *Consolidation of Variable Interest Entities* (FIN 46). This Interpretation of Accounting Research Bulletin 51, *Consolidated Financial Statements*, addresses consolidation by business enterprises of variable interest entities which have one or both of the following characteristics: (i) the equity investment at risk is not sufficient to permit the entity to finance its activities without additional subordinated financial support from other parties, which is provided through other interests that will absorb some or all of the expected losses of the entity, and (ii) the equity investors lack one or more of the characteristics of a controlling financial interest. This interpretation applies immediately to variable interest entities created after January 31, 2003, and to variable interest entities in which an enterprise obtains an interest after that date. It applies no later than the first reporting period ending March 15, 2004 to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. Noven s investment in Novogyne is not considered a variable interest in a Variable Interest Entity (VIE) under the provisions of FIN 46. Therefore, the consolidation and disclosure rules of FIN 46 are not applicable to Noven, and Noven does not expect any impact on its financial statements from adopting this interpretation. These conclusions are based on currently available information and require Noven to assess its investment interest and ownership rights in Novogyne. If Noven s conclusions or its underlying assumptions of factual information concerning its investment in Novogyne were to change, Novogyne may be considered a VIE and Noven s investment in Novogyne could become subject to the consolidation and disclosure rules of FIN 46. In that case, a determination would have to be made as to the primary beneficiary of Novogyne s interest. The primary beneficiary would then consolidate Novogyne. Noven believes that even if a determination were made that Novogyne was a VIE at December 31, 2003, Novartis is the primary beneficiary due to its preferred return and its 51% equity interest in Novogyne and would continue to consolidate Novogyne.

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In April 2003, the FASB issued Statement No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities*. This statement amends and clarifies financial reporting for derivative instruments and for hedging activities accounted for under Statement 133 and is effective for contracts entered into or modified, and for hedges designated, after June 30, 2003. Noven has not experienced, and does not anticipate, a significant impact on its financial statements from adopting this statement.

In May 2003, the FASB issued Statement No. 150, *Accounting for Certain Instruments with Characteristics of Both Liabilities and Equity.* This statement establishes how an issuer classifies and measures certain freestanding financial instruments with characteristics of liabilities and equity and requires that such instruments be classified as liabilities. This statement is effective for financial instruments entered into or modified after May 31, 2003 and is otherwise effective at the beginning of the first interim period beginning after December 15, 2003. Noven has not experienced, and does not anticipate, a significant impact on its financial statements from adopting this statement.

3. CASH FLOW INFORMATION:

Cash payments for income taxes were $13.2 million, $6.1 million and $3.9 million in 2003, 2002 and 2001, respectively. Cash payments for interest were $1,000, $14,000 and $35,000 in 2003, 2002 and 2001, respectively.

Non-cash Operating Activities

In connection with the CombiPatch® transaction described in Note 5 below, in March 2001, Noven recorded a $40.0 million receivable from Novogyne and a $40.0 million payable to Aventis Pharmaceuticals, the United States pharmaceuticals business of Aventis Pharma AG (Aventis). In 2002 and 2001, Novogyne paid $10 million and $30 million, respectively, directly to Aventis.

In 2002, the State of New Jersey enacted legislation that requires Novogyne to remit estimated state tax payments on behalf of its owners, Noven and Novartis. In April 2003, Novogyne paid $1.7 million to the New Jersey Department of Revenue, representing Noven s portion of Novogyne s estimated state tax payment. This payment was deemed a distribution to Noven.

Noven recorded a $0.5 million, $0.2 million and $1.4 million income tax benefit to additional paid-in capital derived from the exercise of non-qualified stock options and disqualifying dispositions of incentive stock options in 2003, 2002 and 2001, respectively.

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4. PROPERTY, PLANT AND EQUIPMENT, NET:

Property, plant and equipment consists of the following at December 31, 2003 and 2002 (in thousands, except estimated useful lives):

	2003	2002	Estimated Useful Lives (in years)
Land	$ 2,540	$ 2,540	
Building and improvements	3,107	2,875	40
Leased property and leasehold improvements	9,926	8,918	15-31
Manufacturing and testing equipment	12,844	10,036	3-10
Furniture	1,210	1,103	9-10
Software and software development costs	2,115	1,870	3
	31,742	27,342	
Less accumulated depreciation and amortization	(13,388)	(11,110)	
	$ 18,354	$ 16,232	

5. LICENSE AND CONTRACT AGREEMENTS:

Noven has license agreements with Aventis, Novartis, Novartis Pharma and Novogyne. At the time of the formation of Novogyne, Novartis sublicensed its rights under its license agreement to Novogyne. Noven s agreement with Novogyne grants Novogyne the right to market Noven s transdermal estrogen delivery systems in the United States and Canada. Novartis Canadian affiliate markets Noven s second generation estrogen delivery system in Canada. The agreement provides for royalty payments based on sales by Novogyne and Novartis Canadian affiliate.

AVENTIS LICENSE:

Noven has two license agreements with Aventis. These agreements grant Aventis the right to market Noven s first generation transdermal estrogen delivery system worldwide except for the United States and Canada and to market Noven s transdermal combination estrogen/progestin delivery system worldwide. The agreements also grant Aventis the right to market Noven s second generation transdermal estrogen delivery system in Japan. In June 1992, as part of the license agreements, Aventis funded $7 million for the construction of a manufacturing facility for the production by Noven of transdermal drug delivery systems. Noven leases the facilities from Aventis for $1.00 per year for a term that expires upon the earlier of 2024 or the termination of our license agreement with Aventis. Noven has the right to purchase the facility at any time for Aventis book value, or when fully depreciated, for $1.00. Aventis may terminate the lease prior to the expiration of its term upon termination or expiration of Noven s 1992 license agreement with Aventis. For accounting purposes, Noven treated the exchange of the funding of the facility for the license as a non-monetary exchange at fair value. Since Aventis paid $7 million for the construction of the manufacturing facility,

that amount was determined to be the fair market value. Noven recorded both the facility and deferred license revenues at amounts equal to the funds advanced by Aventis, which are deferred and recognized as depreciation expense and license revenues over the life of the underlying lease, which expires in 2024. At December 31, 2003 and 2002, the carrying amount of the leased property and deferred revenues was $4.5 million and $4.7 million, respectively.

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NOVARTIS PHARMA SUBLICENSES FROM AVENTIS:

In October 1999, Novartis Pharma sublicensed Aventis rights to market (i) Noven s combination estrogen/progestin transdermal delivery system in all countries other than the United States and Japan, and (ii) Noven s first generation estrogen transdermal delivery system in all countries other than the United States, Canada and Japan.

NOVARTIS PHARMA LICENSE OF ESTRADOT®:

In November 2000, Noven entered into an exclusive license agreement with Novartis Pharma pursuant to which Noven granted Novartis Pharma the right to market Noven s second generation transdermal estrogen delivery system under the name Estradot® in all countries other than the United States, Canada and Japan. The agreement also grants Novartis Pharma marketing rights in the same territories to any product improvements and future generations of estrogen patches developed by Noven. Noven received an up-front license payment of $20.0 million upon execution of the agreement. The up-front payment was deferred and is being recognized as license revenues over 10 years beginning in the fourth quarter of 2000. Noven subsequently received a $5.0 million milestone payment in the fourth quarter of 2001 that is being recognized as license revenues beginning in the first quarter of 2002 through the fourth quarter of 2010.

NOVOGYNE MARKETING RIGHTS OF COMBIPATCH®:

Novogyne acquired the exclusive United States marketing rights to CombiPatch® in March 2001 in a series of transactions involving Novogyne, Noven, Novartis and Aventis. Prior to the transaction, Aventis had been Noven s exclusive licensee for CombiPatch® in the United States. The transaction was structured as (i) a direct purchase by Novogyne from Aventis of certain assets for $25.0 million, which was paid at closing, (ii) a grant-back by Aventis to Noven of certain intellectual property rights relating to CombiPatch®, and (iii) a simultaneous license by Noven to Novogyne of these intellectual property rights. The consideration payable by Noven to Aventis, and by Novogyne to Noven, was $40.0 million, due in four quarterly installments of $10.0 million each, payable beginning June 1, 2001. Novogyne agreed to indemnify Noven against Noven s obligation to Aventis. In 2002 and 2001, Novogyne paid $10 million and $30 million, respectively, directly to Aventis. As a consequence of the transaction and under the terms of Noven s existing license agreement with Aventis, Noven received $3.5 million from Aventis, which amount was deferred and is being recognized as license revenues over ten years beginning in the first quarter of 2001.

In a related transaction, Novartis Pharma acquired from Aventis the development and marketing rights to future generations of Noven s combination estrogen/progestin patch in all markets other than Japan. Noven is developing a next generation combination patch with Novartis Pharma. Novogyne may seek to sublicense the United States rights to these product improvements from Novartis Pharma but Noven cannot assure that Novogyne will elect to do so or that Novartis will agree to sublicense any of these products on commercially reasonable terms. If future generation combination products are commercialized, Novogyne expects that it will pay a royalty to Novartis Pharma on the United States sales of such products. Noven manufactures and supplies CombiPatch® to Novogyne and expects to manufacture and supply any future combination products to Novartis Pharma and to Novogyne if licensed by Novartis Pharma. In June 2001, Noven and Novartis Pharma entered into a development agreement relating to future generations of combination estrogen/progestin patch products.

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SHIRE LICENSE OF METHYPATCH®:

In the first quarter of 2003, Noven signed an agreement to license the exclusive global rights to market MethyPatch® to Shire for payments of up to $150 million and ongoing manufacturing revenues. Consideration for the transaction is as follows: (i) $25 million was paid upon closing of the transaction in April 2003; (ii) $50 million is payable upon receipt of final marketing approval for MethyPatch® by the FDA; and (iii) three installments of $25 million each are payable upon Shire s achievement of $25 million, $50 million and $75 million in annual net sales of MethyPatch®, respectively. Shire s annual net sales will be measured quarterly on a trailing 12-month basis, with each milestone payment due 45 days after the end of the first quarter during which trailing 12-month sales exceed the applicable threshold. Shire has agreed that it will not sell any other product containing methylphenidate as an active ingredient until the earlier of (i) five years from the closing date or (ii) payment of all of the sales milestones. On the closing date, Noven entered into a long-term supply agreement under which it expects to manufacture and supply MethyPatch® to Shire. The agreement gives Shire the right to qualify a second manufacturing source and purchase a portion of its requirements from the second source. If Shire were to exercise this right, Noven s revenues from sales of MethyPatch® would be adversely affected. Pursuant to the agreement, under certain circumstances Shire has the right to require Noven to repurchase the product rights for $5 million.

In April 2003, Noven received a not approvable letter from the FDA relating to its MethyPatch® NDA. A not approvable letter is issued if the FDA does not consider the application approvable because one or more deficiencies in the application preclude the FDA from approving it. The letter cited clinical and other issues as the basis for non-approval. In October 2003, Noven submitted with Shire a jointly prepared, proposed study protocol for an additional clinical study for MethyPatch® to the FDA for review and comment. The purpose of this additional proposed study was to address clinical issues and risks raised in the FDA s not approvable letter. In November 2003, the FDA responded to the proposed study protocol and reported that the proposed study design did not address the clinical risk-benefit issues raised in the April 2003 not approvable letter. In its November 2003 response, the FDA provided specific recommendations regarding the proposed study design. Noven and Shire are working together to review and respond to the FDA s comments and recommendations with respect to the study design. Noven believes this study is necessary to amend the NDA and that other studies may also be required or advisable. Under a November 2003 letter agreement with Shire, if Noven agrees with Shire on a study design, Shire will manage the new clinical study and Noven will fund it. Under Noven s agreement with Shire, Noven is responsible for providing clinical supplies for the study and Noven may also incur certain additional expenses in pursuit of regulatory approval, including all or a portion of the cost of any other studies that Noven decides to conduct. At the conclusion of the trial, if Shire determines that submission of the study results to the FDA would not result in a commercially-viable product, Shire will have the right to terminate the original transaction agreement. If Shire exercises its termination right under these circumstances, however, Shire will forfeit its right to require Noven to repurchase the product rights, and the product rights will revert to Noven without payment to Shire. If Shire elects to proceed after reviewing the study results, the parties are expected to cooperate in submitting the new study results to the FDA and pursuing regulatory approval of MethyPatch®. Noven cannot assure that any revised study design will be acceptable to the FDA or, even if accepted by the FDA, produce study results that will result in a commercially-viable product. If the parties are unable to reach agreement with each other or the FDA on a study design, the parties may not continue to pursue regulatory approval of MethyPatch®.

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Of the $25 million received from Shire at closing, $5 million has been deferred and is expected to be recognized as license revenues over time beginning when Shire s right to require Noven to repurchase MethyPatch® rights expires. A portion of the remaining $20 million was recognized as revenues in the 2003 second quarter using a 10-year amortization period, which is the estimated product life cycle. Beginning in the 2003 third quarter, Noven ceased amortization of the balance of the $20 million due to the planned initiation of an additional clinical trial and the significant costs expected to be incurred in pursuing MethyPatch® approval.

Noven is committed to continuing to seek regulatory approval for MethyPatch® for as long as it remains a commercially practicable strategy. Noven has determined that it cannot yet estimate the total cost of pursuing MethyPatch® approval, but Noven does not expect that the total cost will exceed the deferred revenue balance of $19.1 million as of December 31, 2003. Noven expects to defer direct expenses incurred in pursuit of MethyPatch® regulatory approval (including the cost of any clinical studies) against the deferred revenue balance. License revenues deferred under this arrangement will be recorded net of the direct expenses incurred in pursuing regulatory approval. During 2003, $414,000 of direct expenses incurred in pursuit of approval were offset against the deferred license revenue balance. Once Noven can estimate the expected total cost in obtaining regulatory approval, Noven expects to recognize any unused portion of the deferred revenue balance over the remainder of the initial 10-year period. The accounting treatment of amounts received from Shire would be expected to change if Shire were to exercise its right to require Noven to repurchase the product rights or if MethyPatch® development were abandoned. In either of these scenarios, Noven would expect to recognize the remaining deferred license revenue immediately into income in the period of exercise, or abandonment, net of the $5 million repurchase price in the case of repurchase.

P&G PHARMACEUTICALS CONTRACT:

In April 2003, Noven established a collaboration with P&GP for the development of new prescription patches. The products under development explore follow-on product opportunities for Intrinsa®, P&GP s in-licensed investigational transdermal testosterone patch designed to help restore desire in menopausal women who have Hypoactive Sexual Desire Disorder. P&GP recently initiated studies of the first product in humans. Potential development milestones totaling $4.8 million remain to be received under the P&GP collaboration, a portion of which is expected to be received in the remainder of 2004.

6. INVESTMENT IN VIVELLE VENTURES LLC (d/b/a NOVOGYNE):

In 1998, Noven invested $7.5 million in return for a 49% equity interest in Novogyne. In return for a 51% equity interest, Novartis granted an exclusive sublicense to Novogyne of a license agreement with Noven (see Note 5). This sublicense assigned certain of Novartis rights and obligations under license and supply agreements with Noven, and granted an exclusive license to Novogyne of the Vivelle® trademark.

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The condensed Statements of Operations of Novogyne for the years ended December 31, 2003, 2002 and 2001 are as follows (in thousands):

	2003	2002	2001
Gross revenues	$120,278	$130,359	$104,146
Sales allowances	11,275	13,602	8,786
Sales returns allowances	7,926	14,272	5,402
Sales allowances and returns	19,201	27,874	14,188
Net revenues	101,077	102,485	89,958
Cost of sales	21,485	26,136	20,833
Selling, general and administrative expenses	30,673	33,091	27,347
Amortization of intangible assets	6,179	6,179	4,635
Income from operations	42,740	37,079	37,143
Interest income	182	350	734
Net income	$ 42,922	$ 37,429	$ 37,877
Noven s equity in earnings of Novogyne	$ 17,094	$ 14,368	$ 14,013

The activity in the Investment in Novogyne account for the years ended December 31, 2003, 2002 and 2001 is as follows (in thousands):

	2003	2002	2001
Investment in Novogyne, beginning of year	$ 34,684	$ 32,043	$ 15,431
Equity in earnings of Novogyne	17,094	14,368	14,013
Cash distributions from Novogyne	(21,739)	(11,727)	(13,081)
Non-cash distribution from Novogyne	(1,671)		
Contributions to Novogyne			15,680

Investment in Novogyne, end of year	$ 28,368	$ 34,684	$ 32,043

Non-cash distribution from Novogyne represented a $1.7 million tax payment to the New Jersey Department of Revenue made by Novogyne on Noven s behalf in April 2003. As discussed in Note 3, such payment was deemed a distribution from Novogyne to Noven.

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The condensed Balance Sheets of Novogyne at December 31, 2003 and 2002 are as follows (in thousands):

	2003	2002
Current assets	$24,977	$34,827
Long-term assets	44,801	50,981
Total assets	69,778	85,808
Allowance for returns	14,240	12,780
Other liabilities	7,338	4,688
Total liabilities (all of which are current)	21,578	17,468
Members capital	$48,200	$68,340

The activity for the allowance for returns for the three years ended December 31, 2003 is as follows (in thousands):

Balance December 31, 2000	$ 5,873
Expense related to expired product	5,402
Deductions	(4,602)
Balance December 31, 2001	6,673
Expense related to expired product	14,272
Deductions	(8,165)
Balance December 31, 2002	12,780
Expense related to expired product	1,426
Expense related to product recalls	6,500
Deductions	(6,466)
Balance December 31, 2003	$14,240

Under the terms of the joint venture agreements, Noven is responsible for the manufacture of the products, retention of samples and regulatory documentation, design and implementation of an overall marketing and sales program in the hospital and retail sales sectors of the market, including the preparation of marketing plans and sales force staffing and management, and the procurement of advertising services in connection with the marketing and promotion of the products. All other matters, including inventory control and distribution, management of marketing and sales programs for the managed care sector of the market, customer service support, regulatory affairs support, legal, accounting and other administrative services are provided by Novartis.

The joint venture operating agreement includes a buy/sell provision that either Noven or Novartis may trigger by notifying the other party of the price at which the triggering party would be willing to acquire 100% of the joint venture. Upon receipt of this notice, the non-triggering party has the option to either purchase the triggering party s interest in Novogyne or to sell its own interest in Novogyne to the triggering party at the price established by the triggering party. If Noven is the purchaser, then Noven must pay an additional amount equal to the net present value of Novartis preferred profit return. This amount is calculated by applying a specified discount rate and a period of 10 years to Novartis $6.1 million annual preferred return. Novartis is a larger company with greater financial resources, and therefore may be in a better position to be the purchaser if the provision is triggered. In addition, this buy/sell provision may have an anti-takeover effect on Noven since a potential acquirer of Noven will face the possibility that Novartis could trigger this provision at any time and thereby require any acquirer to either purchase Novartis interest in Novogyne or to sell its interest in Novogyne to Novartis.

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Novartis has the right to dissolve the joint venture in the event of a change in control of Noven if the acquirer is one of the ten largest pharmaceutical companies (as measured by annual dollar sales). Upon dissolution, Novartis would reacquire the rights to market Vivelle® and Vivelle-Dot® subject to the terms of Novartis prior arrangement with Noven, and Novogyne s other assets would be liquidated and distributed to the parties in accordance with their capital account balances as determined pursuant to the joint venture operating agreement.

During the years ended December 31, 2003, 2002 and 2001, Noven had the following transactions with Novogyne (in thousands):

	2003	2002	2001
Revenues:			
Trade product	$12,411	$21,984	$13,634
Sample product and other	3,521	3,410	3,055
Royalties	4,978	4,505	4,037
	$20,910	$29,899	$20,726
Reimbursed expenses:			
Services	$18,652	$18,345	$16,187
Product specific marketing expenses	5,608	7,535	5,849
Reimbursed expenses	$24,260	$25,880	$22,036

As of December 31, 2003 and 2002, the Accounts Receivable Novogyne, net is as follows (in thousands):

	2003	2002
Sales of product	$ 2,867	$ 1,631
Services provided by Noven	4,255	2,029
Royalty	1,556	905
Allowance for product recall	(1,513)	
Deferred profit on Novogyne inventory	(845)	(1,984)
	$ 6,320	$ 2,581

7. CREDIT FACILITY, MASTER FINANCE LEASE AND OPERATING LEASES:

CREDIT FACILITY:

In December 2000, Noven entered into a credit agreement with a bank for a secured revolving credit facility (the Credit Facility) providing for borrowings up to the lesser of (a) $10.0 million or (b) eligible accounts receivable. The Credit Facility expired in April 2003. Noven decided not to renew the Credit Facility since Noven had not utilized it and had no plans to utilize it.

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MASTER FINANCE LEASE:

In May 1999, Noven entered into a Master Finance Lease agreement (the Master Lease) for $1.0 million with a base lease term of three or four years depending upon the equipment type. The terms of the Master Lease included, among other provisions, minimum net worth, revenues and operating results requirements, as well as certain financial ratios, measured on a quarterly basis. Transactions under the Master Lease have been accounted for as financing arrangements. Noven paid the remaining amount due under the Master Lease during the fiscal year 2003 and the Master Lease was cancelled with no further obligation.

OPERATING LEASES:

The Company has various operating leases for computers and equipment. Lease expense under operating leases was approximately $309,000, $343,000 and $293,000 for the years ended December 31, 2003, 2002 and 2001, respectively.

The future minimum rental payments required under noncancelable operating leases as of December 31, 2003 are as follows (in thousands):

2004	$336
2005	254
2006	84
2007	22
2008	10
Thereafter	10
	$716

8. INCOME TAXES:

The provision (benefit) for income taxes in 2003, 2002 and 2001 consists of (in thousands):

	2003	2002	2001
Current income taxes:			
Federal	$10,816	$4,430	$5,400
State	1,729	803	627
	12,545	5,233	6,027
Deferred income tax (benefit) expense:			
Federal	(4,920)	2,518	448
State	(1,324)	68	261

	(6,244)	2,586	709
Income tax expense	$ 6,301	$7,819	$6,736

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Deferred income taxes reflect the tax effects in future years for temporary differences between the tax bases of assets and liabilities and their financial reporting amounts. The following table summarizes the significant components of Noven s net deferred tax asset (in thousands):

	2003	2002
Deferred income tax assets:		
Deferred license revenue	$14,735	$ 8,814
Joint venture interest	3,182	2,397
Allowance for returns	789	
General business credit	4	515
Alternative minimum tax credit		483
Other	599	697
Total deferred income tax assets	19,309	12,906
Deferred income tax liabilities:		
Basis difference in fixed assets	(634)	(475)
Net deferred income tax asset	$18,675	$12,431

Realization of the net deferred income tax asset of $18.7 million and $12.4 million at December 31, 2003 and 2002, respectively, is dependent upon generating sufficient future taxable income. Although realization is not assured, management believes it is more likely than not that the net deferred income tax asset will be realized based upon estimated future income of Noven and, accordingly, no valuation allowance for the net deferred income tax asset was deemed necessary at December 31, 2003 and 2002.

At December 31, 2003 and 2002, Noven s research and development credit carryforwards were not material.

The income tax benefits derived from the exercise of non-qualified stock options and disqualifying dispositions of incentive stock options, when realized, are credited to additional paid-in capital. For the years ended December 31, 2003, 2002 and 2001, Noven credited $0.5 million, $0.2 million and $1.4 million, respectively, to additional paid-in capital related to the tax benefits from the exercise of stock options.

The difference between the income taxes resulting from applying the statutory federal income tax rate to pretax income and the total income tax expense (benefit) is reconciled as follows (dollars in thousands):

	2003		2002		2001	
	Amount	%	Amount	%	Amount	%
Income taxes at statutory rate	$6,124	35.0	$7,594	35.0	$6,589	35.0

Increase (decrease) in taxes:						
State income tax, net of federal benefits	264	1.5	566	2.6	577	3.1
Research and development expenditures	(5)		(396)	(1.8)	(458)	(2.4)
Other	(82)	(0.5)	55	0.2	28	0.1
Income tax expense (benefit)	$6,301	36.0	$7,819	36.0	$6,736	35.8

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9. STOCKHOLDERS EQUITY:

Noven established its 1999 Long-Term Incentive Plan (the 1999 Plan) on June 8, 1999. The 1999 Plan replaced Noven s 1997 Stock Option Plan (the 1997 Plan) and no future stock option awards may be granted under the 1997 Plan. The 1999 Plan provides for the granting of incentive and non-qualified stock options, stock awards (including restricted stock), and other permitted awards to selected individuals for up to 3,768,848 shares, including 2,768,848 shares that remained available under the 1997 Plan at the time of its termination. At December 31, 2003, all awards granted under the 1999 Plan have been stock options with the exception of unrestricted stock awards for a total of 2,776 shares. The terms and conditions of stock options (including price, vesting schedule, term and number of shares) and other permitted awards under the 1999 Plan are determined by the Compensation and Stock Option Committee, which administers the 1999 Plan. The per share exercise price of (i) non-qualified stock options granted to directors and all other persons can not be less than the fair market value of the common stock on the date of grant, (ii) incentive stock options granted to employees can not be less than the fair market value of the common stock on the date of grant and (iii) incentive stock options granted to employees owning in excess of 10% of Noven s issued and outstanding common stock can not be less than 110% of the fair market value of the common stock on the date of grant.

Each option granted under the 1999 Plan is exercisable after the period(s) specified in the relevant option agreement, and no option can be exercised after ten years from the date of grant (or five years from the date of grant in the case of a grantee of an incentive stock option holding more than 10% of the issued and outstanding Noven common stock). At December 31, 2003, there were approximately 3,245,815 stock options outstanding under the 1999 Plan. Generally, the options vest over a period of five years, beginning one year after date of grant, and expire seven years after date of grant.

The 1997 Plan, originally effective January 1, 1997, provided for the granting of up to 4,000,000 incentive and non-qualified stock options. At December 31, 2003, there were approximately 672,858 stock options outstanding under the 1997 Plan. The 1997 Plan is also administered by the Compensation and Stock Option Committee, and the terms and conditions of the 1997 Plan are similar to those of the 1999 Plan.

Noven also has an earlier stock option plan, which had provisions similar to those of the 1997 and 1999 Plans. This plan terminated on December 31, 1996, and no additional options may be granted under this plan. At December 31, 2003, all stock options outstanding under this plan had expired.

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Stock option transactions related to the plans are summarized as follows (options and shares in thousands):

	2003		2002		2001	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding at beginning of year	3,410	$15.20	2,845	$15.57	2,501	$14.57
Granted	956	10.60	871	14.08	792	17.59
Exercised	(245)	6.60	(101)	8.02	(308)	10.45
Canceled and expired	(202)	17.17	(205)	19.14	(140)	20.32
Outstanding at end of year	3,919	14.51	3,410	15.20	2,845	15.57
Options exercisable at end of year	1,669	14.78	1,404	13.23	960	11.89
Shares of common stock reserved	4,414		4,722		4,895	

The following table summarizes information concerning outstanding and exercisable options at December 31, 2003 (options in thousands):

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding at Year End	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable at Year End	Weighted Average Exercise Price
$4.19 - 6.25	590,371	1.5	$ 5.76	558,496	$ 5.77
7.03 - 10.45	1,148,583	5.7	10.15	245,097	9.38
11.12 - 16.50	1,546,519	5.2	13.87	477,503	14.08
17.03 - 21.47	70,500	6.5	19.96	51,700	20.33
31.31 - 41.81	562,700	4.0	33.69	336,420	33.84

3,918,673	1,669,216

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

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

10. SHARE REPURCHASE PROGRAM:

In the first quarter of 2003, Noven s Board of Directors authorized a share repurchase program under which Noven may acquire up to $25 million of its common stock. As of December 31, 2003, Noven had repurchased 105,000 shares of its common stock at an aggregate price of approximately $1.3 million. These shares were retired on March 31, 2003.

11. 401(k) SAVINGS PLAN:

On January 1, 1997, Noven established a savings plan under section 401(k) of the Internal Revenue Code (the 401(k) Plan) covering substantially all employees who have completed three months of service and have reached the age of twenty-one. This plan allows eligible participants to contribute from one to fifteen percent of their current compensation to the 401(k) Plan subject to the maximum permitted by law. Effective January 2001, the 401(k) provided for employer matching of 50% of employee contributions up to the first 3% of the participants contributions. The employer matching of 50% of the employee contributions was increased to the first 6% of the participants contribution as of January 1, 2003. Noven contributed $274,000, $148,000 and $126,000 for the year ended December 31, 2003, 2002 and 2001, respectively.

12. SEGMENT, GEOGRAPHIC AND CUSTOMER DATA:

Noven is engaged principally in one line of business, the research, development, manufacture and marketing of advanced transdermal drug delivery technologies and prescription transdermal products, which represents substantially all of its revenues and income. There were no inter-company sales or transactions between geographic areas.

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The following table presents information about Noven s revenues by geographic area (in thousands):

	2003	2002	2001
United States	$22,130	$28,995	$25,018
Other countries	21,036	26,377	20,929
Net revenues	$43,166	$55,372	$45,947

The following table presents information about Noven s revenues by customer, including product, royalty, contract and license revenues (in thousands):

	2003	2002	2001
Novogyne	$20,910	$29,899	$20,726
Novartis Pharma/Novartis	18,701	23,201	19,809
Aventis	1,462	1,212	4,736
Other	2,093	1,060	676
Net revenues	$43,166	$55,372	$45,947

13. UNAUDITED QUARTERLY CONDENSED FINANCIAL DATA:
(in thousands, except per share amounts):

2003	First	Second	Third	Fourth	Full Year
Net revenues	$10,025	$12,261	$ 9,096	$11,784	$43,166
Gross profit (product revenues less cost of products sold)	4,833	4,800	4,047	3,954	17,634
(Loss) income from operations	(934)	774	(1,547)	1,451	(256)
Equity in earnings of Novogyne	1,525	3,795	4,529	7,245	17,094
Net income	$ 473	$ 3,050	$ 2,011	$ 5,662	$11,196
Basic earnings per share	$ 0.02	$ 0.14	$ 0.09	$ 0.25	$ 0.50

Diluted earnings per share	$ 0.02	$ 0.13	$ 0.09	$ 0.24	$ 0.49

2002	**First**	**Second**	**Third**	**Fourth**	**Full Year**
Net revenues	$12,735	$16,156	$13,198	$13,283	$55,372
Gross profit (product revenues less cost of products sold)	5,536	8,457	7,103	6,130	27,226
Income from operations	533	3,143	2,010	822	6,508
Equity in earnings of Novogyne	1,515	7,132	2,010	3,711	14,368
Net income	$ 1,453	$ 6,643	$ 2,763	$ 3,020	$13,879
Basic earnings per share	$ 0.06	$ 0.29	$ 0.12	$ 0.13	$ 0.62
Diluted earnings per share	$ 0.06	$ 0.28	$ 0.12	$ 0.13	$ 0.60

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14. COMMITMENTS AND CONTINGENCIES:

HT STUDIES:

In July 2002, the National Institutes of Health (NIH) released data from its Women s Health Initiative (WHI) study on the risks and benefits associated with use of oral combination hormone therapy (HT). The study revealed an increase in the risk of developing breast cancer and increased risks of stroke, heart attack and blood clots. Also in July 2002, results of an observational study sponsored by the National Cancer Institute (NCI) on the effects of estrogen therapy (ET) were announced. The main finding of the study was that postmenopausal women who used ET for 10 or more years had a higher risk of developing ovarian cancer than women who never used HT. In June 2003, a new analysis of study data indicated that use of combination HT may increase the frequency of abnormal mammograms beginning in the first year of therapy and/or may cause tumors at the time of diagnosis to be more advanced. In August 2003, further WHI data analysis suggested that the use of combination therapy increased the risk of heart disease beginning in the first year of therapy, and a large study in the United Kingdom suggested that the use of both estrogen-only and combination therapy increased the risk of breast cancer, and the risk of death from breast cancer, whether administered orally, transdermally or via implant. In December 2003, a Scandinavian study on the effects of HT on breast cancer survivors was discontinued after the study found a high risk of cancer recurrence. The NIH discontinued the estrogen-only arm of the WHI study because of an increased risk of stroke and because, after nearly seven years of follow-up, the NIH determined that it had sufficient data to assess the risks and benefits of estrogen use in the trial. This arm of the WHI study also found that the use of an estrogen-only oral formulation appeared to decrease the risk of hip fracture, and did not appear to affect heart disease or to increase the risk of breast cancer. Researchers continue to analyze data from both arms of the WHI study and other studies. Other studies evaluating HT are currently underway or in the planning stages.

These studies and others have caused the HT market, and the market for Noven s products, to significantly decline. Prescriptions for CombiPatch®, our combination estrogen/progestin patch, continue to decline in the post-WHI environment. Novogyne recorded the acquisition of CombiPatch® marketing rights at cost and tests this asset for impairment on a periodic basis. Further adverse change in the market for HT products could have a material adverse impact on the ability of Novogyne to recover its investment in these rights, which could require Novogyne to record an impairment loss on the CombiPatch® intangible asset. Impairment of the CombiPatch® intangible asset would adversely affect Novogyne s and Noven s financial results. Management can not predict whether these or other studies will have additional adverse effects on Noven s liquidity and results of operations, or Novogyne s ability to recover the carrying value of the CombiPatch® intangible asset.

PRODUCTION ISSUES:

In 2003, Noven s product stability testing program revealed that certain lots of CombiPatch® and Vivelle-Dot® did not maintain required specifications throughout the products shelf lives, resulting in product recalls. Revenues for 2003 are net of approximately $1.4 million and $6.5 million in allowances for returns at Noven and Novogyne, respectively, related to the recalls. In addition, Noven s marketing, selling and administrative expenses in 2003 include $850,000 in estimated costs associated with these recalls.

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The CombiPatch® issue resulted from a production issue related to a problematic raw material supplied by one vendor. This issue caused Noven to temporarily suspend shipments of CombiPatch® to Novogyne in the 2003 first quarter, and caused Novartis to recall one lot of CombiPatch® in July 2003. Since identifying the issue, Noven has been monitoring all lots of CombiPatch® product manufactured with the problematic material. Even though interim testing indicated that these additional lots were expected to maintain specifications throughout their shelf lives, Noven experienced an unexpected stability failure in one additional lot. In light of this event, Novartis initiated a recall of all lots of CombiPatch® product remaining in distribution that are potentially affected by this problematic raw material. After addressing the issues with the specific raw material, Noven continues to manufacture and ship CombiPatch® to Novogyne and expects no interruption of trade supplies.

Noven is working to identify the root cause of the Vivelle-Dot® issue, and in the interim has initiated more rigorous testing of Vivelle-Dot® and Estradot® product. In October 2003, a quantity of Vivelle-Dot® tested out of specification. In November 2003, an additional quantity tested out of specification. Novartis has announced a recall of the Vivelle-Dot® product that tested out of specification in October and November 2003. Noven has identified additional product that demonstrates adverse stability trends but remains within required specifications. Based on results of Noven s testing and analysis to date, Noven does not believe that any additional Vivelle-Dot® product that is currently in distribution or in its inventory is unlikely to maintain required stability. Noven has established allowances for estimated sales returns for product that has been recalled as a result of testing out of specification. Novogyne has increased its allowance for sales returns in light of the same issue. If a root cause determination or additional testing indicates that the production issue affects more product than Noven s current testing and analysis suggests, additional recalls may be required, Noven s allowances may prove insufficient and/or it may be forced to suspend shipping. If Noven is unable to ship Vivelle-Dot® and/or Estradot®, Novogyne and/or Novartis would be unable to supply its customers, which would result in lost sales and potentially lost market share, and Noven s results of operations and prospects would be materially adversely affected.

SUPPLY AGREEMENT:

Noven s supply agreement with Novogyne for Vivelle® and Vivelle-Dot® expired in January 2003. Since expiration, the parties have continued to operate in accordance with the supply agreement s commercial terms. There is no assurance that the agreement s non-commercial terms would be enforceable with respect to post-expiration occurrences. Failure to extend the agreement could have a material adverse effect on Noven s financial statements.

EMPLOYMENT AGREEMENT AND BONUS PLAN:

Noven has entered into an amended and restated employment agreement with Robert C. Strauss, its President, Chief Executive Officer and Chairman, that provides for a base salary subject to cost of living increases each year and other increases and bonuses. This agreement provides for annual commitments of approximately $0.5 million and has a term extending through 2006.

Noven has a formula bonus plan that includes company and individual performance goals. Noven incurred $2.8 million, $2.5 million and $0.7 million of bonus expenses in 2003, 2002 and 2001, respectively. Under the plan, a fixed percentage of each employee s base salary is set as a target incentive bonus award for such employee. To the extent that actual company performance is equal to, exceeds or is less than the company performance targets, an employee s bonus award may be equal to, greater than or less than his target award. An employee s non-financial goals are then considered in determining his or her final bonus award. In 2001, Noven did not meet the Company performance goals and Noven s officers received no bonus. During 2001, Noven set revised goals for non-officer employees, and the revised goals were met, resulting in a total bonus payment of $0.7 million. In 2003 and 2002, Noven met or exceeded each of the company performance goals, and in accordance with the plan formula the bonus awards to most employees were greater than their initial target awards.

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

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LITIGATION, CLAIMS AND ASSESSMENTS:

On August 7, 2003, an individual filed a lawsuit on behalf of a purported class of purchasers of Noven s common stock during the period from October 29, 2001 through April 28, 2003. The complaint alleges that, during the subject period, Noven and its officers named as defendants violated the Securities Exchange Act of 1934 by making false and misleading statements in its public disclosures regarding MethyPatch®. Following the filing of Plaintiff s complaint, five other substantially similar complaints were filed against Noven and its officers named as defendants in the above referenced action. In response to a joint motion, on or about January 6, 2004, the Court entered an order consolidating the six related actions. Pursuant to this order, plaintiffs must file a consolidated class action complaint not later than 60 days after the entry of an order appointing lead plaintiff and lead counsel. An order appointing lead plaintiff and lead counsel has not yet been entered. This development 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.

Noven is involved in certain litigation and claims incidental to its business. Noven does not believe, based on currently available information, that these matters will have a material adverse effect on the accompanying financial statements.

LICENSE AGREEMENTS:

In certain circumstances, Noven is required to indemnify its licensees from damages caused by the products Noven manufactures as well as claims or losses related to patent infringement.

15. SUBSEQUENT EVENTS:

On February 25, 2004, Noven licensed its developmental generic fentanyl patch to Endo. Noven s fentanyl patch is intended to be the generic equivalent of Johnson & Johnson s Duragesic® (fentanyl transdermal system).

Noven received an $8.0 million up-front payment from Endo on signing. Upon Endo s first commercial sale of the fentanyl patch, Noven is entitled to receive an additional payment ranging from $5.0 million to $10.0 million, depending on the number of generic fentanyl competitors in the market. Noven will manufacture and supply the product at its cost and will share in Endo s profit from product sales.

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Based on the current patent and exclusivity status of Duragesic®, Noven believes that the earliest its generic fentanyl patch could be launched is January 2005, assuming FDA approval is received by that time, but Noven cannot assure that it will receive FDA approval by that time or at all. Noven and Endo may elect to manufacture launch supplies prior to receipt of tentative approval. If launch supplies are manufactured and approval is not ultimately received or is delayed, the agreement provides that Noven and Endo will share the cost of manufacturing product that cannot be sold by Endo in accordance with an agreed-upon formula. However, in that case, Noven would not be able to offset all of its up-front production costs with sales of the product. If the product has not been approved or we have not supplied Endo s launch requirements by May 2005, Endo may have the right to terminate the license, depending on the number of generic competitors in the market.

In addition to the fentanyl license, Noven has established a collaboration with Endo to identify and develop new transdermal therapies. Of the $8.0 million up-front payment, $1.5 million will be allocated to fund feasibility studies that we expect to undertake to seek to determine whether certain compounds identified by the parties can be delivered using Noven s transdermal technology. Endo is expected to fund and manage clinical development of those compounds proceeding into clinical trials.

The $8.0 million received by Noven at signing is expected to be recognized as revenues over a period of years.

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Report of Independent Auditors

To the Management Committee of
Vivelle Ventures LLC d/b/a Novogyne Pharmaceuticals

In our opinion, the accompanying balance sheet and the related statements of operations, members capital and cash flows present fairly, in all material respects, the financial position of the Vivelle Ventures LLC at December 31, 2003 and 2002, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2003 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company s management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

PricewaterhouseCoopers LLP

Florham Park, New Jersey
February 12, 2004, except for paragraph 3 of Note 7 as to which the date is March 2, 2004.

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Balance Sheets
December 31, 2003 and 2002

	2003	2002
Assets		
Current assets		
Due from Affiliate Novartis Pharmaceuticals Corporation	$21,332,627	$28,470,812
Due from Novartis Pharmaceuticals Canada, Inc.	696,620	
Finished goods inventory (net of reserves of $949,137 and $975,624 as of December 31, 2003 and 2002)	2,682,113	6,315,282
Other current assets	265,521	41,390
Total current assets	24,976,881	34,827,484
Long-term assets (Note 3)	44,801,117	50,980,582
Total assets	$69,777,998	$85,808,066
Liabilities and Members Capital		
Current liabilities		
Due to Affiliate Noven Pharmaceuticals, Inc.	$ 7,164,624	$ 4,565,279
Accrued liabilities	173,250	122,383
Allowance for returns (Note 4)	14,240,281	12,780,006
Total current liabilities	21,578,155	17,467,668
Commitments and contingencies (Note 7)		
Members capital		
Capital contributions	32,857,909	32,857,909
Accumulated earnings	15,341,934	35,482,489
Total members capital	48,199,843	68,340,398
Total liabilities and members capital	$69,777,998	$85,808,066

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

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Statements of Operations
Years Ended December 31, 2003, 2002 and 2001

	2003	2002	2001
Net Sales			
Third parties	$ 98,572,264	$ 97,755,546	$88,808,362
Novartis Pharmaceuticals Canada, Inc.	2,505,148	4,729,216	1,149,817
	101,077,412	102,484,762	89,958,179
Cost of Sales			
Third parties	15,454,422	19,550,963	16,272,541
Noven royalties	4,978,247	4,504,663	4,036,972
Novartis Pharmaceuticals Canada, Inc.	1,052,221	2,079,829	523,358
	21,484,890	26,135,455	20,832,871
Gross profit	79,592,522	76,349,307	69,125,308
Operating Expenses			
Administrative expenses	2,652,908	2,195,203	1,926,320
Sales and marketing expenses	28,019,902	30,895,914	25,420,730
Amortization expense	6,179,465	6,179,465	4,634,598
Income from operations	42,740,247	37,078,725	37,143,660
Other Income			
Interest income	181,957	349,741	733,600
Net income	$ 42,922,204	$ 37,428,466	$37,877,260

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

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Statements of Members Capital
Years Ended December 31, 2003, 2002 and 2001

	Total
Member s Capital at December 31, 2000	$ 31,425,906
Net income	37,877,260
Distributions to Novartis	(30,819,000)
Distributions to Noven	(13,081,000)
Capital contributions by Novartis	16,320,000
Capital contributions by Noven	15,680,000
Members Capital at December 31, 2001	57,403,166
Net income	37,428,466
Distributions to Novartis	(14,763,251)
Distributions to Noven	(11,727,983)
Members Capital at December 31, 2002	68,340,398
Net income	42,922,204
Distributions to Novartis	(39,652,880)
Distributions to Noven	(23,409,879)
Members Capital at December 31, 2003	$ 48,199,843

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

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Statements of Cash Flows
Years Ended December 31, 2003, 2002 and 2001

	2003	2002	2001
Operating Activities			
Net income	$ 42,922,204	$ 37,428,466	$ 37,877,260
Adjustments to reconcile net income to net cash provided by operating activities			
Amortization of marketing rights	6,179,465	6,179,465	4,634,598
Obsolescence reserve	(26,487)	725,624	50,000
Changes in assets and liabilities, net of assets acquired			
Due from affiliate Novartis Pharmaceuticals Corporation	7,138,185	(11,977,785)	19,486,451
Due from Novartis Pharmaceuticals Canada, Inc.	(696,620)	876,263	(631,575)
Inventories	3,659,656	(1,064,501)	3,111,424
Other current assets	(224,131)	308,017	(349,407)
Due to affiliate Noven Pharmaceuticals, Inc.	2,599,345	(2,095,479)	2,188,408
Other liabilities	1,511,142	6,111,164	804,753
Net cash provided by operating activities	63,062,759	36,491,234	67,171,912
Investing Activities			
Cash paid to purchase the Combipatch® marketing rights and inventory (Note 3)		(10,000,000)	(55,271,912)
Net cash provided by investing activities		(10,000,000)	(55,271,912)
Financing Activities			
Contribution by members (Note 3)			32,000,000
Distributions to members (Note 5)	(63,062,759)	(26,491,234)	(43,900,000)
Net cash provided by financing activities	(63,062,759)	(26,491,234)	(11,900,000)
Net change in cash			
Cash and Cash Equivalents			
Beginning of year			
End of year	$	$	$

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

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
December 31, 2003

1. Organization, Business and Basis of Accounting

Vivelle Ventures LLC (the Company) was organized to maintain and grow a franchise in women s health in the United States of America focusing initially on the marketing and sale of an estradiol transdermal patch product under the trademark Vivelle® . During 1999, the Company began doing business under the name Novogyne Pharmaceuticals .

The Company is a limited liability company between Novartis Pharmaceuticals Corporation (Novartis) and Noven Pharmaceuticals, Inc. (Noven) (collectively referred to as the Members), pursuant to a Formation Agreement dated as of May 1, 1998 (date of inception). Prior to the formation of the Company, Vivelle® was marketed by Novartis pursuant to a license (License Agreement) granted by Noven which owns the patent rights and know-how for Vivelle®. Noven had previously supplied Vivelle® to Novartis under a supply agreement (the Supply Agreement) (Note 7). On May 1, 1998, Novartis granted an exclusive sublicense to the Company of the License Agreement, assigned the Company certain of its rights and obligations under the Supply Agreement, and granted an exclusive license to the Company of the Vivelle® trademark as its contribution of capital to the Company. These assets, with a value of $7,800,000 as agreed to by the Members, have been recorded by the Company at Novartis carryover basis of zero. Noven contributed $7,500,000 in cash to the Company. Pursuant to the Formation Agreement, the initial capital interests of the Company were owned 51 percent by Novartis and 49 percent by Noven.

Novartis is responsible for providing distribution, administrative and marketing services to the Company, pursuant to certain other agreements, as amended. Noven is responsible for supplying products to the Company and for providing marketing and promotional services pursuant to certain other agreements, as amended. The Company has no discrete employees (Note 5).

The Company commenced selling its second generation transdermal estrogen delivery system Vivelle-Dot® in 1999. The patent rights and know-how for Vivelle-Dot® have been transferred to the Company by means of the original sublicense granted by Novartis for Vivelle® as discussed above.

On March 30, 2001, the Company acquired the exclusive United States marketing rights to CombiPatch® (estradiol/norethindrone acetate transdermal system) in a series of transactions involving the Company, Noven, Novartis and Aventis Pharmaceuticals (Aventis) (Note 3).

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include the deductions from gross sales for allowances, returns and discounts, provisions for inventory obsolescence, and assumptions for cash flows when testing assets for impairment.

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
December 31, 2003

Cash and Cash Equivalents

For the purposes of the Statement of Cash Flows, cash is defined as unrestricted cash balances and investment securities with original maturities of three months or less.

Inventory

Inventory is stated at the lower of cost or market value utilizing the first-in, first-out method. Inventory provisions are recorded in the normal course of business, and relate primarily to product that is within nine months of expiration as of the balance sheet dates.

Revenue Recognition

Revenues are recognized at the time goods are shipped and title and risk of loss pass to the customer. Provision is made at the time of sale for discounts and estimated sales allowances and returns.

Sales Allowances

Novartis records the Company s 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 the Company and pays all moneys owed and issues credits to individual customers as deemed necessary. Revenues for the years ended December 31, 2003, 2002 and 2001 are net of $11,274,795, $13,601,706 and $8,785,599, respectively, for such sales allowances. The contracts that underlie these transactions are maintained by Novartis for its business as a whole and those transactions relating to the Company are estimated. Based on an analysis of the underlying activity, the amounts recorded by the Company represent Novartis best estimate of these charges that apply to sales of the Company.

Revenues for the years ended December 31, 2003, 2002 and 2001 are net of sales returns allowances of $7,925,829, $14,272,112 and $5,401,758, respectively. Returns are estimated based on historical experience and may vary in future periods.

Advertising Costs

Advertising costs are expensed as incurred.

Income Taxes

The Company s income, gains, losses and tax credits are passed to its Members who report their share of such items on their respective income tax returns. Accordingly, income taxes have not been provided.

Reclassifications

Certain prior year amounts have been reclassified to conform to the current year presentation.

Impairment of Long Lived Assets

The Company evaluates whether events and circumstances have occurred that indicate the remaining estimated useful life of long-lived assets may warrant revision or that the remaining balance may not be recoverable. When factors indicate that an asset should be evaluated for possible impairment, the Company reviews such long lived asset to assess recoverability from future operations using undiscounted cash flows. Impairments would be recognized in earnings to the extent that carrying value exceeds fair value. To date, no impairment has been identified (Note 3).

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
December 31, 2003

3. Acquisition of CombiPatch® Marketing Rights and Inventory

On March 30, 2001, the Company acquired the exclusive United States marketing rights to CombiPatch® in a series of transactions involving the Company, Noven, Novartis and Aventis. The transaction was structured as (a) a direct purchase by the Company from Aventis of the sales and marketing rights and inventory for $25,000,000 which was paid at closing, (b) a grant-back by Aventis to Noven of certain intellectual property rights relating to CombiPatch®, and (c) a simultaneous license by Noven to the Company of these intellectual property rights. The consideration payable by Noven to Aventis, and by the Company to Noven, is $40,000,000, due in four quarterly installments of $10,000,000 each, payable beginning June 1, 2001. The Company agreed to indemnify Noven against its obligation to Aventis. In 2002 and 2001, the Company paid $10 million and $30 million respectively, directly to Aventis. The Company has assigned $3,477,267 to the value of the inventory and the remainder and various costs totaling $61,794,645 to an intangible asset representing license and marketing rights. This intangible asset is being amortized over a period of 10 years. To fund the purchase price of approximately $65,000,000, the members contributed a total of $32,000,000 in cash. The remaining amount was funded by a reduction in the Novartis due from affiliate account.

The accumulated amortization for this intangible asset was $16,993,528 and $10,814,063 as of December 31, 2003 and 2002. Amortization expense is $6,179,465 per year, and will total $30,897,325 over the next five years.

4. Allowance for Returns

The methodology used by the Company to estimate product returns related to expired product is based on (i) historical experience of actual product returns and (ii) the estimated lag time between when an actual sale takes place in relation to when the products are physically returned by a customer. The historical actual returns rate is then applied to product sales during the estimated lag period to develop the returns estimate.

The activity for the returns reserve for the three years ended December 31, 2003 is as follows:

Balance December 31, 2000	$ 5,873,352
Additions charged to expense	5,401,758
Deductions	(4,602,001)
Balance December 31, 2001	6,673,109
Additions charged to expense	14,272,112
Deductions	(8,165,215)
Balance December 31, 2002	12,780,006
Additions charged to expense	7,925,829
Deductions	(6,465,554)

Balance December 31, 2003	$14,240,281

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
December 31, 2003

Product Recall

In October 2003, product stability testing revealed that certain CombiPatch® and Vivelle-Dot® products did not maintain required specifications resulting in a product recall. As a result, the Company recorded a $6,500,000 returns reserve related to the announced recall. Through December 31, 2003, $535,057 of actual CombiPatch® and Vivelle-Dot® returns associated with the recall were received resulting in a year end reserve balance of $5,964,943, which is included in the table above. In addition to the returns reserve, the Company recorded $432,661 in inventory provisions related to product that was affected by the recall.

5. Operating Agreement

The Company s Operating Agreement provides, among other things, for the following:

Allocation of Net Income and Loss

Net income is allocated at the end of each fiscal year in accordance with the accounting method followed by the Company for federal income tax purposes in the following order of priority:

First, to Novartis until the cumulative amount of net income allocated under the relevant provisions of the Operating Agreement equals $6,100,000 annually for the current and all prior fiscal years.

Second, any remaining net income attributable to sales of Vivelle® for each fiscal year is to be allocated 70 percent to Novartis and 30 percent to Noven until the cumulative amount of such net income equals the product of $30,000,000 multiplied by a fraction, the numerator of which is the aggregate net income from sales of Vivelle® and the denominator of which is the aggregate net sales of Vivelle® in that period.

Third, any remaining net income attributable to sales of Vivelle® for each fiscal year is to be allocated 60 percent to Novartis and 40 percent to Noven until the cumulative amount of such net income equals the product of $10,000,000 multiplied by a fraction, the numerator of which is the aggregate net income from sales of Vivelle® and the denominator of which is the aggregate net sales of Vivelle® in that period.

Lastly, all remaining net income attributable to Vivelle® and all other net income, including Vivelle-Dot® and CombiPatch®, are to be allocated to the members in proportion to their respective percentage interests.

Net loss for any fiscal year is to be allocated between the Members in proportion to their respective percentage interests, with the exception of any net loss resulting from the termination of any license or know-how which would be allocated to the Member to whom such license or know-how reverts upon termination.

Distributions

Distributable funds are equal to the Company s Net Cash Flow during the period, as defined in the Operating Agreement, less reserves for working capital and other purposes of $3,000,000 or as determined by the Management Committee.

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
December 31, 2003

Distributable funds are payable to the Members quarterly or as determined by the Management Committee. Distributions are made to the Members based on taxable income. In 2002, the state of New Jersey enacted legislation that requires the Company to remit estimated tax payments on behalf of its owners, Novartis and Noven. Included in the 2003 distributions to Novartis and Noven of $39,652,880 and $23,409,879, respectively, are payments related to New Jersey state taxes of $2,514,880 and $1,670,879, respectively.

Management Committee

The Operating Agreement, as amended, provides for the formation of a Management Committee. The Members act on any matters to be determined by them through their representatives on the Management Committee. The Management Committee has general management powers with respect to the management and operation of the business and affairs of the Company and is responsible for policy setting and approval of the overall direction of the Company. The Management Committee consists of five individuals of whom three are designated by Novartis and two by Noven. A decision by the Management Committee is made by the affirmative vote of a majority of the Committee members. The Operating Agreement, as amended, also provides for certain actions or decisions to require the vote of at least four of the five members of the Management Committee. Those actions or decisions include but are not limited to approval of material amendments to the annual operating and capital budget for activities outside normal business, amendments to the documents concerning the formation of the Company, incurrence of indebtedness in excess of $1 million, admitting a new member, acquiring or disposing of assets with a value in excess of $500,000 or settlement of litigation in excess of $1 million. The Members have further agreed that the approval of both Members is required to adopt or materially amend the annual sales and marketing plan or to enter into any contract with a third party sales force.

Buy/Sell and Dissolution Provisions

The joint venture operating agreement includes a buy/sell provision that either Noven or Novartis may trigger by notifying the other party of the price at which the triggering party would be willing to acquire 100 percent of the joint venture. Upon receipt of this notice, the non-triggering party has the option to either purchase the triggering party s interest in the Company or to sell its own interest in the Company to the triggering party at the price established by the triggering party. If Noven is the purchaser, then Noven must pay an additional amount equal to the net present value of Novartis preferred profit return. This amount is calculated by applying a specified discount rate and a period of ten years to Novartis $6.1 million annual preferred return. Either party may dissolve the Company in the event that the Company does not achieve certain financial results.

Novartis has the right to dissolve the joint venture in the event of a change in control of Noven if the acquirer is one of the ten largest pharmaceutical companies (as measured by annual dollar sales). Upon dissolution, Novartis would reacquire the rights to market Vivelle® and Vivelle-Dot® subject to the terms of the prior arrangement between Noven and Novartis, and the Company s other assets would be liquidated and distributed to the parties in accordance with their capital account balances as determined pursuant to the joint venture operating agreement.

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals
Notes to Financial Statements
December 31, 2003

6. Transactions with Affiliates

Services

The Company relies on Novartis and Noven for providing certain services. These are detailed below.

Novartis is responsible for providing the following services:

Shipment of the products, fulfillment of product orders, inventory control and distribution, processing of invoices and cash management.

Management of the overall marketing and sales program for the products in the managed care sector of the market, including but not limited to all corporate, institutional and government accounts.

Customer service support and assistance for the products.

Regulatory affairs support and assistance for the products.

Bookkeeping and accounting, administrative functions relating to the distribution and sale of the products, and assistance with tax matters, insurance coverage and treasury services.

Legal services.

Charges for these services are based upon predetermined budgeted amounts that are ratified by the Management Committee of the Company on an annual basis. The Company believes this method is a reasonable basis for determining those charges.

During the years ended December 31, 2003, 2002 and 2001, Novartis charged the Company $3,205,708, $2,324,055 and $1,976,952, respectively, for these services.

Bookkeeping, Accounting and Treasury

The books and records of the Company are maintained by Novartis. The Company s transactions are initially recorded in Novartis general ledger and are transferred to the Company s ledger on a monthly basis with the corresponding entry being recorded as an amount due to or from Novartis. The balances in this account of $21,332,627, $28,470,812, $16,493,027 as of December 31, 2003, 2002 and 2001, respectively, represent the net balance of these transactions for the period from commencement of the Company to those dates.

The Company received interest on amounts due from Novartis during the year ended December 31, 2003, 2002 and 2001 at an average annual rate of 1.2 percent, 2 percent and 5 percent, respectively. During these periods, interest of $181,957, $349,741 and $733,600, respectively, was earned and is reflected in the amount due from Novartis.

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Novartis records the accounts receivable balances due from the Company s sales in its general ledger and records these in the Company s general ledger as amounts due from Novartis. The Members have agreed that Novartis is responsible for managing the receivables balances and Novartis bears the risk of the balances not being recovered in full. However, the Company records receivables for sales to Novartis Pharmaceuticals Canada, Inc. and retains the risk related to these balances. These receivables are reflected in the amount due from Novartis Pharmaceuticals Canada, Inc. on the financial statements.

The following summarizes the transactions processed through the Due from affiliate Novartis account:

	Years Ended December 31,		
	2003	**2002**	**2001**
Balance at the beginning of the period	$ 28,470,812	$ 16,493,027	$ 35,979,478
Capital contributions by members			32,000,000
Net sales (excluding returns)	106,498,093	112,027,659	94,210,120
Sales returns processed	(6,465,554)	(8,165,215)	(4,602,001)
Copromotion income	900,000		
Interest income on cash balances	181,957	349,741	733,600
Distributions to members	(63,062,759)	(26,491,234)	(43,900,000)
Payment to Noven for inventory purchases, royalties, and other items	(42,717,694)	(58,528,474)	(40,284,456)
Disbursements made on behalf of the Company	(1,608,162)	(804,134)	(1,001,799)
Novartis service charges	(3,205,708)	(2,324,055)	(1,976,952)
Cash received from Novartis Canada	1,808,528	5,605,479	518,241
Payments for CombiPatch® license		(10,000,000)	(55,000,000)
Other	533,114	308,018	(183,204)
Total	$ 21,332,627	$ 28,470,812	$ 16,493,027

Noven is responsible for providing the following services:

Manufacturing and packaging products for distribution by Novartis.

Retention of samples and regulatory documentation of the products.

Design and implementation of an overall marketing and sales program for the products in the hospital and

retail sales sectors of the market, including the preparation of annual and quarterly marketing plans and field sales force staffing.

Quality control and quality assurance testing of finished goods prior to shipment to Novartis.

During the years ended December 31, 2003, 2002 and 2001, Noven charged the Company $18,652,109, $18,344,551 and $16,187,211, respectively, for these services.

Noven also provides advertising and other services in connection with the marketing and promotion of the products. Such costs charged during the years ended December 31, 2003, 2002 and 2001 were $8,835,488, $11,599,911 and $8,628,409, respectively.

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Royalties

Royalties are payable to Noven by the Company on the sale of Vivelle® and Vivelle-Dot® in the United States of America. The royalty formula is based upon a percentage of the products net sales. In addition, a minimum annual royalty formula is specified. During the years ended December 31, 2003, 2002 and 2001, total royalties of $4,978,247, $4,504,663 and $4,036,972, respectively, were incurred, of which $1,555,573, $905,407 and $952,312 remained payable to Noven as of December 31, 2003, 2002, and 2001, respectively.

Product Transactions

Vivelle®, Vivelle-Dot® and CombiPatch® are manufactured by Noven and sold to the Company at an agreed upon price. During the years ended December 31, 2003, 2002 and 2001, the Company purchased products from Noven in the amounts of $12,410,859, $21,983,870 and $13,634,475, respectively.

Research and Development

Noven assumes responsibility for research and development costs associated with the development of Vivelle®, Vivelle-Dot®, CombiPatch® and all future generation products.

Due to Affiliate-Noven Pharmaceuticals, Inc.

The following represents the amounts payable to Noven related to:

	December 31,	
	2003	**2002**
Purchases of inventory	$1,353,721	$1,630,975
Services provided by Noven	4,255,330	2,028,897
Royalties	1,555,573	905,407
	$7,164,624	$4,565,279

7. Commitments and Contingencies

The Company is subject to legal proceedings, including product liability claims, related to its normal course of business. The Company is not currently a party to any pending litigation which, if decided adversely to the Company, would have a material adverse effect on the business, financial condition, results of operations or cash flows of the Company.

As a result of an amended and restated Supply Agreement between Novartis and Noven, Noven supplies finished goods to the Company. The Company is obligated to purchase a nominal amount of inventory in the subsequent fiscal year. The Supply Agreement expired in January 2003. Since expiration, the parties have continued to operate in accordance with the supply agreement s commercial terms. Failure to renew the Supply Agreement could have a material adverse impact on the Company s financial position, results of operations and cash flows.

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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 use of oral combination hormone therapy (HT). The study revealed an increase in the risk of developing breast cancer and increased risks of stroke, heart attack and blood clots. Also in July 2002, results of an observational study sponsored by the National Cancer Institute on the effects of estrogen therapy (ET) were announced. The main finding of the study was that postmenopausal women who used ET for 10 or more years had a higher risk of developing ovarian cancer than women who never used HT. In June 2003, a new analysis of study data indicated that use of combination HT may increase the frequency of abnormal mammograms beginning in the first year of therapy and/or may cause tumors at the time of diagnosis to be more advanced. In August 2003, further WHI data analysis suggested that the use of combination therapy increased the risk of heart disease beginning in the first year of therapy, and a large study in the United Kingdom suggested that the use of both estrogen-only and combination therapy increased the risk of breast cancer, and the risk of death from breast cancer, whether administered orally, transdermally or via implant. In March 2004, the NIH discontinued the estrogen-only arm of the WHI study because of an increased risk of stroke and because, after nearly seven years of follow-up, the NIH determined that it had sufficient data to assess the risks and benefits of estrogen use in the trial. This arm of the WHI study also found that the use of an estrogen-only oral formulation appeared to decrease the risk of hip fracture, and did not appear to affect heart disease or to increase the risk of breast cancer. Researchers continue to analyze data from both arms of the WHI study and other studies. Other studies evaluating HT are currently underway or in the planning stages.

These studies and others have caused the HT market, and the market for the Company s product, to significantly decline. Prescriptions for CombiPatch®, the Company s combination estrogen/progestin patch, continue to decline in the post-WHI environment. The Company recorded the acquisition of CombiPatch® marketing rights at cost and tests this asset for impairment on a periodic basis. Further adverse change in the market for HT products could have a material adverse impact on the ability of the Company to recover its investment in these rights, which could require the Company to record an impairment loss on the CombiPatch® intangible asset. Impairment of the CombiPatch® intangible asset would adversely affect the Company s financial results. The Members can not predict whether these or other studies will have additional adverse effects on the Company s liquidity and results of operations, or the Company s ability to recover the carrying value of the CombiPatch® intangible asset.