NOVEN PHARMACEUTICALS INC
Form 10-K/A
March 26, 2003

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

FORM 10-K/A
(Amendment No. 1)

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

For the fiscal year ended December 31, 2002 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. x

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, 2003, there were 22,580,100 shares of Common Stock outstanding.

The aggregate market value of the voting stock held by non-affiliates of the registrant on March 1, 2003, was approximately $244 million.

The aggregate market value of such voting stock held by non-affiliates of the registrant was approximately $573 million (computed by reference to the price at which the voting stock was last sold on June 28, 2002, 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 2003 Annual Meeting of Shareholders.

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NOVEN PHARMACEUTICALS, INC.

Annual Report on Form 10-K
for the year ended December 31, 2002

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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. 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.

Our principal commercialized products are transdermal drug delivery systems for use in menopausal hormone therapy. 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 ever approved by the United States Food and Drug Administration (FDA), was launched in the United States under the brand name Vivelle-Dot®. This product was launched in several foreign countries in 2002 and is expected to be launched in additional countries in 2003 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. See Transdermal Drug Delivery Products below for a more complete description of our transdermal products and their marketing status.

In June 2002, we filed a New Drug Application (NDA) with the FDA for our once-daily transdermal methylphenidate delivery system for the treatment of Attention Deficit Hyperactivity Disorder (ADHD), which is intended to be marketed under the trade name MethyPatch®. We believe that this product will address several serious issues associated with existing therapies and, if approved, will compete in the over $1.4 billion market for drugs that treat ADHD in the United States. In February 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 revenue. See Transdermal Drug Delivery Products below for a more complete description of MethyPatch® and the Shire transaction.

We have an active research and development program investigating a broad range of products and therapeutic categories. Two of our projects are currently in active clinical development. We have completed early clinical trials for other products for which we intend to seek development partners before pursuing further trials. In addition, significant pre-clinical research is ongoing as we select new candidates for possible independent and joint development. See Research and Development below for a more complete description of our product development program.

Novogyne Pharmaceuticals

In May 1998, we formed a joint venture limited liability company with Novartis Pharmaceuticals Corporation (Novartis) called Vivelle Ventures LLC to market and sell women s prescription healthcare products. The joint venture does business under the name Novogyne Pharmaceuticals (Novogyne), and markets Vivelle®, Vivelle-Dot® and CombiPatch® in the United

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States. In 2002, Novogyne s sales and marketing efforts resulted in the Vivelle® family of products becoming the most dispensed product family in the transdermal estrogen replacement therapy (ERT) category, with a 38% share of monthly total prescriptions dispensed as of December 2002. In 2002, our equity in earnings of Novogyne, a non-cash item, represented 66% of our income before income taxes.

Novogyne is managed by a committee of five members, three appointed by Novartis and two appointed by us. Pursuant to the joint venture operating agreement, certain significant actions require a supermajority vote of the committee members. The President of Novogyne is Robert C. Strauss, who also serves as President, Chief Executive Officer and Chairman of the Board of Noven.

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 a 49% equity interest in Novogyne. Novartis contributed its rights to Vivelle® to Novogyne and also licensed to Novogyne the right to use the Vivelle® trademark in return for a 51% equity interest in Novogyne. 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 certain of the products. Novartis distributes Vivelle®, Vivelle-Dot® and CombiPatch® and provides certain other services to Novogyne, including marketing to the managed care sector, regulatory, accounting and legal services. Neither the operating agreement for Novogyne nor any other agreement between Novartis and us prohibits Novartis from developing, marketing, selling or promoting any product or family of products. Novartis and its affiliates sell competing products, both in the United States and abroad, and it is possible that Novartis will promote its other competitive products at our expense. Any reduction in the level of support and promotion that Novartis provides to our products, whether as a result of Novartis focus on other products or otherwise, could have a material adverse effect on our business, results of operations, financial condition and prospects.

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%.

Novogyne acquired the exclusive United States marketing rights to CombiPatch® 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. Prior to the transaction, Aventis had been our exclusive licensee for CombiPatch® in the United States. The transaction was structured as (a) a direct purchase by Novogyne from Aventis of certain assets for $25.0 million, which was paid at closing, (b) a grant-back by Aventis to us of certain intellectual property rights relating to CombiPatch®, and (c) a simultaneous license by us to Novogyne of these intellectual property rights. The consideration payable by us to Aventis, and by Novogyne to us, was $40.0 million, which was due in four quarterly installments of $10.0 million each 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 revenue over ten years beginning in the first quarter of 2001.

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In a related transaction, Novartis Pharma AG (Novartis AG) acquired from Aventis the development and marketing rights to future generations of our combination estrogen/progestin patch in all markets other than Japan. Novogyne expects to sublicense the United States rights to these product improvements from Novartis AG. We cannot assure that Novartis AG will agree to sublicense the product to Novogyne upon commercially reasonable terms or at all. If any future generation combination products are commercialized and sublicensed to Novogyne, Novogyne expects that it will pay a royalty to Novartis AG on the United States sales of such products. We manufacture and supply CombiPatch® and expect to manufacture and supply any future combination products to Novogyne and to Novartis AG. We expect that Novogyne s product line will be expanded in the future, although no assurance can be given that Novogyne will add additional products or that such products will be successfully marketed, and any such expansion would be subject to the approval of Novartis.

Either party may dissolve the joint venture in the event that Novogyne does not achieve certain financial results. We expect that the applicable financial targets will be achieved, although we cannot assure that unexpected events will not affect Novogyne s financial performance. Dissolution may also result from a change in control of Noven if the acquirer is a top ten pharmaceutical company (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 operating agreement also has a buy/sell provision which allows either party to compel either the purchase of the other party s interest in Novogyne or the sale of its own interest at a price set by the party triggering the buy/sell provision. 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.

Strategy

Our strategy for continued growth and profitability is to utilize our proprietary transdermal drug delivery technology to establish a 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 and pain management. On a long-term basis, we may seek to (i) form new strategic alliances with other pharmaceutical companies, (ii) expand our transdermal technology base, (iii) establish our own sales force to market certain of our independently developed products and potentially to acquire products to market through our own sales force, and (iv) 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 successfully implement all or part of our long-term strategy or that our strategy will be successful.

HRT Market Overview

There are more than 40 million post-menopausal women in the United States, and this group is expected to grow 50% by 2020. We estimate that, in 2002, worldwide sales of all menopausal

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hormone replacement therapy (HRT) products, including those delivered transdermally, were over $3.5 billion and that worldwide transdermal HRT product sales were over $500 million.

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 replacement therapy relieves hot flashes and night sweats effectively, and prevents drying and shrinking of the reproductive system.

Another condition related to the inability to produce estrogen is osteoporosis, a progressive deterioration of the skeletal system through the loss of bone mass. The loss of estrogen in menopause causes increased skeletal resorption and decreased bone formation. Osteoporosis currently affects over 20 million women and contributes to approximately 1.5 million fractures annually in the United States. Morbidity and suffering associated with these fractures are substantial. Estrogen replacement prevents the loss of bone mass and reduces the incidence of vertebral and hip fractures in older women. There are, however, other approved therapies for osteoporosis and, in light of the HRT studies described below, hormone replacement may no longer be considered by physicians as first line therapy for this condition.

HRT Studies

In July 2002, the National Institutes of Health (NIH) released data from its Women s Health Initiative (WHI) study on the risks and benefits associated with long-term use of oral HRT by healthy women. The NIH announced that it was discontinuing the arm of the study investigating the use of oral estrogen/progestin combination HRT products after an average follow-up period of 5.2 years because the oral HRT 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 ERT were announced. The main finding of the study was that postmenopausal women who used ERT for 10 or more years had a higher risk of developing ovarian cancer than women who never used HRT. In October 2002, a significant HRT study being conducted in the United Kingdom was also halted. Our transdermal HRT products differ from the products used in the WHI study and the primary products observed in the NCI and United Kingdom studies. There are, however, no studies comparing the safety of our products against other HRT therapies.

Although the range of consequences of these studies cannot be predicted, it is possible that they could result in a significant permanent decrease in the market for our HRT products, either as physicians withdraw their patients from HRT or as women elect to discontinue HRT on their own. In addition, the market growth that would have been expected if HRT had been found safe and effective to treat additional indications, such as heart disease, is now unlikely to materialize. In January 2003, the FDA announced that marketers of HRT products, including Novogyne, are required to modify their HRT product labels to include additional safety information and warnings.

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Among other things, the labels must indicate that HRT should be used for short-term therapy only and that, in the absence of clinical studies demonstrating that HRT products other than the oral product studied in the WHI are safe, physicians should assume that all HRT products carry the same risks. Novartis has informed us that it intends to submit proposed revised labeling to the FDA and to begin using the revised label at the time it reaches agreement with the FDA on the label s language. Healthcare regulators also could delay the approval of new HRT products, such as those we are presently developing with Novartis AG (see Products Transdermal Combination Estrogen/Progestin Delivery System below), or require that any new HRT products be subject to more extensive or more rigorous study and testing prior to being approved. The FDA has mandated that all companies engaged in clinical development of HRT products inform study subjects of the risks identified in the referenced studies. Further, because these studies show that certain uses of certain HRT products may result in a higher likelihood of certain adverse health effects, it is possible that we could be named as a defendant in product liability lawsuits relating to our HRT products.

Other studies evaluating HRT are currently underway or in the planning stages. In particular, the estrogen-only arm of the WHI study is ongoing. We are unable to predict the effect of new study results, once available, on the short and long-term prospects for the HRT market or for the market for our transdermal HRT products. Since publication of the WHI and NCI study data, United States prescriptions have declined for substantially all HRT products, including our products, and prescriptions in Europe have also declined. The WHI safety board re-evaluates the risk/benefit profile of the estrogen-only arm as frequently as twice per year. If the estrogen-only study or any other currently ongoing HRT study is halted, the market for HRT products, including ours, both in the United States and abroad, could be further adversely impacted. The HRT label changes mandated by the FDA may also negatively impact our products, particularly with physicians and patients who now believe that transdermal HRT products are safer than orally delivered HRT products. Currently, our liquidity, results of operations and business prospects are almost entirely dependent on sales, royalties and license fees associated with transdermal HRT products. Accordingly, any further adverse change in the market for HRT products (including any adverse changes resulting from the foregoing studies) could have a material adverse impact on our liquidity, results of operations and business prospects.

Transdermal Drug Delivery

Description

Transdermal drug delivery systems utilize an adhesive patch containing medication which is administered through the skin and into the bloodstream over an extended period of time. Transdermal drug delivery systems may offer significant advantages over conventional oral and parenteral dosage forms, including non-invasive administration, controlled delivery, improved patient compliance, reduced abuse potential, 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.

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DOT Matrix patches, such as Vivelle-Dot®/Estradot®, CombiPatch®/Estalis® and MethyPatch®, utilize a patented blend of silicone, acrylic and drug. This blend causes thousands of 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 minimizes 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 improve a patient s quality of life by reducing skin irritation sometimes associated with transdermal drug delivery systems, by improving adhesion and by minimizing patch size. Our transdermal drug delivery systems are capable of being modified to deliver a wide variety of chemical entities. With DOT Matrix technology, molecules previously believed unsuitable for transdermal delivery can be administered at efficacious doses with minimal irritation. 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.

Products

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 offers five dosage strengths, thereby allowing physicians to maintain patients on the appropriate dose of estrogen.

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 AG in all other territories. Novartis AG is selling this product under the brand name Menorest® in over 10 foreign countries. Novogyne and Novartis AG 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 AG, 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, and the parties are currently negotiating an extension to the agreement. Since the expiration of the Vivelle® supply agreement, the parties have continued to operate in accordance with the supply agreement s commercial terms, and we expect that the supply agreement will be extended on satisfactory terms. However, we cannot assure that the agreement will be extended on satisfactory terms or at all. Failure to extend the supply agreement could have a material adverse effect on our business, results

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of operations, financial condition and prospects. Designation of a supplier and approval of a new supply agreement require the affirmative vote of 4 of the 5 members of Novogyne s Management Committee. Accordingly, Novartis and we must both agree on Novogyne s supplier.

Second Generation Transdermal Estrogen Delivery System

Our continued efforts to improve our matrix patch technology have resulted in the successful development of a second generation transdermal estrogen delivery system called Vivelle-Dot®. This second generation system, utilizing our proprietary DOT Matrix technology, is one-third the area of a Vivelle® or 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 HRT studies described above and the expected label changes, many physicians may consider alternative treatments for 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 AG pursuant to which we granted Novartis AG 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 AG marketing rights in the same territories to any product improvements and future generations of estrogen patches developed by us. We received an up-front license payment of $20.0 million upon execution of the agreement. For accounting purposes, that payment was deferred and is being recognized as license revenue over 10 years beginning in the fourth quarter of 2000. We subsequently received a $5.0 million milestone payment that is being recognized as license revenue beginning in the first quarter of 2002 through the fourth quarter of 2010. Under the terms of the agreement, Novartis AG 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 AG s registration applications. Novartis AG has launched the product in Germany and a number of smaller European countries. However, Novartis AG has informed us that pricing and reimbursement issues are adversely impacting its launch plans in many countries, including the United Kingdom, France, Spain and Italy. Accordingly, there can be no assurance that Novartis AG will be successful in effecting additional registrations of Estradot® or that Novartis AG will launch Estradot® in any particular country. In some countries, including the United Kingdom and France, Novartis AG is seeking a marketing partner to launch the product but to date has been unsuccessful. We cannot assure that Novartis AG will be successful in securing a marketing partner or in launching Estradot® in those countries.

Novartis AG markets several other estrogen patches in addition to our products. The growth of Estradot® sales depends, in part, on Novartis AG s willingness and ability to convert sales of its existing patches to Estradot®. We cannot assure that Novartis AG will choose to actively convert sales of its existing patches to Estradot®.

Pursuant to license and supply agreements with Novartis AG 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 and Vivelle-Dot® is supplied under the same

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agreement as Vivelle®. As discussed above, although we expect that the United States supply agreement will be extended, we cannot assure that it will be extended on satisfactory terms or at all.

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 a progestin, norethindrone acetate. Benefits of estrogen replacement therapy include menopausal symptom control and osteoporosis prevention. For women who have an intact uterus (non-hysterectomized), estrogen-only replacement therapy has been associated with an increased risk of endometrial cancer. To address this situation, a combination therapy of estrogen and progestin may be prescribed. Using both products together has been shown to reduce the risk of endometrial cancer while continuing to produce the benefits of estrogen replacement 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, where it is the only available combination HRT patch. Novogyne had been unable to increase CombiPatch® prescriptions after acquiring and relaunching the product, and since publication of the HRT studies described above, CombiPatch® prescriptions and sales have declined significantly.

Novartis AG also 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. Estalis® is presently approved in only one dosage strength in most European countries. Novartis AG has advised us that it filed an application for approval of a second dosage strength in Sweden in December 2002, but no assurance can be given that approval will be obtained, and launch timing in any given country cannot be predicted. We expect that growth in Estalis® sales will be limited unless and until a second dosage strength is approved and launched.

In June 2001, we entered into a development agreement with Novartis AG relating to future generations of combination estrogen/progestin patch products. In the fourth quarter of 2002, we received a $1.0 million milestone payment from Novartis AG in connection with ongoing development under this agreement. The payment is being recognized as income as the specific performance criteria are achieved.

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

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

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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).

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. Prevalence rates vary among studies because of differences in diagnostic criteria. Stimulant therapies, including methylphenidate, are the most prescribed drug type for the treatment of ADHD. ADHD symptoms often persist into adolescence and adulthood. Some studies have reported that ADHD will persist into adulthood in up to 60% of individuals. Industry analysts estimate that annual United States sales of ADHD medications exceed $1.4 billion, with as many as 1.5 million children receiving pharmacological treatment for ADHD.

Presently, all ADHD medications approved in the United States are delivered orally, and a significant number of patients require more than one dose per day. We expect that our patch, worn under clothing, would eliminate the stigma that many children suffer when receiving oral medication during the school day, and may reduce the drug diversion and abuse issues that may be associated with many oral formulations. We also believe that our product will provide physicians with broad dosing flexibility, because dosing can be discontinued by simply removing the patch.

In the first quarter of 2002, we completed a second Phase III clinical trial for MethyPatch®, and our review of the primary efficacy data from the trial indicates that MethyPatch® reduces the symptoms of ADHD. We filed an NDA with the FDA in June 2002.

In February 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 revenue. Consideration for the transaction is payable as follows: (a) $25 million payable upon closing of the transaction; (b) $50 million upon receipt of final marketing approval for MethyPatch® by the FDA; and (c) three installments of $25 million each 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. For accounting purposes, all payments (other than manufacturing revenue) will be deferred and recognized as revenue over a period of years. Closing of the transaction is conditioned on, among other things, the expiration of any regulatory waiting period under the Hart Scott Rodino Antitrust Improvements Act of 1976, and is expected to take place in April 2003.

Under the terms of the transaction, we remain responsible for securing final regulatory approval for MethyPatch® from the FDA. If we receive a non-approval letter from the FDA or if FDA approval has not been granted within two years of the closing date, Shire may require us to repurchase the product rights for $5 million. Shire has agreed that it will not sell any other product containing methylphenidate as an active ingredient until the earlier of (a) five years from the closing date or (b) payment of all of the sales milestones.

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On the closing date, we will enter into a long-term supply agreement under which we will manufacture and supply MethyPatch® to Shire. The agreement will give Shire the right to qualify a second manufacturing source and purchase a portion of its requirements from the second source.

We cannot assure that the product will be approved by the FDA. The FDA will examine efficacy data from the recently completed Phase III study together with safety and other data from this and other MethyPatch® studies we sponsored, and we cannot assure that the FDA will deem all of such data sufficient to approve the product for marketing or to authorize the product s use in the manner we described. We believe that MethyPatch® is the first transdermal ADHD product submitted to the FDA for approval, and we cannot assure that the FDA will not have questions or raise objections that could delay or prevent an approval. Additionally, we cannot assure that the FDA will not place conditions or restrictions on any approval that it may grant, which conditions or restrictions could adversely affect the market potential of MethyPatch®.

The market for ADHD drugs is 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. Shire currently markets non-methylphenidate products for treatment of ADHD, and we cannot assure that Shire will market MethyPatch® aggressively or effectively. There are several other once-daily ADHD medications on the market. Other products which may have improved safety and efficacy profiles are also in development. We cannot assure that Shire will successfully commercialize the product or that it 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. A recent entrant to the market is Strattera , a non-stimulant, non-controlled substance therapy marketed by Lilly. We are unable to predict the impact of Strattera on the ADHD market. 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.

Dependence on Licensees and Joint Venture

During 2002, 54% and 42% of our revenues were generated from sales to, and contract revenue, fees and royalties received from, Novogyne and Novartis AG, respectively, and 66% 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 AG, Novogyne and Shire, as well as fees, milestone payments 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. With respect to

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Novartis AG s and Shire s marketing efforts, our agreements with these companies 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 HRT study data described above, CombiPatch® prescription trends had not improved significantly since Novogyne acquired marketing rights in March 2001. Since the HRT study data was published, CombiPatch® prescriptions have, like most HRT products, declined, and we cannot assure that Novogyne s sales force will be successful in growing CombiPatch® sales. Failure of Novogyne to successfully market Vivelle®, Vivelle-Dot® or CombiPatch® would have a material adverse effect on our business and results of operations. See Competition below for a more complete description of the competitive factors affecting us and our business.

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 amelioration of pain from oral injections and soft tissue dental procedures. It is the first topical anesthetic clinically proven to prevent 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® do not contribute meaningfully to our results of operations.

Research and Development

Our research and development strategy is to identify drugs that can be delivered transdermally, which can be developed rapidly and which have substantial market potential. We also seek therapies that can be improved by using our innovative technologies. We will typically seek to develop products that use established agents which currently are being delivered to patients other than transdermally. In addition, we may enter into agreements to develop transdermal drug delivery systems utilizing proprietary compounds of other companies. For the years ended December 31, 2002, 2001 and 2000, we spent $11.6 million, $11.0 million and $13.6 million, respectively, for research and development activities. From time to time, we may supplement our research and development efforts by entering into research and development agreements, joint ventures and other collaborative arrangements with other companies. In allocating research and development dollars and

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resources, we may devote greater resources to the development of products that we believe we can market and sell without a business partner.

Our research and development expense may vary significantly from quarter to quarter depending on product development cycles and the timing of clinical studies. 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 length of time necessary to complete clinical trials, and from submission of an application for market approval to a final decision by a regulatory authority, 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.

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The following table summarizes as of March 1, 2003 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 in early development and continuously evaluate other drugs that may be suitable for transdermal delivery.

Product	Indication	Regulatory Status	Marketing Rights
Transdermal HRT			
Estrogen Vivelle®/Menorest®/ Femiest®	Menopausal Symptoms	FDA-approved; Approved in over 40 foreign countries	Novogyne U.S. Aventis Japan Novartis AG all other territories
	Osteoporosis	FDA-approved; Approved in over 40 foreign countries	
Second Generation Estrogen Vivelle-Dot®/ Estradot®	Menopausal Symptoms	FDA-approved; Approved in over 30 foreign countries	Novogyne U.S. Aventis Japan Novartis AG all other territories
	Osteoporosis	FDA-approved; Approved in over 30 foreign countries	
Combination Estrogen/Progestin CombiPatch®/Estalis®	Menopausal Symptoms	FDA-approved; Approved in over 25 foreign countries	Novogyne U.S. Aventis Japan Novartis AG all other territories
Second Generation Combination Estrogen/Progestin Methyltestosterone*	Menopausal Symptoms/Osteoporosis Female Libido	Phase I (sponsored by Novartis AG) Phase I	Aventis Japan Novartis AG all other territories Noven
Other Transdermals			
Methylphenidate MethyPatch®	Attention Deficit Hyperactivity Disorder	NDA filed	Shire worldwide
Dextroamphetamine	Attention Deficit Hyperactivity Disorder	Pre-clinical	Noven

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Product	Indication	Regulatory Status	Marketing Rights
Fentanyl	Pain Relief	Clinical Development	Noven
Transmucosal			
Lidocaine/DentiPatch®	Dental Pain Control	FDA-approved	Noven

* This product is available for licensing. We do not intend to further the development of this product unless and until we have entered an agreement with another company to assist in the development. We cannot assure that we will be able to identify any such development partner or that we will be able to enter into a license or development agreement on commercially reasonable terms. The failure to enter into such an agreement may result in the discontinuation of this development project.

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 Control 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®. 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) are, however, available from limited sources, and in some cases, a single source. Our NDA for MethyPatch®, for example, includes only one active drug ingredient supplier. In addition, the DEA controls access to controlled substances (including methylphenidate), and we must receive authorization from the DEA to obtain these substances. 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, with consequent adverse effects on our business and results of operations. In addition, because raw material sources for pharmaceutical products 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.

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Marketing

Except for DentiPatch®, we have historically granted marketing rights to our products to our joint venture company, Novogyne, or to other pharmaceutical companies. As we develop new products, we will evaluate whether to license such products to a larger company or utilize our own clinical, marketing and sales capabilities. Our evaluation will be conducted on a product-by-product basis and will include consideration of the characteristics of the particular market and the estimated costs associated with clinical studies, sales, marketing and distribution. These combined costs and our financial position will be factored into the decision whether to license or market the product. We expect that we will seek to retain manufacturing rights in any future licensing transactions, partly in an effort to safeguard our proprietary technology. There can be no assurance that we will be able to reach a favorable agreement in any particular transaction or collaborative arrangement.

We have substantial day-to-day management control over the Novogyne sales force. If we develop any products in the future for the women s healthcare market, we may seek to license the marketing rights for such products to Novogyne.

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. 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 face competition from a number of companies in the development, marketing and sale of transdermal drug delivery products, and competition is expected to intensify. Competitors include Elan Corporation, plc, Watson Pharmaceuticals, Inc., Mylan Pharmaceuticals, Inc., LTS Lohmann Therapie-Systeme AG, Johnson & Johnson, Schering-Plough Corporation, 3M Corporation, Groupe Fournier, Women First HealthCare, Inc., Novavax, Inc. and others, including Novartis, Novartis AG and their affiliates. Some of these companies are substantially larger and have greater resources than we do, as well as greater experience in developing and commercializing pharmaceutical products. 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.

Other competitive factors affecting our business include the prevalence and influence of managed care organizations, government organizations, buying groups and similar institutions that seek

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price discounts and rebates on pharmaceutical products. As the influence of these entities continues to grow, we and our marketing partners may face increased pricing pressure. Outside of the United States, our products may be affected by government price controls and reimbursement policies.

Patents and Proprietary Rights

We seek to obtain patent protection on our delivery systems and manufacturing processes whenever possible. We have obtained over 25 United States patents and over 140 foreign patents relating to our transdermal and transmucosal delivery systems and manufacturing processes, and have over 110 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 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.

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.

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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) or, in some cases, an Abbreviated New Drug Application (ANDA); and (v) review and approval of the NDA or ANDA 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 ANDA involves an abbreviated approval process that 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, if clinical studies have demonstrated bio-equivalence of the new product to the FDA-approved product. 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 or that such patent has expired. If the applicant certifies that its product does not infringe on the approved product s patent, 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 are developing products for which we intend to file an ANDA. There can be no assurance that we will not be sued for patent infringement, that we would prevail in any litigation or that the costs of litigation would not be prohibitive.

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 the approval of the institution participating in the trials, must be submitted to the FDA prior to commencement of each

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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. If practical and acceptable to the FDA, we intend to design our protocols for the clinical studies of our products to permit acceptance of the data by foreign regulatory authorities and thereby to reduce the risk of duplication of clinical studies. However, 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.

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 insure 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. 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 is site specific. In the event an approved manufacturing facility for a particular drug 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.

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

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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.

Employment

We employ approximately 274 people; approximately 161 are engaged in manufacturing, process development, quality assurance and quality control, 20 in research and development, 9 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 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 90 individuals that we manage under the terms of the Novogyne joint venture agreements.

Seasonality

There are no significant seasonal aspects to our existing HRT business. New ADHD patients are often diagnosed during the start of a school year, so initial sales of MethyPatch® may be affected by the timing of FDA approval and product launch. Thereafter, we expect that MethyPatch® will be prescribed and dispensed more frequently during the school year than in the summer months, which may affect the timing of orders received from Shire.

Available Information

Noven s Internet website address is www.noven.com. Noven s 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. Noven s Internet website and the information contained therein or connected thereto are not incorporated into this Annual Report on Form 10-K.

Item 2. Properties.

Our headquarters and manufacturing facilities are located on a 10 acre site in Miami, Florida. On this site, we own an approximately 28,000 square foot building, which is used for laboratory, office and administrative purposes. We also lease from Aventis, for nominal rent, two approximately 40,000 square foot buildings on this site, which we use for manufacturing, engineering, administrative and warehousing purposes. One of these facilities has been certified by the DEA to manufacture products containing controlled substances. The lease expires in 2024 and we have an option to purchase the leased facilities at any time during the term. 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

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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 our sales and marketing operations. In addition, we own 5 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.

Item 3. Legal Proceedings.

In re: Noven Pharmaceuticals, Inc. Securities Litigation, United States District Court for the Southern District of Florida.

This action consolidated several essentially identical actions brought by plaintiffs purporting to represent a class of purchasers of Noven s common stock during the period March 27 through November 1, 2001. Plaintiffs alleged that during that period, Noven and its officers and directors named as defendants violated Sections 10 and 20 of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder by making material misstatements and omissions regarding international sales of certain of our products that are the subject of an exclusive license agreement with Novartis AG. Plaintiffs sought unspecified damages, for themselves and the class, based on the allegedly artificially inflated prices they paid for their shares of Noven s common stock.

On May 13, 2002, the defendants filed Motions to Dismiss, seeking to have the Court dismiss the plaintiff s Consolidated Amended Complaint. On December 20, 2002, the Court dismissed the Consolidated Amended Complaint for failing to meet the requirements of the Private Securities Litigation Reform Act of 1995. The Court s order dismissed the Consolidated Amended Complaint without prejudice but gave the plaintiffs leave to amend the Consolidated Amended Complaint to attempt to cure its defects. Subsequently, the plaintiffs decided not to amend the Consolidated Amended Complaint, and on February 24, 2003, the parties filed a joint motion for voluntary dismissal of the Consolidated Amended Complaint with prejudice which the Court granted. Under the terms of the Court s order, each party is to bear its own costs and attorneys fees.

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.

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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, 2002.

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, 2003. 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.

Jeffrey F. Eisenberg. Mr. Eisenberg, age 37, 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 50, 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 44, 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.

James B. Messiry. Mr. Messiry, age 60, has been Vice President & Chief Financial Officer of Noven since January 1999. From 1979 through 1984, and subsequently from 1991 until 1998, he served the Bacardi group of companies in a variety of senior executive positions in Europe and North America, most recently as Vice President of Bacardi-Martini, Inc. Between 1985 and 1991, Mr. Messiry held senior finance positions at Beatrice Latin America and Dole Fresh Fruit. From 1973 to 1979, Mr. Messiry served Pfizer, Inc. in various financial and strategic planning roles.

Robert C. Strauss. Mr. Strauss, age 61, 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.

(a) Market Information

Our Common Stock is listed on the Nasdaq Stock Market and is traded under the symbol NOVN. 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, 2001	$41.50	$17.25
Second Quarter, 2001	40.02	16.38
Third Quarter, 2001	39.80	16.19
Fourth Quarter, 2001	22.30	13.12
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

(b) Holders.

As of March 1, 2003, we had 333 stockholders of record.

(c) Dividends.

We have never paid a cash dividend on our Common Stock and do not anticipate paying cash dividends in the foreseeable future.

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Securities Authorized for Issuance under Equity Compensation Plans.

We generally issue stock options under our Amended and Restated Stock Option Plan, our 1997 Stock Option Plan, and our 1999 Long Term Incentive Plan. All of the stock options that we grant to our employees and directors are granted under these plans. In addition to the stock options that we grant under these plans, we have made charitable donations to the University of Miami for the years 2002, 2001 and 2000 in the form of options to acquire shares of our common stock at a price per share equal to the market price of our Common Stock on the date of grant. These options were granted outside of our stock option plans, vested immediately and have ten year terms. One of our non-employee directors serves as Dean of the University of Miami School of Medicine and does not accept any compensation for his service on our Board of Directors.

Equity Compensation Plan Information

The following table provides summary information concerning the equity awards under these compensation plans (option and share amounts in thousands):

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	3,410	$ 15.20	1,290
Equity compensation plans not approved by security holders	23	12.58	
Total	3,433	15.18	1,290

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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.

	Years Ended December 31,				
	2002	2001	2000	1999	1998
	(in thousands, except per share amounts)				
Statement of Operations Data:					
Revenues	$ 55,372	$ 45,947	$ 42,924	$31,650	$21,842
Expenses:					
Cost of products sold	22,973	20,376	19,219	12,721	9,447
Research and development	11,634	10,973	13,621	7,171	6,808
Marketing, general and administrative	14,257	11,554	8,737	7,860	10,105
Total expenses	48,864	42,903	41,577	27,752	26,360
Income (loss) from operations	6,508	3,044	1,347	3,898	(4,518)
Equity in earnings of Novogyne	14,368	14,013	9,294	1,487	
Interest income, net	822	1,770	1,385	343	439
Income (loss) before income taxes	21,698	18,827	12,026	5,728	(4,079)
Income tax expense (benefit)	7,819	6,736	(7,608)	(4,732)	
Net income (loss)	$ 13,879	$ 12,091	$ 19,634	$10,460	$ (4,079)
Basic earnings (loss) per share	$ 0.62	$ 0.54	$ 0.90	$ 0.49	$ (.19)
Diluted earnings (loss) per share	$ 0.60	$ 0.51	$ 0.84	$ 0.48	$ (.19)
Balance Sheet Data:					
Cash and cash equivalents	$ 58,684	$ 49,389	$ 40,976	$15,338	$ 5,573
Working capital	59,342	45,788	46,697	16,581	8,847
Investment in Novogyne	34,684	32,043	15,431	8,365	7,500
Total assets	137,702	136,228	104,031	56,888	40,156
Long-term notes payable	5	13	265	604	
Deferred license revenue	29,445	32,758	27,109	8,028	5,644
Stockholders equity	96,741	81,898	65,277	39,393	28,325

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

The following discussion and analysis should be read in conjunction with Noven and Novogyne s 2002 financial statements and the related notes included in this Form 10-K.

General

From our inception in 1987 through 1994, we engaged primarily in the development of advanced transdermal and transmucosal drug delivery systems. During this period, our revenues consisted primarily of amounts paid to us under license agreements with Novartis and Aventis. Beginning in 1995, when our first generation transdermal estrogen delivery system received initial regulatory approvals, we derived a significant portion of our revenues from the sale of our products to our licensees, Novartis and Aventis.

Novogyne and Novartis

In May 1998, we formed Novogyne with Novartis to market and sell women s prescription healthcare products in the United States and Canada. Novogyne markets Vivelle®, Vivelle-Dot® and CombiPatch® in the United States. 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 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 certain of the products. Novartis distributes Vivelle®, Vivelle-Dot® and CombiPatch® and provides certain other services to Novogyne, including marketing to the managed care sector, legal, accounting and regulatory services.

Our share of Novogyne s income, after an annual $6.1 million preferred return to Novartis, increases as product sales increase, subject to a maximum of 49%. Novogyne s income resulted in our recognition of $14.4 million, $14.0 million and $9.3 million in income in 2002, 2001 and 2000, respectively. The income we recognize from Novogyne is a non-cash item. We receive cash from Novogyne in the form of cash distributions declared by Novogyne s Management Committee. 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 2002, 2001 and 2000, we received $11.7 million, $13.1 million and $2.2 million in distributions from Novogyne based upon Novogyne s results of operations for the years ended December 31, 2001, 2000 and 1999, respectively. We invested all of the distributions 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. These investments did not increase our share of Novogyne s equity. 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 you of Novogyne s future profitability or cash distributions. See Novogyne s Audited Financial Statements included herein.

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

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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 revenue over ten years beginning in the first quarter of 2001. See Products Transdermal Combination Estrogen/Progestin Delivery System above for a more complete description of the transaction.

Novogyne s relaunch of CombiPatch® in May 2001 did not meaningfully increase total prescriptions, and since the publication of the HRT studies described below, prescriptions for CombiPatch® have declined. If Novogyne is unable to increase CombiPatch® prescriptions, Novogyne s growth may slow and its contribution to our earnings and cash flow may be reduced. Any failure by Novogyne to remain profitable or to continue to make distributions could have a material adverse effect on our results of operations or financial condition.

Under the terms of the Novogyne joint venture, Novartis is responsible for distribution of Novogyne s products, including Vivelle®, and for selling Novogyne s products to its trade customers. Novartis regularly reports inventory information to the Novogyne Management Committee. In the third quarter of 2002, Novartis reported that trade inventory levels of Vivelle® in the aggregate were higher than in prior periods and appeared to have grown to levels that exceeded current demand. This situation has continued into 2003. During 2002, Vivelle® returns also increased, and Novogyne increased its reserve for sales allowances and returns.

Based on information that we have received from Novartis, we believe that current inventory levels at Novogyne have increased and are higher than desirable in light of our trade customers current and expected demand. To align inventories with demand, Novogyne is curtailing product shipments to its trade customers, and we are deferring product shipments to Novogyne. These actions will adversely impact Novogyne s and our financial results. We expect that sales of Novogyne s products in future periods will be adversely impacted as trade customers are expected to reduce their inventories and as Novogyne and we take affirmative steps to attempt to reduce Novogyne s inventory levels. We also expect that our sales to Novogyne, and our gross margin on those sales, will be adversely impacted, both as a result of an expected decline in orders from trade customers seeking to reduce their inventory levels (which would reduce Novogyne s sales) and by Novogyne s reduction of its higher than normal inventory levels (which would reduce our sales to Novogyne). A further decline in prescriptions of Novogyne s HRT products, whether as a result of the HRT studies, related product label changes, or otherwise, could further exacerbate this situation. We are unable to predict either the timing or the magnitude of the impact of this situation on future sales and results of operations.

Our supply agreement with Novogyne for Vivelle® and Vivelle-Dot® expired in January 2003. The parties are negotiating an extension to the agreement. Since the expiration of the Vivelle® and Vivelle-Dot® supply agreement, the parties have continued to operate in accordance with the supply agreement s commercial terms, and we expect that the supply agreement will be extended on satisfactory terms. However, we cannot assure that the agreement will be extended on satisfactory terms or at all. Failure to extend the supply agreement could have a material adverse effect on our business, results of operations, financial conditions and prospects. Designation of a new supplier and approval of a new supply agreement would require the affirmative vote of 4 of the 5 members of

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Novogyne s Management Committee. Accordingly, Novartis and we must agree on Novogyne s supplier.

In November 2000, we entered into an exclusive license agreement with Novartis AG pursuant to which we granted Novartis AG 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 revenue over 10 years beginning in the fourth quarter of 2000. Noven subsequently received a $5.0 million milestone payment that is being recognized as license revenue beginning in the first quarter of 2002 through the fourth quarter of 2010. Under the terms of the agreement, Novartis AG 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 registration applications. Novartis AG has launched the product in Germany and a number of smaller countries. However, Novartis AG has informed us that pricing and reimbursement issues are adversely impacting its launch plans in many countries, including the United Kingdom, France, Spain and Italy. Accordingly, we cannot assure that Novartis AG will be successful in effecting additional registrations of Estradot® or that Novartis AG will launch Estradot® in any particular country. Novartis AG markets several other transdermal HRT products in addition to our products, which may limit the efforts Novartis AG devotes to our products. In some countries, including the United Kingdom and France, Novartis AG is seeking a marketing partner to launch the product but to date has been unsuccessful. We cannot assure that Novartis AG will be successful in securing a marketing partner or in launching Estradot® in those countries.

HRT Studies

In July 2002, the NIH released data from its WHI study on the risks and benefits associated with long-term use of oral HRT by healthy women. The NIH announced that it was discontinuing the arm of the study investigating the use of oral estrogen/progestin combination HRT products after an average follow-up period of 5.2 years because the oral HRT 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 NCI on the effects of ERT were announced. The main finding of the study was that postmenopausal women who used ERT for 10 or more years had a higher risk of developing ovarian cancer than women who never used HRT. In October 2002, a significant HRT study being conducted in the United Kingdom was also halted. Our transdermal HRT products differ from the products used in the WHI study and the primary products observed in the NCI and United Kingdom studies. There are, however, no studies comparing the safety of our products against other HRT therapies.

Although the range of consequences of these studies cannot be predicted, it is possible that they could result in a significant permanent decrease in the market for our HRT products, either as physicians withdraw their patients from HRT or as women elect to discontinue HRT on their own. In addition, the market growth that would have been expected if HRT had been found safe and

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effective for additional indications, such as heart disease, is now unlikely to materialize. In January 2003, the FDA announced that marketers of HRT products, including Novogyne, are required to modify their HRT product labels to include additional safety information and warnings. Among other things, the labels must indicate that HRT should be used for short-term therapy only and that, in the absence of clinical studies demonstrating that HRT products other than the oral product studied in the WHI are safe, physicians should assume that all HRT products carry the same risks. Novartis has informed us that it intends to submit proposed revised labeling to the FDA and to begin using the revised label at the time it reaches agreement with the FDA on the language. Healthcare regulators also could delay the approval of new HRT products, such as those presently under development by Novartis AG and us, or require that any new HRT products be subject to more extensive or more rigorous study and testing prior to being approved. Further, because these studies show that certain uses of certain HRT products may result in a higher likelihood of certain adverse health effects, it is possible that we could be named as a defendant in product liability lawsuits relating to our HRT products.

Other studies evaluating HRT are currently underway or in the planning stages. In particular, the estrogen-only arm of the WHI study is ongoing. We are unable to predict the effect of new study results, once available, on the short and long-term prospects for the HRT market or on the market for our transdermal HRT products. Since publication of the WHI and NCI study data, United States prescriptions have declined for substantially all HRT products, including our products, and prescriptions in Europe have also declined. The WHI safety board re-evaluates the risk/benefit profile of the estrogen-only arm as frequently as twice per year. If the estrogen-only study or any other currently ongoing HRT study is halted, the market for HRT products, including ours, both in the United States and abroad, could be further adversely impacted. The HRT label changes mandated by the FDA may also negatively impact our products, particularly with physicians and patients who now believe that transdermal HRT products are safer than orally delivered HRT products. Currently, our liquidity, results of operations and business prospects are almost entirely dependent on sales, license royalties and fees associated with transdermal HRT products. Accordingly, any further adverse change in the market for HRT products (including any adverse changes resulting from the foregoing studies) could have a material adverse impact on our liquidity, results of operations and business prospects.

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®. Our review of primary efficacy data from our Phase III clinical trial indicates that MethyPatch® reduces the symptoms of ADHD. We filed an NDA with the FDA in June 2002.

In February 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 revenue. Consideration for the transaction is payable as follows: (a) $25 million payable upon closing of the transaction; (b) $50 million upon receipt of final marketing approval for MethyPatch® by the FDA; and (c) $25 million each 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. For accounting purposes, all payments will be deferred and recognized as revenue over a period of years. Closing of the transaction is conditioned on, among other things, the expiration of any regulatory waiting period

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under the Hart Scott Rodino Antitrust Improvements Act of 1976, and is expected to take place in April 2003.

Under the terms of the transaction, we remain responsible for securing final regulatory approval for MethyPatch®. If we receive a non-approval letter from the FDA or if FDA approval has not been granted within two years of the closing date, Shire may require us to repurchase the product rights for $5 million. Shire has agreed that it will not sell any other product containing methylphenidate as an active ingredient until the earlier of (a) five years from the closing date or (b) payment of all of the sales milestones.

On the closing date, we will enter into a long-term supply agreement under which we will manufacture and supply MethyPatch® to Shire. The agreement will give Shire the right to qualify a second manufacturing source and purchase a portion of its requirements from the second source.

No assurance can be given that the product will be approved by the FDA. The FDA will examine efficacy data from the Phase III study together with safety and other data from this and other MethyPatch® studies sponsored by us, and there can be no assurance that the FDA will deem all of such data sufficient to approve the product for marketing or to authorize the product s use in the manner described by us. We believe that MethyPatch® is the first transdermal ADHD product submitted to the FDA for approval, and there can be no assurance that the FDA will not have questions or raise objections including questions or objections specific to transdermal delivery that could delay or prevent an approval. Questions or objections specific to transdermal delivery of methylphenidate could raise new issues that would require us to expend significant additional time and resources to address, and any such questions or objections could necessitate further clinical testing which could significantly delay FDA approval of MethyPatch®. Additionally, there can be no assurance that the FDA will not place conditions or restrictions on any approval, which could adversely affect the market potential of MethyPatch®.

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Results of Operations

Revenues:

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

	2002	Percentage Change	2001	Percentage Change	2000
Product revenue	$45,520	20%	$37,871	(1%)	$38,269
Contract revenue	1,787	70%	1,049	14,886%	7
Royalties	4,679	12%	4,176	12%	3,729
Product sales	51,986	21%	43,096	3%	42,005
License revenue	3,386	19%	2,851	210%	919
Total revenue	$55,372	21%	$45,947	7%	$42,924
Gross profit (product sales less cost of products sold)	$29,013	28%	$22,720		$22,786
Gross margin (as a percentage of sales)	56%		53%		54%

The $9.4 million, or 21%, increase in 2002 revenues compared to 2001 was primarily attributable to an increase in product sales. Product sales were higher in 2002 as a result of increases in sales of Vivelle-Dot® and Vivelle® to Novogyne and the commencement of Estradot® sales to Novartis AG in the first quarter of 2002, partially offset by lower sales of CombiPatch® to Novogyne and Menorest® and Estalis® to Novartis AG. Product sales for the year ended 2001 included $1.4 million in minimum fee payments related to sales of Menorest® in certain European countries in 2000. These minimum fee payments did not recur in 2002.

The $3.0 million, or 7%, increase in 2001 revenues compared to 2000 was primarily attributable to an increase in license revenue, resulting from the license of Estradot® to Novartis AG in the fourth quarter of 2000 and the license of CombiPatch® to Novogyne in the first quarter of 2001. Product sales were slightly higher in 2001 as a result of higher sales of CombiPatch® in the United States and, to a lesser extent, higher sales of Estalis® outside of the United States, partially offset by a decline in sales of Vivelle® and Vivelle-Dot® to Novogyne.

Based on information that we have received from Novartis, we believe that current trade inventory levels of Vivelle® exceed current demand, and current Novogyne Vivelle® inventory levels are higher than desirable. A further decline in prescriptions of Novogyne s HRT products, whether as a result of the HRT studies, related product label changes, or otherwise, could further exacerbate this situation. We are unable to predict either the timing or the magnitude of the impact of this situation on future sales and results of operations. However, as trade customers and Novogyne reduce orders and attempt to return inventories to desirable levels, and as we curtail shipments to facilitate this process, we expect that sales of Novogyne s products and our sales to Novogyne in future periods will be adversely impacted.

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Gross Margin:

Our gross margin was 56% (or gross profit of $29.0 million) in 2002 compared to 53% (or gross profit of $22.7 million) in 2001. The increase 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.

Our gross margin was 53% (or gross profit of $22.7 million) in 2001 compared to 54% (or gross profit of $22.8 million) in 2000. The decrease resulted from an unfavorable product mix (we sold more product outside of the United States where sales have a lower gross margin). The decrease in gross margin was partially offset by higher minimum fee payments from Novartis AG.

As trade customers and Novogyne reduce orders and attempt to return inventories to desirable levels, and as we curtail shipments to facilitate this process, we expect that our gross margin (and gross profit) for future periods will be adversely impacted.

Operating Expenses:

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

	2002	Percentage Change	2001	Percentage Change	2000
Research and development	$11,634	6%	$10,973	(19%)	$13,621
Marketing, general and administrative	14,257	23%	11,554	32%	8,737

Research and Development

The $0.7 million, or 6%, increase in 2002 research and development expenses compared to 2001 was primarily attributable to increases in purchases of materials and personnel costs for new product development, partially offset by a decrease in clinical study expenses for MethyPatch®.

The $2.6 million, or 19%, decrease in 2001 research and development expenses compared to 2000 was primarily attributable to a decrease in clinical study expenses for MethyPatch®, partially offset by increases related to additional personnel.

Marketing, General and Administrative Expenses

The $2.7 million, or 23%, increase in 2002 marketing, general and administrative expenses compared to 2001 was primarily attributable to increases in MethyPatch® pre-launch marketing expenses and higher incentive plan costs, partially offset by lower outside consulting services related to the implementation of our enterprise resource planning system and nonrecurring reserves for obsolete production equipment in 2001.

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The $2.8 million, or 32%, increase in 2001 marketing, general and administrative expenses compared to 2000 was primarily attributable to an increase in outside consulting services related to the implementation of an enterprise resource planning system, consulting costs related to improvements in production efficiencies, reserves for obsolete production equipment and higher legal fees as a result of the CombiPatch® license transaction. The increase in expenses was partially offset by a decline in recruitment costs and other related expenses.

Other Income and Expenses:

Interest Income

Interest income, net, decreased approximately $0.9 million, or 54%, in 2002 compared to 2001, primarily due to lower interest rates.

Interest income, net, increased approximately $0.4 million, or 28%, in 2001 compared to 2000, primarily due to higher average balances in cash and cash equivalents, partially offset by lower interest rates.

Income taxes

Our effective tax rate was 36% for both 2002 and 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, 2002, we had a net deferred tax asset of $12.4 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.

An income tax benefit of $7.6 million for 2000 resulted from the recognition of a deferred income tax benefit of $9.4 million, partially offset by a current income tax expense of $1.8 million. This resulted from an $11.5 million reduction of the valuation allowance on the deferred income tax asset.

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 2002, 2001 and 2000 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):

Novogyne's Summary Results:	2002	Percentage Change	2001	Percentage Change	2000
Revenues	$102,485	14%	$89,958	54%	$58,544
Cost of sales	26,136	25%	20,833	59%	13,127
Gross profit	76,349	10%	69,125	52%	45,417
Gross margin percentage	74%		77%		78%
Selling, general and administrative expenses	33,091	21%	27,347	53%	17,886
Amortization of intangible assets	6,179	33%	4,635	100%	
Income from operations	37,079		37,143	35%	27,531
Interest income	350	(52%)	734	(53%)	1,562
Net income	$ 37,429	(1%)	$37,877	30%	$29,093
Noven s equity in earnings of Novogyne	$ 14,368	3%	$14,013	51%	$ 9,294

Royalties due to us on sales of Vivelle® and Vivelle-Dot® for 2001 and 2000 have been reclassified from selling, general and administrative expenses to cost of sales to conform to the current year s presentation.

Novogyne s increase in revenue of $12.5 million, or 14%, in 2002 compared to 2001 was primarily attributable to increased sales of Vivelle-Dot® and the full year contribution of CombiPatch®, which was acquired in March 2001, partially offset by higher sales allowances and returns. Revenues for 2002 and 2001 are net of sales allowances and returns of $27.9 million and $14.2 million, respectively. The increase in sales allowances and returns is primarily attributable to increased product sales and higher returns of Vivelle®. Novogyne s increase in revenue of $31.4 million, or 54%, in 2001 compared to 2000 was primarily attributable to increased sales of Vivelle-Dot® and the addition of CombiPatch® in March 2001, partially offset by a decrease in Vivelle® sales. Revenues for 2000 are net of sales allowances and returns of $10.2 million.

Novogyne s gross margin was 74% (or gross profit of $76.3 million) in 2002 compared to 77% (or gross profit of $69.1 million) for 2001. The decrease in gross margin was primarily attributable to higher sales allowances and returns in 2002 and an increase in inventory obsolescence reserves for 2002. Novogyne s gross margin was 78% (or gross profit of $45.4 million) for 2001. The decrease in gross margin in 2001 as compared to 2000 was primarily attributable to the addition of CombiPatch® (which has a lower gross margin) in March 2001 and higher sales allowances and returns in 2001.

Novogyne s selling, general and administrative expenses increased to $33.1 million in 2002 from $27.3 million in 2001, primarily due to higher promotional expenses, the full year effect of a larger Novogyne sales force and higher sample expenses. Novogyne s selling, general and administrative expenses increased to $27.3 million in 2001 from $17.9 million in 2000, primarily

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due to expenses relating to the relaunch of CombiPatch® and to an approximate 20% increase in the size of the Novogyne sales force.

Novogyne amortized $6.2 million and $4.6 million related to the CombiPatch® acquisition cost during 2002 and 2001, respectively. CombiPatch® was acquired by Novogyne in March 2001.

Liquidity and Capital Resources:

As of December 31, 2002 and 2001, we had $58.7 million and $49.4 million in cash and cash equivalents and working capital of $59.3 million and $45.8 million, respectively.

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

	2002	2001	2000
Cash flows:			
Operating activities	$11,787	$ 24,683	$23,832
Investing activities	(3,011)	(19,020)	(1,554)
Financing activities	519	2,750	3,360

Amounts related to distributions from Novogyne for 2001 and 2000 have been reclassified from investing activities to operating activities to conform to the current year s presentation.

Operating Activities:

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 Agreements, in the Notes to Financial Statements for more information. Changes in working capital accounted for most of the remaining change over 2000.

Net cash provided by operating activities in 2000 primarily resulted from the receipt of an up-front license fee of $20.0 million in November 2000 from Novartis AG in connection with the Estradot® license agreement and a $2.2 million distribution from Novogyne. A non-cash item (deferred income tax benefit of $9.4 million) constituted 48% of our net income of $19.6 million. Changes in working capital accounted for most of the remaining increase over 1999.

Investing Activities:

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

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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.

Net cash used in investing activities during 2000 was attributable to the purchase of fixed assets and payment of patent development costs.

Financing Activities:

Net cash provided by financing activities in each of 2002, 2001 and 2000 was attributable to cash received in connection with the issuance of common stock from the exercise of stock options, partially offset by payments made on notes payable.

Short-Term and Long-Term Liquidity:

In December 2000, we entered into a secured revolving credit facility (the Credit Facility) providing for borrowings of up to the lesser of $10.0 million or eligible accounts receivable. The Credit Facility was extended in March 2002 and it will terminate in April 2003. We do not expect to extend the Credit Facility s term. The Credit Facility bears interest at LIBOR plus 1.50% (2.882% at December 31, 2002). At December 31, 2002 and 2001, there were no amounts outstanding under the Credit Facility. Terms of the Credit Facility include minimum net worth, revenue and operating results requirements, as well as maintenance of certain financial ratios, measured on a quarterly basis.

Our principal sources of short-term liquidity are existing cash, cash generated from product sales, fees and royalties under license agreements, distributions from Novogyne and is expected to include payments from Shire in connection with the MethyPatch® transaction. For the year ended December 31, 2002, approximately 66% 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 HRT 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 HRT studies, the pending product label changes or decreases resulting from Novogyne and/or Novogyne s trade customers reducing their inventory levels), the failure of the transdermal HRT market to resume its prior growth trends, or the inability or failure of Novogyne to pay distributions would have a material adverse effect on our short-term liquidity and require us to rely more heavily on our existing cash reserves 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. Closing of the Shire transaction is subject to, among other things, termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. We cannot assure that the transaction will close or that, if it closes, we will receive any payments from Shire.

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 March 14, 2003, we had repurchased 105,000 shares of our common stock at an aggregate price of $1.3 million. Any

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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 Have an Impact on Future Results .

We are unable to predict the effect of the results of the discontinued and ongoing HRT studies discussed above on the short and long-term prospects for the HRT market or for the market for our transdermal HRT products. Accordingly, we are not able to predict the effect that those studies may have on our short-term or 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. We do not intend to extend our Credit Facility, which expires in April 2003. 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 Have an Impact on Future Results for a description of certain matters that could affect our short or long-term liquidity.

New Accounting Standards

In April 2002, the FASB issued Statement No. 145, *Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Correction.* This Statement eliminates extraordinary accounting treatment for reporting gain or loss on debt extinguishment, and amends other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. The provisions of this Statement are effective for us with the beginning of fiscal year 2003. Debt extinguishments reported as extraordinary items prior to scheduled or early adoption of this Statement would be reclassified in

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most cases following adoption. We do not anticipate a significant impact on our results of operations from adopting this Statement.

In June 2002, the FASB issued Statement No. 146, *Accounting for Costs Associated with Exit or Disposal Activities.* This Statement requires recording costs associated with exit or disposal activities at their fair values when a liability has been incurred. Under previous guidance, certain exit costs were accrued upon management s commitment to an exit plan, which is generally before an actual liability has been incurred. Adoption of this Statement is required with the beginning of fiscal year 2003. We do not anticipate a significant impact on our financial statements from adopting this statement.

In December 2002, the FASB issued Statement No. 148 (SFAS 148), *Accounting for Stock-Based Compensation Transition and Disclosure*. This Statement amends FASB Statement No. 123 (SFAS 123), *Accounting for Stock-Based Compensation,* to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, this Statement amends the disclosure requirements of Statement 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. We are required to follow the prescribed format and provide the additional disclosures required by SFAS No. 148 in the financial statements for the fiscal year ended December 31, 2002 and for interim periods beginning with the quarterly period ending March 31, 2003.

In November 2002, the FASB issued Interpretation No. 45, *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*. FIN No. 45 elaborates on the disclosures to be made by a guarantor about its obligations under certain guarantees it has issued and clarifies the accounting for such guarantees. The initial recognition and measurement provisions of FIN No. 45 are effective on a prospective basis to guarantees issued or modified after December 31, 2002, and the disclosure requirements are effective for periods ending after December 15, 2002. We do not anticipate a significant impact on our financial statements from adopting this interpretation.

In January 2003, the FASB issued Interpretation No. 46, *Consolidation of Variable Interest Entities.* 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: (1) 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 (2) 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 in the first fiscal year or interim period beginning after June 15, 2003 to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. We do not anticipate a significant impact on our financial statements from adopting this interpretation.

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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 allowance for doubtful accounts, inventories, intangible assets, 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:

Revenue Recognition:

Substantially all of our product sales are to our licensees, Novogyne and Novartis 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. However, we defer the recognition of 49% of the profit on our product sales to Novogyne until those products are sold by Novogyne. Certain license agreements provide for an adjustment to the price of the product based upon the licensee s actual sales price. We record such adjustments to revenues at the time that the information necessary to make the determination is received from the licensees. Certain license agreements entitle us to minimum fees. We record revenue related to minimum fees when sufficient supporting data is provided by the licensee. If the minimum fees are not determinable, we record the fees on a cash basis. These fees are included in product sales. Royalty revenue consists of royalties payable by Novogyne on sales of Vivelle® and Vivelle-Dot®/Estradot® in the United States and Canada. Royalty revenue is recognized when earned and determinable and is included in product sales.

License revenue consists of up-front, milestone and similar payments under license agreements and is recognized when earned under the terms of the applicable agreements. In most cases, license revenue is deferred and recognized over the estimated product life cycle or the length of relevant patents, whichever is shorter. These estimates of product life cycle or the length of relevant patents may prove to be inaccurate, in which case an adjustment to the associated license revenue would be recognized in our revenue at the time of such determination.

Contract revenue consists of contract development fees and milestone payments earned under contracts with third parties. We recognize revenue under the agreements as the work is performed. These estimates of work completed under the contract may prove to be inaccurate, in which case any resulting adjustments to contract revenue recorded would be recognized in our revenue at the time of such determination. Deferred revenue represents the portion of all refundable and nonrefundable payments received that have not been earned. Costs incurred in performing

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contract development services are included in research and development expenses. Refundable development and license fee payments are deferred until the specified performance criteria are achieved. Contract revenue is included in product sales.

Fair Value of Stock Options:

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, 2002, 2001 and 2000.

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.

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, 2002, 2001 and 2000 would have been reduced by 22%, 33% and 8%, 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 2002, 2001 and 2000 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 taxable income and, accordingly, no valuation allowance for the net deferred income tax asset was deemed necessary. Subsequent revisions to the

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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, 2002, Novogyne had a long-term asset of $51.0 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 involves numerous uncertainties because there is no viable actively traded market for the marketing rights of a pharmaceutical product. As permitted by accounting principles generally accepted in the United States, Novogyne determines the estimated fair value of the marketing rights of CombiPatch® utilizing a discounted cash 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 growth, sales price and unit cost 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 a valuation allowance, which would adversely affect Novogyne s operating results in the period in which the determination or allowance were made, and would reduce the earnings attributable to our investment in Novogyne for that period and the amount of our investment in Novogyne. Neither Novogyne nor we are able to predict the effect of the recently discontinued and currently ongoing HRT studies, and the pending product label changes, on the prospects for the HRT market or the market for CombiPatch®. Any adverse change in the market for HRT products could have a material adverse impact on the ability of Novogyne to recover its investment in CombiPatch® which could require Novogyne to revalue that asset.

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 is based in part on Novartis returned goods policy. Novartis controls and maintains the reserves associated with such sales allowances and returns on behalf of Novogyne and pays all monies owed and issues credits to individual customers as deemed necessary. The contracts that underlie these transactions are maintained by Novartis for its business as a whole and those transactions relating to Novogyne are estimated by Novartis. Based on an analysis of the underlying activity, the amounts recorded by Novogyne represent Novartis best estimate of charges that apply to sales by Novogyne. However, neither Novogyne nor we can control Novartis analysis of the

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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.

Outlook:

Among the principal factors that we expect will influence our 2003 financial results are:

Prescription trends in the HRT market, both in the U.S. and abroad;

Inventory levels for our HRT products in the U.S.;

The timing of any major market launches of our HRT products outside the U.S.; and

The timing of any MethyPatch® approval and launch, the magnitude of launch orders placed by Shire and our ability to scale up production to meet Shire s demands.

Full Year 2003

U.S. HRT.

As part of an inventory management initiative intended to align inventory with the reduced demand that followed the early termination of the WHI study, we expect to ship less product in the United States in the 2003 first quarter than in the 2002 fourth quarter. This initiative has reduced Novogyne s inventory since December 31, 2002 but has also reduced the revenue that we recognize on sales to Novogyne. Based on inventory trends at Novogyne and forecast levels of demand for Novogyne s HRT products, we expect that the initiative will align product inventory with demand by mid-2003. We cannot assure, however, that the initiative will have such a result or that demand for Novogyne s HRT products will, in fact, correspond with Novogyne s forecasts. If we are successful in re-aligning inventory, including inventory held in the trade distribution channel, with then current and forecast demand levels by mid-2003, and if prescriptions remain consistent with current levels, we would expect our domestic HRT business to grow in the second half of 2003.

International HRT.

We do not expect international sales to contribute to Noven s growth in 2003 unless Novartis AG launches Estradot® in additional major markets. Estradot® has been launched in Germany and in several other countries, but, according to Novartis AG, significant pricing and reimbursement issues in the remaining major markets, including the United Kingdom, France, Spain and Italy, have to date prevented Novartis AG from launching in those countries. Because of these significant reimbursement and pricing issues and Novartis lack of success to date in securing a marketing partner in the United Kingdom and France for Estradot®, we do not expect any additional major market launches of Estradot® in 2003.

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MethyPatch®.

Under the terms of the Shire transaction, if the Shire transaction closes and MethyPatch® is approved by the FDA this year, we should receive payments totaling at least $75.0 million from Shire in 2003. However, if we do not obtain FDA approval of MethyPatch® during 2003, we would not receive $50.0 million of those payments until FDA approval is obtained. Because we will recognize a portion of any such payments as revenue and do not expect to incur further significant MethyPatch® launch costs, if the transaction closes, we would expect it to be accretive to our 2003 earnings. In addition, we expect that Shire will place launch orders with us when the FDA approves MethyPatch® , which would be expected to generate additional manufacturing revenue for us in 2003.

Cautionary Factors that May Have an Impact on 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, will, would and similar words. These statements are based on our current 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 brief summary of some of the risk factors, which are not listed in order of priority, that could adversely affect our results. Most of these factors are described elsewhere in this report, but the risks described below are not the only risks we face. 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.

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. 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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Our equity in earnings of Novogyne contributed 66% of our income before income taxes in 2002, 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. Novartis has the right to dissolve Novogyne under certain circumstances. Novogyne s Management Committee is comprised of a majority of representatives from Novartis, and we do not control Novogyne. In addition, the joint venture operating agreement has a buy/sell provision which allows either party to compel either the purchase of the other party s interest in Novogyne or the sale of its own interest at a price set by the party triggering the buy/sell provision. 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.

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

Based on information that we have received from Novartis, we believe that current inventory levels at Novogyne have increased and are higher than desirable in light of our trade customers current and expected demand. To align inventories with demand, Novogyne is curtailing product shipments to its trade customers, and we are deferring product shipments to Novogyne. These actions will adversely impact Novogyne s and our financial results. We expect that sales of Novogyne s products in future periods will be adversely impacted as trade customers are expected to reduce their inventories and as Novogyne and we take affirmative steps to attempt to reduce Novogyne s inventory levels. We also expect that our sales to Novogyne, and our gross margin on those sales, will also be adversely impacted, both as a result of an expected decline in orders from trade customers seeking to reduce their inventory levels (which would reduce Novogyne s sales) and by Novogyne s reduction of its inventory levels (which would reduce our sales to Novogyne). A further decline in prescriptions of Novogyne s HRT products, whether as a result of the recent or ongoing studies, required label changes or otherwise, could further exacerbate this situation. We are unable to predict either the timing or the magnitude of the impact of this situation on future sales and results of operations.

Almost all of our revenues are currently generated through sales of HRT transdermal delivery systems. Although the range of consequences of the HRT studies described above cannot be predicted, it is possible that they could result in a significant permanent decrease in the market for our HRT products either as physicians withdraw their patients from HRT or as women elect

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to discontinue HRT on their own. In addition, we do not expect the market growth to materialize as would have been expected had HRT been found safe and effective for additional indications, such as heart disease. In January 2003, the FDA announced that marketers of HRT products, including Novogyne, are required to modify their HRT product labels to include additional safety information and warnings. Among other things, the labels must indicate that HRT should be used for short-term therapy only and that, in the absence of clinical studies demonstrating that HRT products other than the oral product studied in the WHI are safe, physicians should assume that all HRT products carry the same risks. Novartis has informed us that it intends to submit proposed revised labeling to the FDA and to begin using the revised label after reaching agreement with the FDA on the label s language, but we cannot assure you that Novartis proposed labeling will be submitted to the FDA or acted on by the FDA in a timely manner or at all. Healthcare regulators also could delay the approval of new HRT products, such as those presently under development by Novartis AG and us, or require that any new HRT products be subject to more extensive or more rigorous study and testing prior to being approved. The FDA has mandated that all companies engaged in clinical development of HRT products inform study subjects of the risks identified in the referenced studies. Further, because these studies show that certain uses of certain HRT products may result in a higher likelihood of certain adverse health effects, it is possible that we could be named as a defendant in product liability lawsuits relating to our HRT products.

Other studies evaluating HRT are currently underway or in the planning stages. In particular, the estrogen-only arm of the WHI study is ongoing. We are unable to predict the effect of these study results on the short and long-term prospects for the HRT market or on the market for our transdermal HRT products. However, since publication of the WHI and NCI study data, United States prescriptions have declined for substantially all HRT products, including our products, and prescriptions in Europe have also declined. The WHI safety board reevaluates the risk/benefit profile of the estrogen-only arm as frequently as twice per year. If the estrogen-only study or any other currently ongoing HRT study is halted, the market for HRT products, including ours, both in the United States and abroad, could be further adversely impacted. Currently, our liquidity, results of operations and business prospects are almost entirely dependent on sales, license royalties and fees associated with transdermal HRT products. Accordingly, any further adverse change in the market for HRT products (including any adverse changes resulting from the foregoing studies) could have a material adverse impact on our liquidity, results of operations and business prospects.

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 HRT 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.

Because Novartis is responsible for estimating and recording sales allowances for Novogyne, including reserves and allowances related to product returns, 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

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which the determination or reserve were made, and would, consequently also reduce our earnings attributable to our investment in Novogyne for that period.

In 2003, we expect that Estrasorb , the first prescription estrogen cream product in the United States, will be approved by the FDA for the treatment of menopausal symptoms and launched by Novavax, Inc. and King Pharmaceuticals. We are unable to predict the impact of this product launch on Novogyne s sales and market share, but it is expected that this product will gain some market share at the expense of Novogyne s products, and the impact on Novogyne s sales could be material.

We expect to be dependent on sales to Novartis AG and Novogyne, as well as fees and royalties generated from such parties sales of our transdermal HRT delivery systems, for a significant portion of our expected revenues for at least the next several years, and no assurance can be given regarding the amount and timing of such revenues. Failure of either of these parties 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. In the short term, our growth depends in part on Novartis AG s launch plans and marketing efforts with respect to Estalis® and Estradot®. The scope and success of those efforts are outside of our control. We receive firm orders from Novartis AG on a partial year basis, which limits our ability to accurately forecast full year sales to Novartis AG. Novartis and its affiliates sell competing products, both in the United States and abroad, and there can be no assurance that Novartis will promote our products at the expense of its other products. The supply agreement for Vivelle® and Vivelle-Dot® has expired, and the parties are currently negotiating an extension to the agreement. Since the expiration of the Vivelle® supply agreement, the parties have continued to operate in accordance with the supply agreement s commercial terms, and we expect that the supply agreement will be extended on satisfactory terms. However, we cannot assure that we will enter into a new supply agreement on satisfactory terms or at all. Due to our dependence on Novogyne and Novartis AG, 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.

Our pharmaceutical company partners market and sell many of the products we develop and manufacture. Some of those partners, such as Novartis and Shire, market and sell products competitive with ours. If one or more partners fails to pursue the marketing of our products as planned, or if marketing of any of those products (including Estradot®, a second dosage strength of Estalis® or MethyPatch®) is otherwise delayed, our revenues and gross profits may be adversely affected which may also adversely affect our short-term liquidity. We cannot control the timing and other aspects of the development and launch of products incorporating our technologies and marketed by others. Our partners may have different and, sometimes, competing priorities. Even if our marketing partners aggressively pursue the launch and marketing of our products, regulatory matters or other external factors may prevent or delay the launch and marketing. Therefore, the commercialization and marketing of products we have under development may be delayed unexpectedly. Our principal commercialized products are marketed and sold by licensees, and we do not presently have a significant direct marketing channel to health care providers for our drug delivery technologies. 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 marketing efforts

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for our products are not successful, our revenues and results of operations may be adversely affected, which may also adversely affect our short-term liquidity.

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 AG , the growth, if any, in CombiPatch® prescriptions in the United States, the impact of the HRT 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® and the subsequent product launch by Shire, and the success of Shire 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.

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 AG provide for us to receive a percentage of Novartis AG s net selling price (subject to a minimum price), our gross margins are generally much lower for product sold to Novartis AG 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 AG s gross margin realized from selling our products. Because our products compete for sales and marketing resources with other Novartis AG products, including competitive hormone replacement products, there can be no assurance that the relatively low gross margins generated from selling our products will not cause Novartis AG to focus its resources on other products or even not launch our products in certain countries. Novartis AG has informed us that pricing and reimbursement issues are adversely impacting its launch plans for Estradot® in many countries, including the United Kingdom, France, Spain and Italy. Novartis AG is seeking a marketing partner to launch Estradot® in the United Kingdom and France, but to date has been unsuccessful.

Our long-term strategy is dependent, in part, upon the successful development, licensing or acquisition of new products, such as MethyPatch®, 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 sufficient 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 adversely impact 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. In some cases, we have begun and, in the future, may begin development of a

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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.

Historically, our ability to improve our gross margins has depended on our ability to increase our manufacturing throughput. Therefore, if the impact of the HRT studies, the effect of lower pharmaceutical prices outside of the United States, competitive factors or other matters affecting Novartis AG s marketing efforts, or any other factors cause our manufacturing volume to decrease, we would expect our gross margins to decline, which could have a material adverse effect on our financial results.

We depend upon collaborative agreements with pharmaceutical companies, some of whom are our competitors, to obtain regulatory approval for, market and sell certain of our products. Additionally, we intend to seek developmental partners to develop, test and obtain regulatory approval for, and commercialize certain of our products presently under development. The number of our products that are successfully developed and commercialized will affect our revenues. Because transdermal patches generally are more expensive to manufacture than oral formulations, it may be more difficult for us to attract development partners than for drug delivery companies with lower cost delivery systems. If we do not enter into additional agreements in the future, or if our current or future agreements do not result in successful marketing of our products, our revenue and results of operations may be adversely affected.

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, 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.

FDA approval of a product incorporating our technologies, including MethyPatch® and our HRT products, includes approval of the product label. Typically, a pharmaceutical company will submit its initial marketing materials and proposed marketing claims to the FDA s Division of Drug Marketing, Advertising and Communication (DDMAC), although there is no

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requirement to do so. DDMAC then determines whether a company s proposed claims are consistent with the approved product label and may limit the approved claims. In that event, revenues derived from that product may be limited. Failure to comply with these marketing restrictions can result in severe penalties, and there can be no assurance that our marketing partners will comply with the foregoing restrictions with respect to claims that they may assert about our technology or products.

Our supply agreements with our licensees also 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 revenue by us and potential responsibility for damages and losses suffered by our licensees.

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 or operating results.

Substantially all of our revenues are generated through sales of transdermal delivery systems. 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.

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

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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. We also cannot be sure, if we do not receive patents for products arising from our research, that we will be able to maintain the confidentiality of information relating to our products.

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. 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.

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 HRT study data described above may increase the likelihood of product liability claims against us. 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 earnings and our business.

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. Our NDA for MethyPatch®, for example, seeks approval for only one source of the product s active drug ingredient. 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. Additionally, regulatory authorities must generally approve raw material sources for pharmaceutical products. Without adequate approved supplies of raw materials or packaging supplies, our manufacturing operations may be interrupted until another supplier could be 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

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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.

The DEA sets quotas for controlled substances, including methylphenidate, 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 Shire s MethyPatch® production requirements. Failure to meet such requirements would affect our revenues and could affect the success of Shire s product launch.

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 and financial results. 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, 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 receipt of the sales-based milestones under the Shire agreement depends on the MethyPatch® sales levels achieved by Shire. The ADHD market is very competitive. Competitors marketing or developing ADHD products include Johnson & Johnson, Novartis, Glaxo-Smithkline, Bristol-Myers Squibb, Abbott Laboratories, Celltech plc and Eli Lilly. Shire also markets non-methylphenidate ADHD products. There are other once-daily preparations on the market and a non-stimulant, non-controlled substance therapy was launched by Eli Lilly in the first quarter of 2003. There are also other, non-controlled substance drugs in development for the treatment of ADHD. These competitive products, especially 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.

MethyPatch® is a new product that we have never manufactured on a commercial scale. We are modifying our manufacturing plant to prepare for the expected product launch in 2003. We cannot assure that our modifications will be completed successfully or in time to meet Shire s launch requirements or that we will not otherwise experience manufacturing difficulties, particularly in the early stages of commercial manufacture. The terms of the Shire transaction will permit Shire to qualify a second manufacturing source and purchase a portion of its requirements from the second source. Failure to meet Shire s requirements would affect our revenues and could affect the success of Shire s product launch and may result in Shire relying

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more heavily on its second source, reducing the manufacturing revenues that we would otherwise realize.

The active ingredient in MethyPatch® is more expensive than the active ingredients in our HRT 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. In such event, our manufacturing margins would suffer and, in an extreme case, we could suffer losses in manufacturing and supplying MethyPatch® to Shire.

Closing of the Shire transaction is conditioned on, among other things, the expiration of any regulatory waiting period under the Hart Scott Rodino Antitrust Improvements Act of 1976. We cannot assure that the United States antitrust authorities will approve the transaction in a timely manner or at all. If the antitrust authorities do not approve the transaction or if they request additional information from the parties, or if the transaction does not close or if the closing is delayed for any other reason, we may not receive any payments from Shire even if MethyPatch® is approved by the FDA. Failure to receive antitrust approval could prevent the transaction from ever closing, in which case we would be forced to seek other strategies to commercialize MethyPatch®.

Prior to our decision to engage in the Shire transaction, one aspect of our corporate strategy was to establish a sales force, and to launch and market MethyPatch® ourselves. With the Shire transaction, we expect to avoid the significant launch and ongoing marketing expenses that we would have incurred had we launched the product ourselves. We cannot assure that we will deploy the cash expected to be received from Shire, or the cash that we would otherwise have spent, in a manner that will produce a satisfactory return. We also cannot assure that the milestone payments and manufacturing revenue that we may receive from Shire will be greater than the revenues that we would have realized from launching and marketing MethyPatch® ourselves.

There is an 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 launched by Eli Lilly may benefit from this controversy at the expense of the methylphenidate and amphetamine-based products on the market.

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®. There can also be no assurance that managed care agreements established by Novartis will not adversely affect Novogyne s financial results.

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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, and could therefore have an adverse effect on our business and financial results.

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 HRT 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. 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 and financial results.

The Sarbanes-Oxley Act of 2002 imposed significant new administrative burdens on publicly traded companies. We expect to incur significant incremental costs in complying with the provisions of the Sarbanes-Oxley Act. We cannot assure you that these additional costs will result in any increase in revenue or that they will not have a material adverse effect on our financial results. In addition, because we are a small company with relatively few employees, the individuals responsible for complying with the new statutory and regulatory requirements also have responsibility for business matters. As a result, our business may suffer if these individuals are forced to spend a disproportionate amount of time on compliance matters.

In 2001, we implemented a new enterprise resource planning system. We expect that, over time, the new system will result in improved business processes and increased operating efficiencies. As our employees become familiar with the new system, we expect that some errors may occur, some of which could adversely impact our business and financial results. There can be no assurance that the system will perform as expected or that the anticipated improvements in business processes and operating efficiencies will be achieved. In the event of serious system malfunctions or deficiencies, we might experience business interruptions, which could adversely impact our business and financial results.

Our success is dependent 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 and financial results.

Our corporate charter documents, Delaware law and our stockholders rights plan 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

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excess of prevailing market prices in an acquisition of Noven. Our Board of Directors has the authority to issue up to 100,000 shares of preferred stock and to determine the rights, preferences and privileges of those shares without any further vote or action by our stockholders. The rights of holders of our common stock may be adversely affected by the rights of the holders of any preferred stock that may be issued in the future. Additional 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.

We also 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.

The market price of our common stock was extremely volatile in 2002 and may continue to be volatile going forward. In 2002, our common stock traded as low as $8.91 per share and as high as $27.51 per share before closing at $9.23 on December 31, 2002, the last trading day of the year. 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, 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.

Fluctuations in our operating results may lead to fluctuations or declines in our stock price. Our operating results may fluctuate from quarter to quarter and from year to year depending on demand by our customers for our products and timing of shipments to them, new product introductions, pharmaceutical company ordering patterns, the number and timing of product development milestones that we achieve, the timing of royalty and true-up payments and the level of our spending on new drug delivery technology development and technology acquisition, and internal product development.

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

We had no variable rate debt outstanding during the year ended or at December 31, 2002. Therefore, changes in interest rates did not affect interest expense, earnings or cash flows in 2002. We cannot predict market fluctuations in interest rates and their impact on any variable rate debt that we may have outstanding from time to time, nor can there be any assurance that fixed rate long-term debt will be available at favorable rates, if at all.

Item 8. Financial Statements and Supplementary Data.

See Index to Financial Statements at page 66 of this report.

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

Not applicable.

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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 2003 Annual Meeting of Shareholders.

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 2003 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 2003 Annual Meeting of Shareholders.

Item 14. Controls and Procedures.

Within ninety 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

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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 IV

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

(a)(1) Financial Statements

See Index to Financial Statements at page 66 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 Pharmaceuticals, Inc. 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).

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Exhibit Number	Description	Method of Filing
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.
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	Employment Agreement between Noven and Robert C. Strauss dated December 12, 1997.*	Incorporated by reference to Exhibit 10.31 of Noven s Form 10-K for the year ended December 31, 1997 (File No. 0-17254).
10.7	Employment Agreement (Change in Control), dated as of December 1, 1999, between Noven and each of Jeffrey F. Eisenberg, W. Neil Jones, Juan A. Mantelle and James B. Messiry.*	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).

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Exhibit Number	Description	Method of Filing
10.12	Amendment to Operating Agreement between Novartis Pharmaceuticals Corporation and Noven Pharmaceuticals, Inc. 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).
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 Pharmaceuticals, Inc. 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 Pharmaceuticals, Inc. 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 Pharmaceuticals, Inc. 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 Pharmaceuticals, Inc. 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 Pharmaceuticals, Inc. 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 Pharmaceuticals, Inc., dated February 26, 2003, 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.
99.1	Certification of Robert C. Strauss, President, Chief Executive Officer and Chairman of the Board, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
99.2	Certification of James B. Messiry, Vice President and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	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.

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(b) **Reports on Form 8-K.**

No reports on Form 8-K were filed by Noven during the three months ended December 31, 2002.

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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 21, 2003

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 21, 2003
By: /s/ James B. Messiry James B. Messiry (Vice President and Chief Financial Officer)	Principal Financial Officer	March 21, 2003
By: /s/ Diane M. Barrett Diane M. Barrett (Vice President, Finance and Treasurer)	Principal Accounting Officer	March 21, 2003
By: /s/ Sidney Braginsky Sidney Braginsky	Director	March 21, 2003

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Signature	Title	Date
By: /s/ John G. Clarkson, M.D. John G. Clarkson, M.D.	Director	March 21, 2003
By: /s/ Lawrence J. DuBow Lawrence J. DuBow	Director	March 21, 2003
By: /s/ Regina E. Herzlinger Regina E. Herzlinger	Director	March 21, 2003
By: /s/Wayne P. Yetter Wayne P. Yetter	Director	March 21, 2003

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Certifications

Certification of Principal Executive Officer

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

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

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

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

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

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

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

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

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

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

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

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

/s/ Robert C. Strauss

Name: Robert C. Strauss
Title: President, Chief Executive Officer and Chairman of the Board
Date: March 21, 2003

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Certifications

Certification of Principal Financial Officer

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

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

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

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

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

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

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

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

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

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

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

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

/s/ James B. Messiry

Name: James B. Messiry
Title: Vice President and Chief Financial Officer
Date: March 21, 2003

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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, 2002 and 2001, and the related statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2002. 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, 2002, 2001 and 2000. Noven s equity in Vivelle Ventures LLC of $34,684,000 and $32,043,000 at December 31, 2002 and 2001, respectively, and Noven s share of that joint venture s income of $14,368,000, $14,013,000, and $9,294,000 for the years ended December 31, 2002, 2001 and 2000, 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 2002, 2001 and 2000, 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, 2002 and 2001, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2002, in conformity with accounting principles generally accepted in the United States of America.

Deloitte & Touche LLP

Miami, Florida
February 14, 2003, except with respect to the matter
discussed in the fourth paragraph of Note 14, as to
which the date is February 24, 2003, and
February 26, 2003 as to Note 15.

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NOVEN PHARMACEUTICALS, INC.

Balance Sheets

December 31, 2002 and 2001
(in thousands except share amounts)

	2002	2001
Assets		
Current Assets:		
Cash and cash equivalents	$ 58,684	$ 49,389
Accounts receivable trade (less allowance for doubtful accounts of $79 in 2002 and $28 in 2001)	4,359	1,308
Accounts receivable Novogyne	2,581	15,158
Inventories	5,613	4,324
Net deferred income tax asset	2,600	4,800
Prepaid and other current assets	541	304
	74,378	75,283
Property, plant and equipment, net	16,232	15,699
Other Assets:		
Investment in Novogyne	34,684	32,043
Net deferred income tax asset	9,831	10,150
Patent development costs, net	1,996	2,046
Deposits and other assets	581	1,007
	47,092	45,246
	$137,702	$136,228
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable	$ 5,062	$ 5,620
Notes payable, current portion	8	252
Due to Aventis Pharmaceuticals		10,000
Accrued compensation and related liabilities	3,549	1,518
Other accrued liabilities	2,063	2,752
Deferred contract revenue	829	1,417
Deferred license revenue, current portion	3,525	7,936
	15,036	29,495
Long-Term Liabilities:		
Notes payable	5	13
Deferred license revenue	25,920	24,822
	40,961	54,330
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 22,579,112 in 2002 and 22,481,977 in 2001	2	2
Additional paid-in capital	78,358	77,394
Retained earnings	18,381	4,502
	96,741	81,898
	$137,702	$136,228

The accompanying notes are an integral part of these statements.

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NOVEN PHARMACEUTICALS, INC.

Statements of Operations

Years Ended December 31, 2002, 2001 and 2000
(in thousands except per share amounts)

	2002	2001	2000
Revenues:			
Product sales	$51,986	$43,096	$42,005
License revenue	3,386	2,851	919
Total revenues	55,372	45,947	42,924
Expenses:			
Cost of products sold	22,973	20,376	19,219
Research and development	11,634	10,973	13,621
Marketing, general and administrative	14,257	11,554	8,737
Total expenses	48,864	42,903	41,577
Income from operations	6,508	3,044	1,347
Equity in earnings of Novogyne	14,368	14,013	9,294
Interest income, net	822	1,770	1,385
Income before income taxes	21,698	18,827	12,026
Income tax expense (benefit)	7,819	6,736	(7,608)
Net income	$13,879	$12,091	$19,634
Basic earnings per share	$ 0.62	$ 0.54	$ 0.90
Diluted earnings per share	$ 0.60	$ 0.51	$ 0.84
Weighted average number of common shares outstanding:			
Basic	22,532	22,367	21,914
Diluted	23,321	23,511	23,249

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, 2002, 2001 and 2000
(in thousands)

	Common Stock		Additional Paid-in Capital	Retained Earnings/ (Accumulated Deficit)	Total
	Share	Amount			
Balance at December 31, 1999	21,546	$ 2	$66,614	$(27,223)	$39,393
Issuance of shares pursuant to stock option plan, net	574		3,707		3,707
Issuance of shares for bonus compensation	55		782		782
Tax benefit from exercise of stock options			1,650		1,650
Issuance of shares of stock and options to charitable organizations	3		111		111
Net income				19,634	19,634
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

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NOVEN PHARMACEUTICALS, INC.

Statements of Cash Flows

Years Ended December 31, 2002, 2001 and 2000
(in thousands)

	2002	2001	2000
Cash flows from operating activities:			
Net income	$13,879	$ 12,091	$19,634
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	2,216	2,488	1,325
Amortization of patent costs	312	233	237
Amortization of non-competition agreement	400	233	
Deferred income tax expense (benefit)	2,586	709	(9,401)
Recognition of deferred contract revenue	(1,787)	(1,049)	(7)
Recognition of deferred license revenue	(3,386)	(2,851)	(919)
Undistributed earnings of Novogyne	(2,641)	(932)	(7,066)
Expense related to issuance of shares of stock and options to charitable organizations	40	55	111
(Increase) decrease in accounts receivable trade, net	(3,051)	4,369	(2,662)
Decrease (increase) in accounts receivable Novogyne	2,577	(2,241)	767
(Increase) decrease in inventories	(1,289)	1,774	(2,520)
(Increase) decrease in prepaid and other current assets	(237)	191	(80)
Decrease (increase) in deposits and other assets	26	(1,129)	248
(Decrease) increase in accounts payable	(558)	(177)	712
Increase (decrease) in accrued compensation and related liabilities	2,031	(986)	1,049
(Decrease) increase in other accrued liabilities	(603)	1,775	1,561
Increase in deferred contract revenue	1,199	1,630	843
Increase in deferred license revenue	73	8,500	20,000
Cash flows provided by operating activities	11,787	24,683	23,832
Cash flows from investing activities:			
Purchase of property, plant and equipment, net	(2,749)	(3,033)	(1,150)
Contributions to Novogyne		(15,680)	
Payments for patent development costs	(262)	(307)	(404)
Cash flows used in investing activities	(3,011)	(19,020)	(1,554)
Cash flows from financing activities:			
Issuance of common stock	771	3,090	3,707
Repayments of notes payable	(252)	(340)	(347)
Cash flows provided by financing activities	519	2,750	3,360
Net increase in cash and cash equivalents	9,295	8,413	25,638
Cash and cash equivalents, beginning of year	49,389	40,976	15,338
Cash and cash equivalents, end of year	$58,684	$ 49,389	$40,976

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.

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: revenue recognition of certain license agreements containing price adjustments, 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, contract revenue consisting of development fees and milestone payments that require estimates of work completed, determination of the fair value of employee stock options in order to determine compensation expense for disclosure purposes, determination of the net realizable value of the net deferred tax asset, and estimates related to allowance for doubtful accounts, inventories, intangible assets, 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):

	2002	2001
Finished goods	$ 830	$ 458
Work in process	1,390	1,140
Raw materials	3,393	2,726
Total	$5,613	$4,324

Inventories at December 31, 2002 and 2001 relate to Noven s marketed products. As appropriate, provisions are made to reduce inventories to net realizable value. To date, Noven has not experienced and does not anticipate any difficulty acquiring materials necessary to manufacture its products. 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. Retired assets are removed from the cost and accumulated depreciation accounts.

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 state is completed. Capitalized costs include only (1) external direct costs of materials and services consumed in developing or obtaining internal-use software, and (2) 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.

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.

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.

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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 9).

REVENUE RECOGNITION:

Substantially all of Noven s product sales were to its licensees, Novogyne, Novartis AG and Aventis (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 license agreements provide for an adjustment to the price of the product based upon the licensee s actual sales price. Noven records such adjustments to revenues at the time that the information necessary to make the determination is received from the licensees. Certain license agreements for international products entitle Noven to minimum fees. Noven records revenue related to minimum fees when sufficient supporting data is provided by the licensee. If the minimum fees are not determinable, Noven records these fees on a cash basis. These fees are included in product revenue. Royalty revenue consists of royalties payable by Novogyne and Novartis from sales of Vivelle® and Vivelle-Dot®/Estradot® in the United States and Canada. Royalty revenue is recognized when earned and determinable and is included in product sales. Royalty revenue in the amount of $4.7 million, $4.2 million and $3.7 million was included in product sales for 2002, 2001 and 2000, respectively.

License revenue consists of up-front, milestone and similar payments under license agreements and is recognized when earned under the terms of the applicable agreements. In most cases, license revenue is deferred and recognized over the estimated product life cycle or the length of relevant patents, whichever is shorter.

Contract revenue consists of contract development fees and milestone payments earned under contracts with third parties. Noven recognizes revenue under the agreements as the work is performed. Deferred revenue represents the portion of all refundable and nonrefundable payments received that have not been earned. Costs incurred in performing contract development services are included in research and development expenses. Refundable development and license fee payments are deferred until the specified performance criteria are achieved. Noven s contract revenue recognition policy is in compliance with the requirements of EITF 00-21 Accounting for Revenue Arrangements with Multiple Deliverables .

Noven s revenue recognition policy is in compliance with the requirements of Staff Accounting Bulletin 101, Revenue Recognition in Financial Statements .

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 available 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 share equivalents are not included in the diluted earnings per share calculation if the effect of their inclusion would be antidilutive. The total number of share equivalents not included in the diluted earnings per share calculation as of December 31, 2002 was 2,238,306 shares.

COMPREHENSIVE INCOME:

For the years ended December 31, 2002, 2001 and 2000, 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:

	2002	2001	2000
Net income:			
As reported	$13,879	$12,091	$19,634
Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(2,994)	(4,024)	(1,590)
Pro forma	$10,885	$ 8,067	$18,044
Basic earnings per share:			
As reported	$ 0.62	$ 0.54	$ 0.90
Pro forma	$ 0.48	$ 0.36	$ 0.82
Diluted earnings per share:			
As reported	$ 0.60	$ 0.51	$ 0.84
Pro forma	$ 0.47	$ 0.34	$ 0.78

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 2002, 2001 and 2000 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 2002, 2001 and 2000 is estimated as $9.65, $12.80 and $23.44, respectively, on the date of the grant using the Black Scholes option-pricing model with the assumptions listed below:

	2002	2001	2000
Volatility	85.0%	92.0%	84.6%
Risk free interest rate	3.22%	4.11%	5.75%
Expected life (years)	6	6	6

SEGMENT INFORMATION:

Noven discloses segment information in accordance with Statement of Financial Accounting Standards No. 131 (SFAS 131), Disclosure about Segments of an Enterprise and Related 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. SFAS 131 also requires disclosures about geographic areas and major customers (See Note 12).

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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. Noven believes the carrying amounts of Noven s notes payable and obligations under capital leases approximate fair value because the interest rates on these instruments change with, or approximate, market interest rates.

CONCENTRATIONS OF CREDIT RISK:

Noven s customers consist of Novogyne, Novartis AG 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 collectibility of such accounts.

RECLASSIFICATION:

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

RECENT ACCOUNTING PRONOUNCEMENTS:

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

In June 2002, the FASB issued Statement No. 146, *Accounting for Costs Associated with Exit or Disposal Activities.* This Statement requires recording costs associated with exit or disposal activities at their fair values when a liability has been incurred. Under previous guidance, certain exit costs were accrued upon management s commitment to an exit plan, which is generally before an actual liability has been incurred. The provisions of this Statement are effective for Noven with the beginning of fiscal year 2003. Noven does not anticipate a significant impact on its financial statements from adopting this statement.

In December 2002, the FASB issued SFAS 148. This Statement amends SFAS 123, to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, this Statement amends the disclosure requirements of SFAS 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. Noven is required to follow the prescribed format and provide the additional disclosures required by SFAS No. 148 in the financial statements for the year ended December 31, 2002 and for interim periods beginning with the quarterly period ending March 31, 2003.

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In November 2002, the FASB issued Interpretation No. 45, *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*. FIN No. 45 elaborates on the disclosures to be made by a guarantor about its obligations under certain guarantees it has issued and clarifies the accounting for such guarantees. The initial recognition and measurement provisions of FIN No. 45 are effective on a prospective basis to guarantees issued or modified after December 31, 2002, and the disclosure requirements are effective for periods ending after December 15, 2002. Noven does not anticipate a significant impact on its financial statements from adopting this interpretation.

In January 2003, the FASB issued Interpretation No. 46, *Consolidation of Variable Interest Entities.* 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: (1) 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 (2) 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 in the first fiscal year or interim period beginning after June 15, 2003 to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. Noven does not anticipate a significant impact on its financial statements from adopting this interpretation.

3. CASH FLOW INFORMATION:

Cash payments for income taxes were $6.1 million, $3.9 million and $0.6 million in 2002, 2001 and 2000, respectively. Cash payments for interest were $14,000, $35,000 and $64,000 in 2002, 2001 and 2000, respectively.

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 June, September and December 2001, Novogyne paid the first three $10.0 million installments, respectively, directly to Aventis. The final $10.0 million quarterly installment was paid by Novogyne directly to Aventis in March 2002.

Accrued compensation and related liabilities for the year ended December 31, 1999 included bonuses for employees and officers of $0.8 million that were settled by issuance of 55,125 shares of common stock during the quarter ended March 31, 2000.

Noven recorded a $0.2 million, $1.4 million and $1.7 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 2002, 2001 and 2000, respectively.

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4. PROPERTY, PLANT AND EQUIPMENT, NET:

Property, plant and equipment consists of the following at December 31, 2002 and 2001 (in thousands):

	2002	2001
Land	$ 2,540	$ 2,540
Building and improvements	2,875	2,393
Leased property and leasehold improvements	8,918	8,929
Manufacturing and testing equipment	10,036	8,242
Furniture	1,103	1,044
Software and software development costs	1,870	1,448
	27,342	24,596
Less accumulated depreciation and amortization	11,110	8,897
	$16,232	$15,699

5. LICENSE AGREEMENTS:

Noven has license agreements with Aventis, Novartis, Novartis Pharma AG (Novartis AG) 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 Vivelle® and Estradot® in Canada. The agreement provides for royalty payments based on sales by Novogyne and Novartis Canadian affiliate.

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. Aventis funded the construction of a manufacturing facility for the production by Noven of transdermal drug delivery systems. Noven leases the facility at a nominal rate for a term of 31.5 years expiring in 2024 and has the right to purchase the facility at any time during the term of the lease at Aventis book value. Noven has recorded both the facility and deferred revenue at amounts equal to the funds advanced by Aventis which are deferred and recognized as depreciation expense and license revenue over the life of the underlying lease.

In October 1999, Novartis AG sublicensed Aventis rights to market (1) Noven s combination estrogen/progestin transdermal delivery system in all countries other than the United States and Japan, and (2) Noven s first generation estrogen transdermal delivery system in all countries other than the United States, Canada and Japan.

In November 2000, Noven entered into an exclusive license agreement with Novartis AG pursuant to which Noven granted Novartis AG 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 AG marketing rights in the same territories, to any product improvements and future generations of estrogen patches

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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 revenue over 10 years beginning in the fourth quarter of 2000. Noven subsequently received a $5.0 million milestone payment that is being recognized as license revenue beginning in the first quarter of 2002 through the fourth quarter of 2010. This product has been approved for marketing in over 30 foreign countries and the regulatory authorities of other countries are reviewing Novartis registration applications.

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 (a) a direct purchase by Novogyne from Aventis of certain assets for $25.0 million, which was paid at closing, (b) a grant-back by Aventis to Noven of certain intellectual property rights relating to CombiPatch®, and (c) a simultaneous license by Noven to Novogyne of these intellectual property rights. The consideration payable by Noven to Aventis, and by Novogyne to Noven, 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. The first three $10.0 million quarterly installments were paid by Novogyne to Aventis in June, September and December 2001, respectively. The final $10.0 million quarterly installment was paid by Novogyne directly to Aventis in March 2002. As a consequence of the transaction and under the terms of Noven s existing license agreement with Aventis, Noven received $3.5 million from Aventis, which amount was deferred and recognized as license revenue over ten years beginning in the first quarter of 2001.

In a related transaction, Novartis AG acquired from Aventis the development and marketing rights to future generations of Noven s combination estrogen/progestin patch in all markets other than Japan. Novogyne expects to sublicense the United States rights to these product improvements, and, if and when future generation combination products are commercialized, Novogyne expects that it will pay a royalty to Novartis AG on the United States sales of such products. Noven manufactures and supplies CombiPatch® and expects to manufacture and supply any future combination products to Novogyne and to Novartis AG. In June 2001, Noven and Novartis AG entered into a development agreement relating to future generations of combination estrogen/progestin patch products.

6. INVESTMENT IN VIVELLE VENTURES LLC:

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. Noven shares in the income of Novogyne according to an established formula after an annual preferred return of $6.1 million to Novartis. During 2002, 2001 and 2000, Novogyne produced $37.4 million, $37.9 million and $29.1 million, respectively, of net income, and Noven recorded $14.4 million, $14.0 million and $9.3 million, respectively, as equity in earnings of Novogyne. In 2002, 2001 and 2000, Noven received cash distributions of $11.7 million, $13.1 million and $2.2 million, respectively, from Novogyne. These amounts were recorded as reductions in the investment in Novogyne when received. During 2001, Noven contributed $15.7 million to Novogyne in connection with the CombiPatch® transaction described in Note 5 above. This amount was recorded as an increase in the investment in Novogyne when paid.

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During the years ended December 31, 2002, 2001 and 2000, Noven had the following transactions with Novogyne (in thousands):

	2002	2001	2000
Revenue:			
Trade product	$21,984	$13,634	$13,220
Sample product and other	3,410	3,055	2,269
Royalty	4,505	4,037	3,429
	$29,899	$20,726	$18,918
Expenses:			
Services	$18,345	$16,187	$10,180
Product specific marketing expenses	7,535	5,849	4,133
	$25,880	$22,036	$14,313

As of December 31, 2002 and 2001, the Accounts Receivable Novogyne is as follows (in thousands):

	2002	2001
Sales of product	$ 1,631	$ 3,071
Services provided by Noven	2,029	2,637
Royalty	905	952
CombiPatch® license installment		10,000
Deferred profit on Novogyne inventory	(1,984)	(1,502)
	$ 2,581	$15,158

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.

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The condensed Statements of Operations of Novogyne for the years ended December 31, 2002, 2001 and 2000 are as follows (in thousands):

	2002	2001	2000
Revenues	$102,485	$89,958	$58,544
Cost of sales	26,136	20,833	13,127
Selling, general and administrative expenses	33,091	27,347	17,886
Amortization of intangible assets	6,179	4,635	
Income from operations	37,079	37,143	27,531
Interest income	350	734	1,562
Net income	$ 37,429	$37,877	$29,093

Royalties due to Noven on sales of Vivelle® and Vivelle-Dot® for 2001 and 2000 have been reclassified from selling, general and administrative expenses to cost of sales to conform to the current year s presentation.

The condensed Balance Sheets of Novogyne at December 31, 2002 and 2001 are as follows (in thousands):

	2002	2001
Current assets	$34,827	$23,695
Long-term assets	50,981	57,160
Total assets	85,808	80,855
Total liabilities (all of which are current)	17,468	23,452
Members capital	$68,340	$57,403

The joint venture operating agreement also has a buy/sell provision which allows each party to compel either the purchase of the other party s interest in Novogyne or the sale of its own interest in Novogyne at a price set by the party triggering the buy/sell provision. Either party may dissolve Novogyne in the event that Novogyne does not achieve certain financial results. Noven expects that the applicable financial targets will be achieved, although no assurance can be given that unexpected events will not affect Novogyne s financial performance. Dissolution can also result from a change in control of Noven if the acquirer is a top ten pharmaceutical company (as measured by annual dollar sales). Upon dissolution, Novartis would reacquire the rights to market Vivelle® and Vivelle-Dot® 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 operating agreement.

7. 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 will terminate in April

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2003. Amounts outstanding under the credit facility bear interest at LIBOR plus 1.50% (2.882% at December 31, 2002). Amounts outstanding under the Credit Facility are secured by accounts receivable and inventory. Noven pays certain fees in connection with the Credit Facility, including a quarterly commitment fee of 0.0625% of the aggregate unused portion of the Credit Facility. At December 31, 2002 and 2001, there were no amounts outstanding under the Credit Facility. The Credit Facility contains various covenants pertaining to minimum net worth, revenue and operating results requirements, as well as certain financial ratios, measured on a quarterly basis. Noven is not aware of any defaults under the current terms of the Credit Facility. Noven does not expect to extend the term of the Credit Facility beyond its April 2003 expiration.

8. NOTES PAYABLE:

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 include, among other provisions, minimum net worth, revenue 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.

Long-term obligations, less installments due within one year, are summarized below (in thousands):

	2002	2001
Borrowings under Master Lease, 8%		$245
Capitalized equipment lease, 11%, maturing in 2004	13	20
	13	265
Less: installments due within one year	8	252
	$ 5	$ 13

Principal payments on existing long-term debt for the years succeeding December 31, 2002 are $8,000 in 2003 and $5,000 in 2004.

9. INCOME TAXES:

The provision (benefit) for income taxes in 2002, 2001 and 2000 consists of (amounts in thousands):

	2002	2001	2000
Current income taxes			
Federal	$4,430	$5,400	$ 1,251
State	803	627	542
	5,233	6,027	1,793
Deferred income tax expense (benefit)			
Federal	2,518	448	(8,789)
State	68	261	(612)
	2,586	709	(9,401)
Income tax expense (benefit)	$7,819	$6,736	$(7,608)

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Deferred income taxes reflect the tax effects on 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:

	2002	2001
Deferred income tax assets:		
Deferred license revenue	$ 8,814	$10,270
Joint venture interest	2,397	891
General business credit	515	3,131
Alternative minimum tax credit	483	483
Other	697	478
Total deferred income tax assets	12,906	15,253
Deferred income tax liabilities:		
Basis difference in fixed assets	(475)	(303)
Total deferred income tax liabilities	(475)	(303)
Net deferred income tax asset	$12,431	$14,950

At December 31, 1999, Noven established $11.5 million in valuation allowances against its deferred income tax assets, which consisted primarily of net operating loss and research and development credit carryforwards. A portion of the carryforwards was utilized against 2000 income, and Noven recognized the remainder as a deferred income tax asset. Realization of the net deferred income tax asset of $12.4 million and $15.0 million at December 31, 2002 and 2001, 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 taxable income of Noven and, accordingly, no valuation allowance for the net deferred income tax asset was deemed necessary at December 31, 2002 and 2001.

At December 31, 2002 and 2001, Noven had research and development credit carryforwards of $0.5 million and $3.1 million, respectively, which will expire in 2013 through 2022.

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, 2002, 2001 and 2000, Noven credited $0.2 million, $1.4 million and $1.7 million, respectively, to additional paid-in capital related to the tax benefits from the exercise of stock options.

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

	2002		2001		2000	
	Amount	%	Amount	%	Amount	%
Income taxes at statutory rate	$7,594	35.0	$6,589	35.0	$ 4,089	34.0
Increase (decrease) in taxes:						
State income tax, net of federal benefits	566	2.6	577	3.1	470	3.9
Research and development expenditures	(396)	(1.8)	(458)	(2.4)	(700)	(5.8)
Other	55	0.2	28	0.1	63	0.5
Reduction of valuation allowance on deferred income tax assets					(11,530)	(95.9)
Income tax expense (benefit)	$7,819	36.0	$6,736	35.8	$ (7,608)	(63.3)

10. 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 up to 3,768,848 incentive and non-qualified stock options to selected individuals, including 2,768,848 shares that remained available under the 1997 Plan at the time of its termination. The terms and conditions of these options (including price, vesting schedule, term and number of shares) 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, 2002, there were approximately 2,459,138 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, 2002, there were approximately 890,688 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

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may be granted under this plan. At December 31, 2002, there were approximately 59,755 stock options outstanding under this plan.

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

	2002		2001		2000	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding at beginning of year	2,845	$15.57	2,501	$14.57	2,554	$ 8.32
Granted	871	14.08	792	17.59	626	33.37
Exercised	(101)	8.02	(308)	10.45	(634)	8.41
Canceled and expired	(205)	19.14	(140)	20.32	(45)	8.06
Outstanding at end of year	3,410	15.20	2,845	15.57	2,501	14.57
Options exercisable at end of year	1,404	13.23	960	11.89	745	8.87
Shares of common stock reserved	4,722		4,895		4,909	

The following table summarizes information concerning outstanding and exercisable options at December 31, 2002 (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	799	2.4	$ 5.79	681	$ 5.90
6.38 - 8.81	140	2.7	8.53	89	8.43
9.94 - 14.38	1,137	5.5	12.52	216	11.96
15.13 - 21.47	730	6.0	15.65	171	16.59
31.31 - 41.81	604	5.0	33.69	247	33.95
	3,410			1,404	

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

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

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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.

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. Noven amended the 401(k) Plan as of January 2001, and during 2001 and 2002, the 401(k) Plan provided for employer matching of 50% of employee contributions up to the first 3% of the participants contributions. Noven contributed $148,000 and $126,000 for the year ended December 31, 2002 and 2001, respectively. Prior to the Plan amendment, Noven determined, on a year-to-year basis, the amount, if any, that it would provide as a matching contribution. For the year ended December 31, 2000, Noven made no matching contributions.

12. SEGMENT, GEOGRAPHIC AND CUSTOMER DATA:

Noven is engaged principally in one line of business, the development and commercialization of advanced transdermal drug delivery technologies and prescription transdermal products, which represents more than 90% of total revenue. There were no sales or transactions between geographic areas.

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

	2002	2001	2000
United States	$28,995	$25,018	$25,386
Other countries	26,377	20,929	17,538
Total revenues	$55,372	$45,947	$42,924

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

	2002	2001	2000
Novogyne	$29,899	$20,726	$18,918
Novartis AG/Novartis	23,201	19,809	15,614
Aventis	1,212	4,736	7,620
Other	1,060	676	772
Total revenues	$55,372	$45,947	$42,924

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

2002	First	Second	Third	Fourth	Full Year
Revenues	$12,735	$16,156	$13,198	$13,283	$55,372
Total operating expenses	12,202	13,013	11,188	12,461	48,864
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
Interest income, net	207	195	223	197	822
Income tax provision	802	3,827	1,480	1,710	7,819
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

2001	First	Second	Third	Fourth	Full Year
Revenues	$12,689	$12,594	$10,403	$10,261	$45,947
Total operating expenses	9,703	11,480	12,081	9,639	42,903
Income (loss) from operations	2,986	1,114	(1,678)	622	3,044
Equity in earnings of Novogyne	595	3,137	5,278	5,003	14,013
Interest income, net	619	482	398	271	1,770
Income tax provision	1,533	1,510	1,542	2,151	6,736
Net income	$ 2,667	$ 3,223	$ 2,456	$ 3,745	$12,091
Basic earnings per share	$ 0.12	$ 0.14	$ 0.11	$ 0.17	$ 0.54
Diluted earnings per share	$ 0.11	$ 0.14	$ 0.10	$ 0.16	$ 0.51

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14. COMMITMENTS AND CONTINGENCIES:

EMPLOYMENT AGREEMENT AND BONUS PLAN

Noven has an 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 2003.

Noven has a formula bonus plan that includes company and individual performance goals, and Noven incurred $2.5 million, $0.7 million and $2.2 million of bonus expenses in 2002, 2001 and 2000, 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 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 2002 and 2000, 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.

LITIGATION, CLAIMS AND ASSESSMENTS:

In November and December 2001 and January 2002, individuals purporting to be Noven stockholders filed a total of five substantially identical lawsuits against Noven and certain of its directors and officers in the United States District Court for the Southern District of Florida, which actions were subsequently consolidated into a single consolidated lawsuit. The plaintiffs purport to represent a class consisting of all purchasers of Noven s common stock between March 27 and November 1, 2001. The plaintiffs each alleged that during that period, Noven and its officers and directors named as defendants violated Sections 10 and 20 of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder by making material misstatements and omissions regarding international sales of certain of Noven s products that are the subject of an exclusive license agreement with Novartis AG. The plaintiffs sought unspecified damages, for themselves and the purported class, based on the allegedly artificially inflated prices paid for their shares of Noven s common stock. On May 13, 2002, the defendants filed Motions to Dismiss, seeking to have the Court dismiss the plaintiff s Consolidated Amended Complaint. On December 20, 2002, the Court dismissed the Consolidated Amended Complaint for failing to meet the requirements of the Private Securities Litigation Reform Act of 1995. The Court s order dismissed the Consolidated Amended Complaint without prejudice but gave the plaintiffs leave to amend the Consolidated Amended Complaint to attempt to cure its defects. Subsequently, the plaintiff decided not to amend the Consolidated Amended Complaint, and, on February 24, 2003, the parties filed a joint motion for voluntary dismissal of the Consolidated Amended Complaint with prejudice, which the Court granted. Under the terms of the Court s order, each party is to bear its own costs and attorneys fees.

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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 it manufactures.

15. SUBSEQUENT EVENTS:

On February 26, 2003, Noven 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 revenue. Consideration for the transaction is payable as follows: (a) $25 million payable upon closing of the transaction; (b) $50 million upon receipt of final marketing approval for MethyPatch® by the FDA; and (c) three installments of $25 million each 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. For accounting purposes, all payments (other than manufacturing revenues) will be deferred and recognized as revenue over a period of years. Closing of the transaction is conditioned on, among other things, the expiration of any regulatory waiting period under the Hart Scott Rodino Antitrust Improvements Act of 1976, and is expected to take place in April 2003.

Under the terms of the transaction, Noven remains responsible for securing final regulatory approval for MethyPatch®. If Noven receives a non-approval letter from the FDA or if FDA approval has not been granted within two years of the closing date, Shire may require Noven to repurchase the product rights for $5 million. Shire has agreed that it will not sell any other product containing methylphenidate as an active ingredient until the earlier of (a) five years from the closing date or (b) payment of all of the sales milestones.

On the closing date, Noven will enter into a long-term supply agreement under which it will manufacture and supply MethyPatch® to Shire. The agreement will give Shire the right to qualify a second manufacturing source and purchase a portion of its requirements from the second source.

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Report of Independent Accountants

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

In our opinion, the accompanying balance sheets and the related statements of operations, members capital and cash flows present fairly, in all material respects, the financial position of Vivelle Ventures LLC at December 31, 2002 and 2001, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2002 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

January 31, 2003
Florham Park, New Jersey

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals

Balance Sheet

As of December 31, 2002 and 2001

	2002	2001
Assets		
Current assets		
Due from affiliate Novartis Pharmaceuticals Corporation	$28,470,812	$16,493,027
Due from Novartis Pharmaceuticals Canada, Inc.		876,263
Finished goods inventory (net of reserves of $975,624 and $250,000 as of December 31, 2002 and 2001)	6,315,282	5,976,405
Other current assets	41,390	349,407
Total current assets	34,827,484	23,695,102
Long-term assets (see Note 3)	50,980,582	57,160,047
Total assets	$85,808,066	$80,855,149
Liabilities and Members Capital		
Current liabilities		
Due to affiliate Noven Pharmaceuticals, Inc.	$ 4,565,279	$16,660,758
Accrued liabilities	122,383	118,116
Allowance for returns	12,780,006	$ 6,673,109
Total current liabilities	17,467,668	23,451,983
Commitments and contingencies (see Note 6)		
Members capital		
Capital contributions	32,857,909	32,857,909
Accumulated earnings	35,482,489	24,545,257
Total members capital	68,340,398	57,403,166
Total liabilities and members capital	$85,808,066	$80,855,149

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

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals

Statement of Operations

For the Years Ended December 31, 2002, 2001 and 2000

	2002	2001	2000
Net sales			
Third parties	$ 97,755,546	$88,808,362	$57,221,383
Novartis Pharmaceuticals Canada, Inc.	4,729,216	1,149,817	1,322,772
	102,484,762	89,958,179	58,544,155
Cost of sales			
Third parties	19,550,963	16,272,541	9,165,457
Noven royalties	4,504,663	4,036,972	3,429,288
Novartis Pharmaceuticals Canada, Inc.	2,079,829	523,358	532,187
	26,135,455	20,832,871	13,126,932
Gross profit	76,349,307	69,125,308	45,417,223
Operating expenses			
Administrative expenses	2,195,203	1,926,320	1,391,446
Sales and marketing expenses	30,895,914	25,420,730	16,494,690
Amortization expense	6,179,465	4,634,598	
Income from operations	37,078,725	37,143,660	27,531,087
Other income			
Interest income	349,741	733,600	1,562,112
Net income	$ 37,428,466	$37,877,260	$29,093,199

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

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals

Statement of Members Capital

For the Years Ended December 31, 2002, 2001 and 2000

	Total
Members capital at December 31, 1999	$ 15,397,611
Net income	29,093,199
Distribution to members (see Note 4)	(13,064,904)
Members capital at December 31, 2000	31,425,906
Net income	37,877,260
Distributions to members (see Note 4)	(43,900,000)
Capital contributions by members	32,000,000
Members capital at December 31, 2001	57,403,166
Net income	37,428,466
Distributions to members (see Note 4)	(26,491,234)
Members capital at December 31, 2002	$ 68,340,398

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

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals

Statement of Cash Flows

For the Years Ended December 31, 2002, 2001 and 2000

	2002	2001	2000
Operating activities			
Net income	$ 37,428,466	$ 37,877,260	$ 29,093,199
Adjustments to reconcile net income to income to net cash provided by operating activities			
Amortization of marketing rights	6,179,465	4,634,598	
Obsolescence reserve	725,624	50,000	
Changes in assets and liabilities, net of assets acquired			
Due from affiliate Novartis Pharmaceuticals Corporation	(11,977,785)	19,486,451	(13,853,727)
Due from Novartis Pharmaceuticals Canada, Inc.	876,263	(631,575)	(104,292)
Inventories	(1,064,501)	3,111,424	(3,597,441)
Other current assets	308,017	(349,407)	104,040
Due to affiliate Noven Pharmaceuticals, Inc.	(2,095,479)	2,188,408	426,583
Other liabilities	6,111,164	804,753	996,542
Net cash provided by operating activities	36,491,234	67,171,912	13,064,904
Investing activities			
Cash paid to purchase the CombiPatch® marketing rights and inventory (see Note 3)	(10,000,000)	(55,271,912)	
Net cash used in investing activities	(10,000,000)	(55,271,912)	
Financing activities			
Contribution by members (see Note 4)		32,000,000	
Distributions to members (see Note 4)	(26,491,234)	(43,900,000)	(13,064,904)
Net cash used in financing activities	(26,491,234)	(11,900,000)	(13,064,904)
Net change in cash			
Cash and cash equivalents at beginning of year			
Cash and cash equivalents at 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

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) (see Note 6). 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% by Novartis and 49% 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 Vivelle® and other products to the Company and for providing marketing and promotional services pursuant to certain other agreements, as amended. The Company has no discrete employees. (See 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) (see 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 and provisions for inventory obsolescence.

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals

Notes to Financial Statements

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 when title and risk of loss pass to the customer. In fiscal year 2000, the Company adopted Staff Accounting Bulletin (SAB) 101, Revenue Recognition in Financial Statements, the effects of which were immaterial for all periods presented. 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, 2002, 2001 and 2000 are net of $13,601,706, $8,785,599 and $5,989,323, 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 management s best estimate of these charges that apply to sales of the Company.

Revenues for the years ended December 31, 2002, 2001 and 2000 are net of sales returns allowances of $14,272,113, $5,401,758 and $4,221,545, 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

Noven royalty expense has been reclassified from sales and marketing expenses to cost of sales on the accompanying statement of operations for all periods presented.

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals

Notes to Financial Statements

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.

Recently Adopted Accounting Standards

During 2002, the Company adopted the provisions of SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, which supersedes SFAS No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of. SFAS 144 incorporates probability weighting of undiscounted cash flow assumptions, and a primary asset approach to determine the cash flow estimation period for a group of assets. The adoption of SFAS 144 did not affect the financial position, results of operations or cash flows of the Company.

Also during 2002, the Company adopted the provisions of SFAS No. 142, Goodwill and Other Intangible Assets. SFAS 142 requires that goodwill and intangible assets with indefinite useful lives not be amortized but that they be tested for impairment at adoption and at least annually thereafter. The adoption of SFAS 142 did not affect the financial position, results of operations or cash flows of the Company.

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. The first three $10,000,000 quarterly installments were paid by the Company to Aventis on behalf of Noven in June, September and December 2001, respectively. The final $10,000,000 quarterly installment was paid by the Company to Aventis on behalf of Noven in March 2002. 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, the remaining life of the CombiPatch patent at March 31, 2001. To fund the purchase price of approximately $65,000,000 the members contributed $32,000,000 in cash. The remaining amount was funded by the Company and reduced the Novartis due from affiliate account.

The accumulated amortization was $10,814,063 and $4,634,598 as of December 31, 2002 and 2001. Amortization expense is $6,179,465 per year, and will total $30,897,325 over the next five years.

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals

Notes to Financial Statements

4. 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% to Novartis and 30% 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% to Novartis and 40% 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
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Notes to Financial Statements

Distributable funds are payable to the Members quarterly or as determined by the Management Committee. Distributions are made to the Members on the same basis as the allocation of net income. In 2002, distributions of $14,763,251 were made to Novartis and $11,727,983 to Noven related to the period July 1, 2001 to December 31, 2001. During 2001, distributions of $10,719,000 were made to Novartis and $3,581,000 to Noven related to the period January 1, 2001 to June 30, 2001. In addition, in 2001 distributions of $20,100,000 were made to Novartis and $9,500,000 to Noven related to the period January 1, 2000 to December 31, 2000. During 2000, distributions of $10,836,915 were made to Novartis and $2,227,989 to Noven related to the period January 1, 1999 to December 31, 1999. Distributions during the years ended December 31, 2002, 2001 and 2000 were based on taxable income and subject to approval by the Management Committee prior to payment.

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 the annual operating and capital budget for activities outside normal business, approval of the annual sales and marketing plan, amendments to the documents concerning the formation of the Company, entering into any contract for a third party sales force, 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.

Buy/Sell and Dissolution Provisions

The joint venture operating agreement has a buy/sell provision which allows each party to compel either the purchase of the other party s interest in the Company or the sale of its own interest in the Company at a price set by the party triggering the buy/sell provision. Either party may dissolve the Company in the event that the Company does not achieve certain financial results.

Dissolution can also result from a change in control of Noven if the acquirer is a top ten pharmaceutical company (as measured by annual dollar sales). Upon dissolution, Novartis would reacquire the rights to market Vivelle® and Vivelle-Dot® 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 operating agreement.

5. 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.

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals

Notes to Financial Statements

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

During the years ended December 31, 2002, 2001 and 2000, Novartis charged the Company $2,324,055, $1,976,952 and $1,148,953, 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 $28,470,812, $16,493,027 and $35,979,478 as of December 31, 2002, 2001 and 2000, respectively, represent the net balance of these transactions for the period from commencement of the Company to those dates.

The Company maintains a bank account. Transactions which are processed through this account are subsequently transferred to or from Novartis bank accounts under a cash pooling mechanism whereby the Company s bank balance is maintained at zero. Transactions with Novartis on this basis are recorded in the general ledger account referred to above.

The Company received interest on amounts due from Novartis during the year ended December 31, 2002, 2001 and 2000 at an average annual rate of 2%, 5% and 7%, respectively. During these periods, interest of $349,741, $733,600 and $1,562,112, respectively, was earned and is reflected in the amount due from Novartis.

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.

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals

Notes to Financial Statements

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

	For the Years Ended December 31,		
	2002	2001	2000
Balance at the beginning of the period	$ 16,493,027	$ 35,979,478	$ 22,125,751
Capital contributions by members		32,000,000	
Net sales (excluding returns)	112,027,659	94,210,120	62,765,692
Sales returns processed	(8,165,215)	(4,602,001)	(3,250,631)
Interest income on cash balances	349,741	733,600	1,562,112
Distributions to members	(26,491,234)	(43,900,000)	(13,064,904)
Payment to Noven for inventory purchases, royalties, and other items	(58,528,474)	(40,284,456)	(33,363,053)
Disbursements made on behalf of the Company	(804,134)	(1,001,799)	(280,459)
Novartis service charges	(2,324,055)	(1,976,952)	(1,148,953)
Receivable from Novartis Canada transferred to the Company	5,605,479	518,241	(244,687)
Payments for CombiPatch® license	(10,000,000)	(55,000,000)	
Other	308,018	(183,204)	878,610
Total	$ 28,470,812	$ 16,493,027	$ 35,979,478

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, 2002, 2001 and 2000, Noven charged the Company $18,344,551, $16,187,211 and $10,179,559, 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, 2002, 2001 and 2000 were $11,599,911, $8,628,409 and $6,255,770, respectively.

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, 2002, 2001 and 2000, total royalties of $4,504,663, $4,036,972 and $3,429,288, respectively, were incurred, of which $905,407, $952,312 and $935,110 remained payable to Noven as of December 31, 2002, 2001, and 2000, respectively.

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals

Notes to Financial Statements

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, 2002, 2001 and 2000 the Company purchased products from Noven in the amounts of $21,983,870, $13,634,475 and $13,220,064, 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:

	As of December 31,	
	2002	2001
Purchases of inventory	$1,630,975	$ 3,071,180
Services provided by Noven	2,028,897	2,637,266
Royalties	905,407	952,312
CombiPatch® license installment		10,000,000
Total	$4,565,279	$16,660,758

6. 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, and has not been renewed. Failure to renew the Supply Agreement could have a material adverse impact on the Company s financial position, results of operations and cash flows.

In July 2002, the National Institute of Health released data on studies concerning the risks and benefits associated with long-term use of oral hormone replacement therapy. The study revealed an increase in the risk of developing breast cancer and increased risk of stroke, heart attacks and blood clots. Although the Company s products are not orally administered, management can not predict whether the study will have an adverse effect on the Company s results of operations, or its ability to recover the value of the CombiPatch® intangible asset (see Note 3).