NOVEN PHARMACEUTICALS INC
Form 10-K
March 21, 2003

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

FORM 10-K

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

For the fiscal year ended December 31, 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):

	Number of securities to be issued upon exercise of outstanding	Weighted average	Number of securities remaining available for future issuance under equity compensation plans (excluding securities