NOVEN PHARMACEUTICALS INC
Form 10-K
March 21, 2002

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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, 2001 **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 [ ]

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. [ ]

As of March 1, 2002, there were 22,496,632 shares of Common Stock outstanding.

The aggregate market value of the voting stock held by non-affiliates of the registrant on March 1, 2002, was approximately $467 million.

DOCUMENTS INCORPORATED BY REFERENCE:

Part III: Portions of registrant s Proxy Statement for its 2002 Annual Meeting of Shareholders.

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NOVEN PHARMACEUTICALS, INC.

Annual Report on Form 10-K
for the year ended December 31, 2001

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PART I

Item 1. Business.

General

Noven Pharmaceuticals, Inc. (Noven) is a leader in the development and manufacture of advanced transdermal drug delivery products and technologies and prescription transdermal products. Noven was incorporated in Delaware in 1987, and its principal executive offices are located at 11960 S.W. 144th Street, Miami, Florida 33186; its telephone number is (305) 253-5099.

Noven s principal commercialized products are transdermal drug delivery systems for use in hormone replacement therapy. Noven s 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, Noven s 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 has been approved in several foreign countries and is expected to be launched in 2002 under the brand name Estradot®. Noven 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 Noven s transdermal products and their marketing status.

Noven has an active research and development program featuring a broad range of products and therapeutic categories. Two of its development projects are currently in the active clinical trial stage. Noven has completed some clinical trials for several additional products for which it intends to seek a development partner before pursuing further trials. Noven is currently engaged in a second round of Phase III clinical trials for MethyPatch®, its once-daily transdermal methylphenidate delivery system for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) which is expected to be completed and evaluated in the first half of 2002. If the Phase III trial is successful, Noven would expect to file a New Drug Application (NDA) with the FDA thereafter. Noven believes that this product will address several serious issues associated with existing therapies and, if approved, will compete in the over $1 billion market for drugs that treat ADHD in the United States. No assurance can be given that the results of the pending Phase III trial will support an NDA filing, that Noven will be able to successfully complete and file the NDA in a timely manner, that the product will be approved by the FDA or that, if approved, it will be successfully marketed. See Research and Development below for a more complete description of Noven s product development program, and see Transdermal Drug Delivery Products below for a more complete description of Noven s methylphenidate product.

Novogyne Pharmaceuticals

In May 1998, Noven and Novartis Pharmaceuticals Corporation (Novartis) formed a joint venture limited liability company 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 2001, Noven s equity in earnings of Novogyne represented 74% of Noven s income before taxes.

Novogyne is managed by a committee of five members, three appointed by Novartis and two appointed by Noven. 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 Noven 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. Noven 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, Noven manufactures and supplies Novogyne with Vivelle®, Vivelle-Dot® and CombiPatch®, performs marketing, sales and promotional activities, and receives 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.

Novogyne s management committee has the authority to distribute cash to Novartis and Noven 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 Noven depending upon sales levels attained. Noven s 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, Noven, Novartis and Aventis Pharmaceuticals, the U.S. pharmaceuticals business of Aventis Pharma AG (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, which was due in four quarterly installments of $10.0 million each with the final payment 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 Pharma AG (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, and Novogyne expects to sublicense the United States rights to these product improvements from Novartis AG. If and when any future generation combination products are commercialized and sublicensed to Novogyne, Novogyne will pay a royalty to Novartis AG on the United States sales of such products. Noven manufactures and supplies CombiPatch® and

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expects to manufacture and supply any future combination products to Novogyne and to Novartis AG. Noven expects 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. 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 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 Noven, and Novogyne s other assets would be liquidated and distributed to the parties in accordance with their capital account balances as determined pursuant to the joint venture operating agreement. 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 than Noven, and therefore may be in a better position to be the purchaser if the provision is triggered.

Strategy

Noven s strategy for continued growth and profitability is to utilize its proprietary transdermal drug delivery technology to establish a leadership position in this field, and to develop and market products utilizing its proprietary transmucosal drug delivery technology. In pursuing this strategy, Noven intends to focus on developing products for the following therapeutic areas: hormone replacement therapy and central nervous system conditions, including ADHD and pain management. On a long-term basis, Noven will seek to (i) establish its own sales force to market certain of its independently developed products, including MethyPatch®, and potentially to acquire products to market through its own sales force, (ii) expand its transdermal technology base, (iii) form new strategic alliances with other pharmaceutical companies, and (iv) capitalize on the opportunity presented by its collaboration with Novartis through Novogyne by licensing certain of Noven s women s health products to Novogyne and by expanding Novogyne s product range beyond transdermal products. No assurance can be given that Noven will successfully implement all or part of its long-term strategy or that its 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 by 50% by 2020. Noven estimates that worldwide sales of all hormone replacement products, including those delivered transdermally, are over $3.5 billion annually and that worldwide transdermal hormone replacement product sales are over $500.0 million annually. With the aging of the population worldwide, conditions and diseases such as menopause, osteoporosis and heart disease, which may benefit from hormone replacement therapy, are expected to become significantly more prevalent.

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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. Numerous medical studies and the National Institutes of Health recommend a combination of estrogen replacement therapy, exercise and Vitamin D as the most effective method of preventing osteoporosis in post-menopausal women.

Various reported studies have suggested that estrogen replacement therapy may reduce the risk of colon cancer and cardiovascular disease, and may prevent or treat osteoarthritis, Alzheimer s disease, strokes, and tooth loss in menopausal women, but the efficacy of estrogen replacement therapy for the prevention or treatment of these conditions has not been conclusively demonstrated. Other reported studies suggest that prolonged use of estrogen or combination estrogen/progestin hormone replacement therapy may increase the risk of endometrial or breast cancer and/or may present other health risks.

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, and avoidance of certain problems and adverse side-effects.

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

DOT Matrix patches, such as Vivelle-Dot®/Estradot®, CombiPatch®/Estalis® and MethyPatch®, utilize a patented blend of silicone, acrylic and drug. This blend causes thousands of microscopic pockets of concentrated drug to be formed and uniformly dispersed throughout the

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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 innate 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.

Noven believes that its technology enables it 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, improving adhesion and minimizing patch size. Noven s transdermal drug delivery systems are capable of being modified to deliver a wide variety of chemical entities. With DOT Matrix technology, larger molecules, previously believed to be 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 an advantage over competitive patches that deliver similar compounds through a larger patch. DOT Matrix technology may also permit Noven 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

Noven s first generation transdermal estrogen delivery system (marketed as Vivelle®, Menorest®, and Femiest®) is available by prescription and utilizes Noven s advanced transdermal matrix technology. This product delivers 17-beta 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 44 foreign countries, for the treatment of menopausal symptoms. This product has also been approved for marketing in the United States and 40 foreign countries for 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. Marketing rights outside of the United States and Canada were held exclusively by Aventis until October 1999, when Novartis AG sublicensed Aventis rights to market the product in all of Aventis exclusive markets other than Japan. Novartis AG is selling this product under the brand name Menorest® in over 20 foreign countries, including France, Germany and the United Kingdom. Novogyne markets this product under the brand name Vivelle® in the United States, Novartis AG s Canadian affiliate markets this product in Canada, and Aventis markets this product under the brand name Femiest® in Japan.

Pursuant to license and supply agreements with Novartis AG, Novogyne and Aventis, Noven manufactures Vivelle®, Menorest® and Femiest® for these parties and receives fees based on their sales of the products. The supply agreements for Menorest® and Femiest® are long-term agreements and the supply agreement for Vivelle® expires in January 2003. Noven expects that the Vivelle® supply agreement will be extended on satisfactory terms, but there can be no assurance that the agreement will be extended on satisfactory terms or at all. Failure to extend the supply agreement

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could have a material adverse effect on Noven s business and results of operations. Designation of a supplier requires the affirmative vote of 4 of the 5 members of Novogyne s management committee.

Second Generation Transdermal Estrogen Delivery System

Noven s continued efforts to improve its matrix patch technology have resulted in the successful development of a second generation transdermal estrogen replacement system called Vivelle-Dot®. This second generation system, utilizing Noven s proprietary Dot Matrix technology, is only 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 even more flexible and comfortable to wear than the first generation product, with a lower potential for skin irritation. This product is bioequivalent to Noven s first generation product and is available in four dosage strengths. An application is pending with FDA to add a fifth dosage strength and to add a claim for the treatment of osteoporosis. In November 2001, the FDA issued to Novartis an approvable letter relating to this application. There can be no assurance that the conditions in the approvable letter will be met or that the FDA will grant final approval of the application.

In January 1999, Noven received FDA approval to market Vivelle-Dot® for the treatment of the symptoms of menopause, and, in May 1999, Novogyne launched Vivelle-Dot® in the United States. Aventis has marketing rights for Vivelle-Dot® in 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 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 Noven. Noven received an up-front license payment of $20.0 million upon execution of the agreement. For accounting purposes, the up-front payment has been deferred and is being recognized as license revenue over 10 years beginning in the fourth quarter of 2000. Under the terms of the agreement, Novartis AG is responsible for seeking approval to market Estradot® in its territory. In March 2001, Estradot® was approved for marketing in the Netherlands. In November 2001, Estradot® successfully completed the European Mutual Recognition Procedure. The product has since been approved for marketing in certain other European countries and the regulatory authorities of other countries are reviewing Novartis registration applications. The agreement provides that receipt of regulatory approval in one of several specified countries triggers a $5.0 million milestone payment to Noven. Noven received the $5.0 million payment in the fourth quarter of 2001 even though the applicable approvals had not been obtained. This milestone payment has been deferred and will be recognized as license revenue over the same period as the up-front payment, beginning in the quarter when an applicable approval is obtained. There can be no assurance that Novartis AG will be successful in effecting additional registrations of Estradot®. Novartis markets several other estrogen patches in addition to Noven s products. The growth of Estradot® sales depends, in part, on Novartis willingness and ability to convert sales of its existing patches to Estradot®. There can be no assurance that Novartis will choose to actively convert sales of its existing patches to Estradot®.

Pursuant to license and supply agreements with Novartis AG and Novogyne, Noven manufactures the product for these parties and receives 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

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same agreement as Vivelle®. As discussed above, although Noven expects that the supply agreement will be extended, there can be no assurance that it will be extended on satisfactory terms or at all.

Transdermal Combination Estrogen/Progestin Delivery System

Another of Noven s major developments in HRT was the first combination transdermal therapy system approved for marketing by the FDA, a combination patch containing 17-beta estradiol and a progestin, norethindrone acetate. Benefits of estrogen replacement therapy include menopausal symptom control, osteoporosis prevention and cardiovascular protection. For women who have an intact uterus (non-hysterectomized), estrogen replacement therapy has been associated with an increased risk of endometrial cancer. To address this situation, a combination therapy of estrogen and progestin is 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.

In 1998, Aventis, Noven s then exclusive worldwide licensee for this product, received approval from the FDA, as well as regulatory authorities in 13 foreign countries, to market the product for the treatment of menopausal symptoms. As described above in Business Novogyne Pharmaceuticals , Novogyne acquired marketing rights to the product in March 2001 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. Pursuant to the October 1999 sublicense by Aventis to Novartis AG described above, Novartis AG also acquired 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 only approved in one dosage strength in most European countries. While Novartis AG has advised Noven that it intends to seek approval for a second dosage strength, no assurance can be given that Novartis AG will seek such approval or will be successful, and no assurance can be given as to the timing of any such approval or launch in any given country. Noven expects that growth in Estalis® sales outside of the United States will be limited unless and until a second dosage strength (which is approved in the United States) is approved and launched.

In June 2001, Noven and Novartis AG entered into a development agreement relating to future generations of combination estrogen/progestin patch products.

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

Transdermal Methylphenidate Delivery System

Noven has developed a once-daily transdermal methylphenidate patch for the treatment of ADHD. ADHD is the most commonly diagnosed and the most widely studied behavioral disorder in children in the United States. ADHD is characterized by developmentally inappropriate levels of attention, concentration, activity, distractibility and impulsivity symptoms. The disorder typically causes functional impairment that can limit success and create hardship in school, at work, and in

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social and familial relationships. As children age, the symptoms can lead to serious conduct disorders, criminal behavior, substance abuse and accidental injuries.

While prevalence rates can vary dramatically from study to study, it is widely reported that ADHD affects about 3 to 5% 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 have valued the ADHD market at over $1 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 the majority of patients require more than one dose per day. Noven expects that its 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 affect most pill formulations. Noven also believes that its product will provide physicians with broad dosing flexibility, because dosing can be discontinued by simply removing the patch. Noven completed a Phase III clinical study for MethyPatch® in March 2001, and the results of that study were inconclusive. In November 2001, Noven commenced another Phase III study with a revised dosing regimen, which is expected to be completed and evaluated in the first half of 2002. If this study is completed and is successful, Noven would expect to file an NDA with the FDA thereafter. No assurance can be given that the results of the Phase III trial will support an NDA filing, that Noven will be able to successfully complete and file the NDA in a timely manner or that the NDA will be approved.

The market for ADHD drugs is highly competitive, with a product mix that includes generic methylphenidate, other stimulant medications and a variety of other drug types. There are several other once-daily ADHD medications on the market, and other products which may have improved safety and efficacy profiles are also in development. There can be no assurance that Noven will successfully commercialize the product or that it will compete effectively against extended release oral formulations of methylphenidate and/or other ADHD medications. Some of the companies marketing competitive products are substantially larger and have greater financial resources than Noven, as well as greater experience commercializing pharmaceutical products.

Dependence on Licensees and Joint Venture

During 2001, 45%, 43% and 10% of Noven s revenues were generated from sales to, and contract revenue, fees and royalties received from, Novogyne, Novartis AG, and Aventis, respectively, and 74% of Noven s income before taxes was attributable to Noven s equity in Novogyne s earnings. Noven expects to be dependent on sales to Novartis AG and Novogyne, as well as fees and royalties generated from such parties sales of its transdermal delivery systems, for a significant portion of its expected revenues for 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 successfully market Noven s products would cause the quantity of products purchased from Noven and the amount of fees and royalties ultimately paid to Noven to be reduced and would therefore have a

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material adverse effect on Noven s business and results of operations. Noven expects to be able to exert influence on the marketing of Vivelle®, Vivelle-Dot® and CombiPatch® in the United States through its participation in the management of Novogyne, but the management committee of Novogyne is comprised of a majority of Novartis representatives. With respect to Novartis AG s marketing efforts, Noven s agreements with Novartis AG impose certain obligations on Novartis AG, but there can be no assurance that such agreements will provide Noven with any meaningful level of protection or cause Novartis AG to perform at a level that Noven deems satisfactory.

In addition to Noven s dependence on sales by licensees, Noven expects that a significant amount of its earnings for at least the next several years will be generated through its 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. CombiPatch® prescription trends declined during 2000 and have not improved significantly since Novogyne acquired marketing rights to CombiPatch® in March 2001, and there can be no assurance 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 Noven s business and results of operations. See Competition below for a more complete description of the competitive factors affecting Noven and its business.

Transmucosal Drug Delivery

Description

Large, complex, bioengineered molecules such as peptides, proteins and carbohydrates typically require an injectable route of delivery. When taken orally (as capsules or tablets) they are broken down and largely inactivated in the stomach and intestines. The transdermal route is also unsuitable for these molecules because they are often too large to pass through intact skin. Transmucosal drug delivery utilizing Noven s transmucosal patch technology may offer a viable alternative. The lining of the mouth is thin and highly vascular, and drugs can pass rapidly across the mucosa and into the bloodstream without being subjected to breakdown in the gastrointestinal tract. Noven s oral patch technology provides the opportunity to focus and maintain a high concentration of drug against the mucosa to maximize absorption. Noven s transmucosal drug delivery system utilizes a bio-adhesive patch containing medication which adheres to the buccal mucosa. The system then administers the drug across the mucosa and into the bloodstream. Transmucosal drug delivery also has many of the advantages associated with transdermal drug delivery, including non-invasive administration and controlled delivery.

There are many other companies active in the development of transmucosal delivery systems. Challenges faced by Noven and these companies in developing marketable transmucosal systems include designing a stable transmucosal platform that will deliver drug at a predictable rate, creating an adhesive system that will adhere in a wet environment, designing a product that a patient will find comfortable to wear, and identifying suitable compounds for incorporation into the system.

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Products

DentiPatch® Transmucosal Lidocaine Delivery System

Noven s first transmucosal delivery system, the DentiPatch® system, 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 is the first FDA-approved, and still the only commercially available, oral transmucosal patch. Noven 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. Noven is currently marketing the DentiPatch® system in the United States through a network of independent distributors. Sales of DentiPatch® do not contribute meaningfully to Noven s results of operations.

Research and Development

For the years ended December 31, 2001, 2000 and 1999, Noven spent $11.0 million, $13.6 million and $7.2 million, respectively, for company-sponsored research and development activities. From time to time, Noven may supplement its research and development efforts by entering into research and development agreements, joint ventures and other collaborative arrangements with other companies. Research on certain products has been suspended pending the identification of an appropriate business partner. In allocating research and development dollars and resources, Noven may devote greater resources to the development of products that Noven believes it can market and sell without a business partner. Noven s research and development philosophy is to identify drugs that can be delivered either transdermally or transmucosally, which can be developed rapidly and which have substantial market potential. Noven also seeks therapies that can be improved by using Noven s innovative technologies. Noven will typically seek to develop products that use established agents which currently are being delivered to patients other than transdermally or transmucosally. In addition, Noven may enter into agreements to develop transdermal drug delivery systems utilizing proprietary compounds of other companies.

Noven s research and development expense may vary significantly from quarter to quarter depending on product development cycles and the timing of clinical studies. Noven intends 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 Noven s 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. No assurance can be given that Noven will have the financial resources necessary to complete products under development, that those projects to which Noven dedicates sufficient resources will be successfully completed, that Noven 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 Noven or by a licensing partner. Similarly, there can be no

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assurance that Noven s competitors, many of whom have greater resources than Noven, will not develop and introduce products that will adversely affect Noven s business and results of operations.

The following table summarizes as of March 1, 2002 the status of products marketed, approved and/or under development by Noven and is qualified by reference to the more detailed descriptions elsewhere in this Form 10-K. Noven has additional products in early development and continuously evaluates other drugs that may be suitable for transdermal or transmucosal delivery.

Product	Indication	Regulatory Status	Marketing Rights
Transdermal HRT			
Estrogen Vivelle®/Menorest®/ Femiest®	Menopausal Symptoms	FDA-approved; Approved in 44 foreign countries	Novogyne U.S. Aventis Japan Novartis AG all other territories
	Osteoporosis	FDA-approved; Approved in 40 foreign countries	
Second Generation Estrogen Vivelle-Dot®/ Estradot®	Menopausal Symptoms	FDA-approved; Approved in 12 foreign countries	Novogyne U.S. Aventis Japan Novartis AG all other territories
	Osteoporosis	Approvable letter issued in the U.S.; Approved in 12 foreign countries	
Third Generation Estrogen	Menopausal Symptoms/ Osteoporosis	Pre-clinical development	Novogyne U.S. and Canada Aventis Japan Novartis AG all other territories
Combination Estrogen/Progestin CombiPatch®/Estalis®	Menopausal Symptoms	FDA-approved; Approved in 27 foreign countries	Novogyne U.S. Aventis Japan Novartis AG all other territories
Second Generation Combination Estrogen/Progestin	Menopausal Symptoms/ Osteoporosis	Phase I (sponsored by Novartis AG)	Aventis Japan Novartis AG all other territories
Methyltestosterone*	Female Libido	Phase I	Noven

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Product	Indication	Regulatory Status	Marketing Rights
Transmucosal			
Lidocaine/DentiPatch®	Dental Pain Control	FDA-approved	Noven
Other Transdermals			
Methylphenidate MethyPatch®	Attention Deficit Hyperactivity Disorder	Phase III	Noven
Undisclosed molecule	Attention Deficit Hyperactivity Disorder	Pre-clinical development	Noven
Ketoprofen*	Pain Relief	Phase II	Noven
Undisclosed molecule	Pain Relief	Pre-clinical development	Noven

* These products are available for licensing, and Noven does not intend to further the development of these products unless and until it has entered an agreement with another company to assist in the development. There can be no assurance that Noven will be able to identify any such development partner or that it will be able to enter into a license or development agreement on commercially reasonable terms. The failure to enter into such an agreement could negatively affect the ability of Noven to develop, manufacture and commercialize these products and may result in the discontinuation of these development projects.

Manufacturing

Noven conducts its 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. This facility is currently producing Menorest®, Vivelle®, Femiest®, Vivelle-Dot®, Estradot®, CombiPatch®, Estalis® and DentiPatch® for commercial sale. With this facility, Noven s 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 Noven s manufacturing capacity to accommodate additional products under development. Noven anticipates that full development of this site, including possible new construction on the property, can accommodate Noven s space requirements for the foreseeable future. No assurance can be given that Noven will have the financial resources necessary to expand adequately its manufacturing capacity if and when the need arises.

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Noven has the capacity to design, develop, build and maintain its production equipment, including fabrication of replacement parts where appropriate. Additionally, Noven s engineering expertise provides valuable support to its research and development groups by rapidly fabricating or modifying equipment essential in the product development program.

Raw materials essential to Noven s business are generally readily available from multiple sources. Certain raw materials and components used in the manufacture of Noven s products are, however, available from limited sources, and in some cases, a single source. 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 Noven s 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.

Marketing

Except for the DentiPatch® product, Noven has historically granted marketing rights to its products to its joint venture company, Novogyne, or to larger pharmaceutical companies. As Noven develops new products, it will evaluate whether to license such products to a larger company or to Novogyne or to utilize its own clinical, marketing and sales capabilities. Noven s 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 Noven s financial position will be factored into the decision whether to license or directly conduct clinical trials and market the product. Noven expects that it will seek to retain manufacturing rights in any future licensing transactions, partly in an effort to safeguard its proprietary technology. There can be no assurance that Noven will be able to reach a favorable agreement in any particular transaction or collaborative arrangement.

The establishment of Novogyne provided Noven with a sales force over which it has substantial day-to-day management control. If Noven develops any products in the future for the women s healthcare market, it may seek to license the marketing rights for such products to Novogyne.

If Noven is able to successfully complete its clinical program and file an NDA for its MethyPatch® product, Noven expects to establish a sales force to sell MethyPatch® in the United States rather than granting exclusive marketing rights to a third party. Establishing a sales force, and expanding Noven s sales and marketing infrastructure to support the sales force, would require the expenditure of substantial funds. There can be no assurance that, if MethyPatch® is approved for marketing by the FDA, Noven will generate sufficient sales of the product to cover the expense of Noven s sales and marketing organization and/or to realize adequate profits. In addition, some of these expenses may be incurred prior to receipt of marketing approval. In the event that MethyPatch® is not approved for marketing, these expenses will not be recovered. Additionally, any delays in organizing a sales force for Noven s MethyPatch® product could have an adverse impact on Noven s ability to market the product and to realize profits from sales of the product.

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Competition

The markets for Noven s products are highly competitive. All drug delivery products being developed by Noven will face competition from both conventional forms of drug delivery (i.e., oral and parenteral), and possibly alternate forms of drug delivery, such as controlled release oral delivery, liposomes, implants, gels and creams. In addition, some or all of the products being marketed or developed by Noven face, or will face, competition from other transdermal or transmucosal 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 developments by others will not render Noven s products or technologies noncompetitive or obsolete.

Noven faces competition from a number of companies in the development of transdermal and transmucosal drug delivery products, and competition is expected to intensify as more companies enter the field. Competitors include Elan Corporation, plc, Watson Pharmaceuticals, Inc., Mylan Pharmaceuticals, Inc., LTS Lohmann Therapie-Systeme AG, Ethical Holdings, plc, Johnson & Johnson, Schering-Plough Corporation, 3M Corporation, Groupe Fournier and others. Some of these companies are substantially larger than Noven and have greater financial and research and development resources than Noven, as well as greater experience in developing and commercializing pharmaceutical products. Noven also competes with other drug delivery companies in the establishment of business arrangements with large pharmaceutical companies to assist in the development or marketing of products.

Noven has attempted to minimize certain competitive risks by its technological innovation and by developing strategic alliances with larger pharmaceutical companies. Noven also believes that its hormone replacement systems have certain competitive advantages, such as their small size, excellent adhesion, reduced skin irritation and broad dosing ranges.

Other competitive factors affecting Noven s business include the prevalence and influence of managed care organizations, government organizations, buying groups and similar institutions that are able to seek price discounts and rebates on pharmaceutical products. As the influence of these entities continues to grow, Noven and its marketing partners may face increased pricing pressure. Outside of the United States, Noven s products may be affected by government price controls and reimbursement policies.

Patents and Proprietary Rights

Noven seeks to obtain patent protection on its delivery systems and manufacturing processes where possible. Noven has obtained over 25 United States patents and over 120 foreign patents relating to its transdermal and transmucosal delivery systems and manufacturing processes, and has over 100 pending patent applications worldwide.

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As a result of the 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 existing Noven patents have been extended beyond the term of seventeen years from the date of grant. Noven patents filed after June 7, 1995 will have a term of twenty years computed from the effective filing date.

Noven is unaware of the existence of any challenge to the validity of its patents or of any third party claim of patent infringement with respect to any of its products that could have a material adverse effect on Noven s 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. There is no assurance that Noven s patents or any future patents will prevent other companies from developing similar or functionally equivalent products. Furthermore, there is no assurance that any of Noven s future processes or products will be patentable, that any pending or additional patents will be issued in any or all appropriate jurisdictions or that Noven s processes or products will not infringe upon the patents of third parties.

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

Government Regulation

Noven s 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. Noven devotes significant time, effort and expense to address the extensive government regulations applicable to its business.

The marketing of pharmaceutical products requires the approval of the FDA in the United States. The FDA has established regulations, guidelines and safety standards which apply to the pre-clinical evaluation, clinical testing, manufacturing and marketing of pharmaceutical products. The process of obtaining FDA approval for a new product may take several years 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.

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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.

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, and the FDA may not finally approve the ANDA until a court finally determines that the applicable patent is invalid or would not be infringed by the applicant s product.

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 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 an ANDA for approval. If an application is submitted, there can be no assurance that the FDA will review and approve the NDA or an ANDA in a timely manner. The FDA may deny an NDA or an 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 a manufacturing facility, an NDA or an 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.

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The approval procedures for the marketing of Noven s 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, Noven intends to design its protocols for the clinical studies of its products to permit acceptance of the data by foreign regulatory authorities and to thereby 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 (GMP) regulations and each domestic drug manufacturing facility must be registered with the FDA. Foreign regulatory authorities may also have similar regulations. In complying with standards set forth in these regulations, Noven must expend significant time, money and effort in the area of quality assurance to insure full technical compliance. Facilities handling controlled substances, such as Noven s, also must be licensed by the United States Drug Enforcement Administration, and are subject to more extensive regulatory requirements than those facilities not licensed to handle controlled substances. Noven has produced transdermal drug delivery products in accordance with the FDA s GMP 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 Noven s 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 and implementation, Noven cannot predict what impact any reform proposal ultimately adopted may have on the pharmaceutical industry or on the business or operating results of Noven.

Noven s 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, Noven 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 Noven s earnings or competitive position.

Employment

Noven employs approximately 252 people; approximately 97 are engaged in manufacturing and process development, 19 in research and development, 57 in clinical research, regulatory affairs, quality assurance and quality control and 79 in marketing and administration. No employee is

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represented by a union and Noven has never experienced a work stoppage. Noven believes its employee relations are good. In addition to the employees employed directly by Noven, Novogyne has a contract sales force of approximately 120 individuals that are managed by Noven under the terms of the Novogyne joint venture agreements.

Risk of Product Liability Claims

Testing, manufacturing and marketing pharmaceutical products subject Noven to the risk of product liability claims. Noven believes that it maintains an adequate amount of product liability insurance, but there can be no assurance that its insurance will cover all future claims or that Noven will be able to maintain existing coverage or obtain additional coverage at reasonable rates. There can be no assurance that claims arising under any product liability cases, whether or not covered by insurance, will not have a material adverse effect on Noven s business, financial condition or results of operations.

Seasonality

There are no significant seasonal aspects to Noven s business.

Item 2. Properties.

Noven s headquarters and manufacturing facilities are located on a 10 acre site in Miami, Florida. On this site, Noven owns an approximately 28,000 square foot building which is used for laboratory, office and administrative purposes. Noven also leases from Aventis, for nominal rent, two approximately 40,000 square foot buildings on this site, which are being used by Noven for manufacturing, engineering, administrative and warehousing purposes. One of these facilities has been certified by the Drug Enforcement Administration to manufacture products containing controlled substances. The lease expires in 2024 and Noven has 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 the 1992 license agreement between Noven and Aventis. Noven expects that it will have sufficient cash to purchase the facility in this event. Nonetheless, if Noven were unable to purchase the facility, termination of the lease by Aventis could have a material adverse effect on the business and results of operations of Noven.

Noven also owns 5 acres of vacant land on a contiguous site that could accommodate new buildings for a variety of manufacturing, warehousing and developmental purposes. Noven believes that its facilities are in satisfactory condition, are suitable for their intended use and, in the aggregate, have capacities in excess of those necessary to meet Noven s present needs.

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

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Item 3. Legal Proceedings.

Deborah A. Kaliser v. Noven Pharmaceuticals, Inc., Robert C. Strauss, James B. Messiry, and Steven Sablotsky, United States District Court, Southern District of Florida; November 8, 2001.

Bernard Middleton, et al., v. Noven Pharmaceuticals, Inc., Robert C. Strauss, James B. Messiry, and Steven Sablotsky, United States District Court for the Southern District of Florida; November 20, 2001.

Evelyne Shabo, et al., v. Noven Pharmaceuticals, Inc., Robert C. Strauss, James B. Messiry, and Steven Sablotsky, United States District Court for the Southern District of Florida; December 12, 2001.

Leah Constantine, et al., v. Noven Pharmaceuticals, Inc., Robert C. Strauss, James B. Messiry, and Steven Sablotsky, United States District Court for the Southern District of Florida; December 17, 2001.

Joseph A. Papa, et al., v. Noven Pharmaceuticals, Inc., Robert C. Strauss, James B. Messiry, and Steven Sablotsky, United States District Court for the Southern District of Florida; January 3, 2002.

These actions are essentially identical actions brought by plaintiffs that purport to represent a class of purchasers of Noven s common stock during the period March 27 through November 1, 2001. Plaintiffs allege 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 Pharma AG. Plaintiffs seek 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 March 12, 2002, the Court entered an order consolidating all of the captioned actions into a single consolidated action and directing plaintiff s counsel to file a single amended and consolidated complaint.

Noven believes that these lawsuits are without merit and intends to vigorously defend these lawsuits, but their respective outcomes cannot be predicted. Any of such lawsuits, if determined adversely to Noven, could have a material adverse effect on Noven s financial position and results of operations. Noven s ultimate liability with respect to any of the foregoing proceedings is not presently determinable.

Noven is a party to other pending legal proceedings arising in the normal course of business, none of which Noven believes is material to its financial position or results of operations.

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

Noven did not submit any matters to a vote of stockholders during the fourth quarter of the fiscal year ended December 31, 2001.

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Executive Officers of the Registrant

Set forth below is a list of the names, ages, positions held and business experience of the persons serving as executive officers of Noven as of March 1, 2002. 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 Noven s 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 36, 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.

W. Neil Jones. Mr. Jones, age 49, 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 43, 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 59, 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 60, 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

Noven s 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, 2000	$27.25	$10.38
Second Quarter, 2000	30.50	6.53
Third Quarter, 2000	48.88	23.75
Fourth Quarter, 2000	64.25	22.50
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

(b) Holders.

As of March 1, 2002 the number of stockholders of record was 345.

(c) Dividends.

Noven has never paid a cash dividend on its Common Stock and intends to retain all earnings for the operation and expansion of its business and does not anticipate paying cash dividends in the foreseeable future.

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Item 6. Selected Financial Data.

The selected financial data presented below is derived from the audited financial statements of Noven. 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,				
	2001	2000	1999	1998	1997
Statement of Operations Data:	(in thousands, except per share amounts)				
Revenues	$ 45,947	$ 42,924	$31,650	$21,842	$ 14,267
Expenses:					
Cost of products sold	20,376	19,219	12,721	9,447	5,180
Research and development	10,973	13,621	7,171	6,808	9,723
Marketing, general and administrative	11,554	8,737	7,860	10,105	9,845
Total expenses	42,903	41,577	27,752	26,360	24,748
Income (loss) from operations	3,044	1,347	3,898	(4,518)	(10,481)
Equity in earnings of Novogyne	14,013	9,294	1,487		
Interest income, net	1,770	1,385	343	439	924
Income (loss) before income taxes	18,827	12,026	5,728	(4,079)	(9,557)
Income tax expense (benefit)	6,736	(7,608)	(4,732)		
Net income (loss)	$ 12,091	$ 19,634	$10,460	$ (4,079)	$ (9,557)
Basic earnings (loss) per share	$ 0.54	$ 0.90	$ 0.49	$ (.19)	$ (.47)
Diluted earnings (loss) per share	$ 0.51	$ 0.84	$ 0.48	$ (.19)	$ (.47)
Balance Sheet Data:					
Cash and cash equivalents	$ 49,389	$ 40,976	$15,338	$ 5,573	$ 17,148
Working capital	45,788	46,697	16,581	8,847	18,683
Investment in Novogyne	32,043	15,431	8,365	7,500	
Total assets	136,228	104,031	56,888	40,156	38,224
Long-term notes payable	13	265	604		
Deferred license revenue	32,758	27,109	8,028	5,644	5,870
Stockholders equity	81,898	65,277	39,393	28,325	29,881

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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 the 2001 financial statements and the related notes included in this Form 10-K.

General

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

In May 1998, Noven and Novartis formed Novogyne 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. Novogyne is managed by a committee consisting of five members, three of which are appointed by Novartis and two of which are appointed by Noven. 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 Noven 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. Noven 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, Noven manufactures and supplies Novogyne with Vivelle®, Vivelle-Dot® and CombiPatch®, performs marketing, sales and promotional activities, and receives 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.

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 Noven according to a contractual formula depending upon sales levels attained. Novogyne s management committee has the authority to distribute cash to Novartis and Noven based upon a contractual formula. Noven s share of income increases as product sales increase, subject to a maximum of 49%. Novogyne s income resulted in the recognition by Noven of $14.0 million, $9.3 million and $1.5 million in income in 2001, 2000 and 1999, respectively. In 2001, 2000 and 1999, Noven received $13.1 million, $2.2 million and $0.6 million in distributions from Novogyne based upon Novogyne s results of operations for the years ended December 31, 2000, 1999 and 1998, respectively. All of Noven s 2001 distributions from Novogyne plus an additional $2.6 million were reinvested in Novogyne to fund Noven s portion of the CombiPatch® license transaction. Noven expects that a significant portion of its earnings and cash flow for the next several years will be generated through its interest in

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Novogyne, but no assurance can be given regarding Novogyne s future profitability or cash distributions. See Note 6 of Noven s Audited Financial Statements herein for a summary of Novogyne s audited financial statements.

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, which was due in four quarterly installments of $10.0 million each with the final payment 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. Since the relaunch of CombiPatch® by Novogyne in May 2001, CombiPatch® total prescriptions have not increased meaningfully. If Novogyne is unable to grow CombiPatch® prescriptions, Novogyne s growth may slow and its contribution to Noven s earnings and cash flow may be limited. Any failure by Novogyne to remain profitable or to continue to make distributions could have a material adverse effect on Noven s results of operations or financial condition.

Marketing rights outside of the United States and Canada for both Noven s first generation transdermal estrogen delivery system (marketed as Menorest®) and Noven s transdermal combination estrogen/progestin delivery system (marketed as Estalis®) were held exclusively by Aventis until October 1999, when Novartis AG sublicensed Aventis rights to market these products in all of Aventis exclusive markets other than Japan. In connection with the transaction Noven received $2.7 million in cash from Aventis as Noven s share of the sublicense fee paid to Aventis. This amount was recorded as deferred license revenue and is being recognized as license revenue over seven and one-half years beginning in the fourth quarter of 1999. Novartis AG is selling Menorest® in over 20 foreign countries, including France, Germany and the United Kingdom, and is selling Estalis in a number of countries. Estalis® is only approved in one dosage strength in most European countries. While Novartis AG has advised Noven that it intends to seek approval for a second dosage strength, no assurance can be given that Novartis AG will seek such approval or will be successful, and no assurance can be given as to the timing of any such approval or launch in any given country. Noven expects that growth in Estalis® sales outside of the United States will be limited unless and until a second dosage strength is approved and launched.

In a transaction related to Novogyne s acquisition of United States marketing rights to CombiPatch®, 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, and Novogyne expects to sublicense the United States rights to these product improvements from Novartis AG. If and when any future generation combination products are commercialized and sublicensed to Novogyne, Novogyne 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.

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In November 2000, Noven entered into an exclusive license agreement with Novartis AG pursuant to which Noven 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 Noven. Noven received an up-front license payment of $20.0 million upon execution of the agreement. For accounting purposes, the up-front payment has been deferred and is being recognized as license revenue over 10 years beginning in the fourth quarter of 2000. Under the terms of the agreement, Novartis AG is responsible for seeking approval to market Estradot® in its territory. In March 2001, Estradot® was approved for marketing in the Netherlands. In November 2001, Estradot® successfully completed the European Mutual Recognition Procedure. The product has since been approved for marketing in certain other European countries and the regulatory authorities of other countries are reviewing Novartis registration applications. The agreement provides that receipt of regulatory approval in one of several specified countries triggers a $5.0 million milestone payment to Noven. Noven received the $5.0 million payment in the fourth quarter of 2001 even though the applicable regulatory approvals had not been obtained. This milestone payment has been deferred and will be recognized as license revenue over the same period as the up-front payment, beginning in the quarter when an applicable approval is obtained. There can be no assurance that Novartis AG will be successful in effecting additional registrations of Estradot®. Novartis markets several other estrogen patches in addition to Noven s products. The growth of Estradot® sales will depend, in part, on Novartis willingness and ability to convert sales of its existing patches to Estradot®. There can be no assurance that Novartis will choose to actively convert sales of its existing patches to Estradot®.

Noven is developing a once-daily transdermal methylphenidate delivery system called MethyPatch® for the treatment of ADHD. In March 2001, Noven learned that its first large-scale Phase III trial for this product was inconclusive. This result caused a delay of at least one year in the commercialization of this product and resulted in additional research and development expenses in 2001 and 2002. Noven is now engaged in a second Phase III clinical trial for MethyPatch®, which is expected to be completed and evaluated in the first half of 2002. If the Phase III trial is successful, Noven would expect to file an NDA with the FDA thereafter. If Noven s MethyPatch® NDA is approved, Noven intends to establish its own sales force to market the product. In such event, Noven would expect that its sales and marketing expenses would increase as it prepares for the expected commercialization of the product. No assurance can be given that the results of the pending Phase III trial will support an NDA filing, that Noven will be able to successfully complete and file the NDA in a timely manner, that the product will be approved by the FDA or that, if approved, it will be successfully marketed.

Noven expects that revenues from product sales to its licensees will fluctuate from quarter to quarter and year to year depending upon various factors not in Noven s control, including, but not limited to, 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 product pricing of each licensee and the timing of certain royalty reconciliations and payments under Noven s license agreements. Noven s 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. Other factors that could impact Noven s revenues or earnings are discussed under Cautionary Factors that May Have an Impact on Future Results herein.

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Results of Operations

Revenues:

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

	2001	Percentage Change	2000	Percentage Change	1999
Product sales	$43,096	3%	$42,005	34%	$31,334
License revenue	2,851	210%	919	191%	316
Total revenue	$45,947	7%	$42,924	36%	$31,650
Gross profit (product sales less cost of products sold)	$22,720	(0.3%)	$22,786	22%	$18,613
Gross margin (as a percentage of sales)	53%		54%		59%

The $3.0 million, or 7%, increase in 2001 revenues versus 2000 revenues was primarily attributable to an increase in license revenue, which related to 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 due to planned inventory reductions at Novogyne.

The $11.3 million, or 36%, increase in 2000 revenues versus 1999 revenues was primarily attributable to an increase in product sales. The increase in product sales was primarily a result of sales of Estalis®, which Noven began shipping to Novartis AG beginning in the fourth quarter of 1999, and to a lesser extent, higher sales of Vivelle® and Vivelle-Dot®. Vivelle-Dot® was launched by Novogyne in May 1999. A decline in sales of CombiPatch® in the United States from 1999 to 2000 partially offset the increased sales of Noven s other products.

Gross Margin:

Noven s gross margin declined to 53% for 2001 from 54% in 2000. The decrease resulted from unfavorable product mix as Noven sold more product outside of the United States (where sales have a lower gross margin), while United States sales declined. The decrease in gross margin was partially offset by higher minimum fee payments from Novartis AG.

Noven s gross margin declined to 54% for 2000 from 59% in 1999. The decrease was primarily attributable to Novogyne increasing its inventory during 2000 in anticipation of an increase in product demand, which caused an increase in the profit that Noven was required to defer with respect to product sold to Novogyne that remained in Novogyne s inventory at December 31, 2000. Noven defers the recognition of 49% of its profit from products sold to Novogyne until such

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inventory is sold by Novogyne. (See Note 1, Description of Business - Vivelle Ventures LLC, in the Notes to Financial Statements for more information.) In addition, product mix contributed to the decline in gross margin as Noven sold more product outside of the United States while United States sales remained generally consistent with the prior year.

Operating Expenses:

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

	2001	Percentage Change	2000	Percentage Change	1999
Research and development	$10,973	(19%)	$13,621	90%	$7,171
Marketing, general and administrative	11,554	32%	8,737	11%	7,860

Research and Development

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

The $6.5 million, or 90%, increase in 2000 research and development expenses versus 1999 research and development expenses was primarily attributable to clinical studies and related expenses for MethyPatch®.

Marketing, General and Administrative Expenses

The $2.8 million, or 32%, increase in 2001 marketing, general and administrative expenses versus 2000 marketing, general and administrative expenses 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 related to the CombiPatch® license transaction. The increase in expenses was partially offset by a decline in recruitment costs and other related expenses.

The $0.9 million, or 11%, increase in 2000 marketing, general and administrative expenses versus 1999 marketing, general and administrative expenses was primarily due to higher personnel, recruitment costs and outside consulting services.

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Other Income and Expenses:

Interest Income

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

Interest income, net increased approximately $1.0 million, or 304%, in 2000 compared to 1999, primarily due to higher average balances in cash and cash equivalents due to the receipt of $20.0 million related to the license of Estradot®.

Income taxes

Noven s effective tax rate was 36% for the year ended December 31, 2001. The provision for income taxes is based on the Federal and state statutory rates. Realization of the deferred income tax asset of approximately $15.0 million at December 31, 2001 depends upon generating sufficient future taxable income. Although realization is not assured, management believes it is more likely than not that the deferred income tax asset will be realized based upon estimated future taxable income.

Income tax benefit of $7.6 million for the year ended December 31, 2000 resulted from the recognition of a deferred income tax benefit of $9.4 million offset by current income tax expense of $1.8 million. This was caused by an $11.5 million reduction of valuation allowance on deferred income tax asset.

Equity in Earnings of Novogyne

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

Novogyne's Summary Results:	2001	Percentage Change	2000	Percentage Change	1999
Revenues	$89,958	54%	$58,544	71%	$34,274
Cost of sales	16,796	73%	9,698	49%	6,530
Gross profit	73,162	50%	48,846	76%	27,744
Gross margin percentage	81%		83%		81%
Selling, general and administrative expenses	31,384	47%	21,315	20%	17,720
Amortization of intangible assets	4,635	100%			
Income from operations	37,143	35%	27,531	175%	10,024
Interest income	734	(53%)	1,562	136%	661
Net income	$37,877	30%	$29,093	172%	$10,685
Noven s equity in earnings of Novogyne	$14,013	51%	$ 9,294	525%	$ 1,487

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Novogyne s increase in revenue of $31.4 million, or 54%, in 2001 as compared to the prior year is primarily attributable to increased sales of Vivelle-Dot® and the addition of CombiPatch® (licensed in March 2001), partially offset by a decrease in Vivelle® sales. Novogyne s selling, general and administrative expenses increased to $31.4 million for the year ended December 31, 2001 from $21.3 million in 2000, primarily 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 $4.6 million related to the CombiPatch® acquisition cost during the year ended December 31, 2001.

Novogyne s increase in revenue of $24.3 million, or 71%, in 2000 as compared to the prior year is attributable to increased sales of Vivelle-Dot®, which was launched in the second quarter of 1999. Novogyne s selling, general and administrative expenses increased to $21.3 million from $17.7 million in the prior year, primarily due to higher sales force and promotional expenses due to higher sales.

Liquidity and Capital Resources:

As of December 31, 2001 and 2000, Noven had $49.4 million and $41.0 million in cash and cash equivalents and working capital of $45.8 million and $46.7 million, respectively.

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

	2001	2000	1999
Cash flows:			
Operating activities	$11,602	$21,604	$9,544
Investing activities	(5,939)	674	(799)
Financing activities	2,750	3,360	1,020

Operating Activities:

Net cash provided by operating activities in 2001 primarily resulted from the receipt of a one-time license fee in the amount of $3.5 million from Aventis in connection with the CombiPatch® license transaction and a one-time $5.0 million milestone payment in connection with the Estradot® license to Novartis AG. See Note 5, License Agreements, in the Notes to Financial Statements for more information. A non-cash item (equity in earnings of Novogyne of $14.0 million) constituted more than 100% of Noven s net income of $12.1 million. Changes in working capital accounted for most of the remaining change over the prior period.

Net cash provided by operating activities in 2000 primarily resulted from the receipt of a one-time up-front license fee of $20.0 million in November 2000 from Novartis AG in connection with the Estradot® license agreement. Non-cash items (equity in earnings of Novogyne of $9.3 million and deferred income tax benefit of $9.4 million) constituted 95% of Noven s net income of $19.6 million. Changes in working capital accounted for most of the remaining increase over 1999.

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Net cash provided by operating activities in 1999 was generated by a one-time $2.7 million license fee from Aventis in connection with the sub-license of Estalis® and Menorest® to Novartis AG. Non-cash items (equity in earnings of Novogyne of $1.5 million and deferred income tax benefit of $5.0 million) constituted 62% of Noven s net income of $10.5 million. Changes in working capital accounted for most of the remaining increase.

Investing Activities:

Net cash used in investing activities in 2001 was primarily attributable to the implementation of an enterprise resource planning system and a $2.6 million net investment in Novogyne related to the CombiPatch® license transaction. Net cash provided by investing activities during 2000 was attributable to $2.2 million of cash distributions from Novogyne, partially offset by the purchase of fixed assets and payment of patent development costs. Net cash used by investing activities in 1999 was attributable to the purchase of fixed assets and payment of patent development costs, partially offset by a $0.6 million cash distribution from Novogyne.

Financing Activities:

Net cash provided by financing activities in each of 2001, 2000 and 1999 was attributable to cash received in connection with the issuance of common stock from the exercise of stock options, partially offset by payments made on notes payable.

In December 2000, Noven entered into a secured revolving credit facility (the Credit Facility) providing for borrowings of up to the lesser of $10.0 million or eligible accounts receivable. The Credit Facility will terminate in April 2003 and bears interest at LIBOR plus 1.50% (1.876% at December 31, 2001). At December 31, 2001 and 2000, there were no amounts outstanding under the Credit Facility. Terms of the Credit Facility include, among other things, minimum net worth, revenue and operating results requirements, as well as certain financial ratios, measured on a quarterly basis.

Noven s principal sources of short-term liquidity are existing cash, cash generated from product sales, fees and royalties under license agreements, distributions from Novogyne, and borrowings under its Credit Facility. Presently, Noven s short-term liquidity is largely dependent on sales of, and license royalties and fees related to sales of, a relatively small number of products. As a result, any decrease in the sales of those products by Noven or its licensees could have a material adverse effect on Noven s short-term liquidity or require Noven to rely more heavily on its existing cash reserves or on borrowings under its Credit Facility to support its operations and business. Many factors that could impact sales of Noven s products are discussed under Cautionary Factors that May Have an Impact on Future Results herein.

Noven believes that it will have sufficient cash available to meet its operating needs and anticipated short-term capital requirements. For the long term, Noven intends to utilize funds derived from the above sources, as well as funds generated through sales of products under development or products that Noven may license or acquire from others. Noven expects that such funds will be comprised of payments received pursuant to future licensing arrangements, as well as Noven s direct sales of its own products. Noven expects that its cash requirements will continue to increase, primarily to fund clinical studies for products under development and for plant and

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equipment to expand production capacity. There can be no assurance that Noven will successfully complete the development of such products, that Noven will obtain regulatory approval for any such products, that any approved product may be produced in commercial quantities, at reasonable costs, and be successfully marketed, or that Noven will successfully negotiate future licensing arrangements. Because much of the cost associated with product development is incurred prior to product launch, if Noven is unable to launch additional commercially viable products that it develops or that it licenses or acquires from others, Noven will have incurred the up-front costs associated with product development or acquisition without the benefit of the liquidity generated by sales of those products, which could adversely effect Noven s long-term liquidity needs. Many factors that could impact Noven s ability to develop or acquire and launch additional commercially viable products are discussed under Cautionary Factors that May Have an Impact on Future Results herein. To the extent that capital requirements exceed available capital, Noven will seek alternative sources of financing to fund its operations. In addition to the Credit Facility which expires in April 2003, alternative financing may be needed to fund further activities. No assurance can be given that alternative financing will be available, if at all, in a timely manner, or on favorable terms. If Noven is unable to obtain satisfactory alternative financing, Noven may be required to delay or reduce its proposed expenditures, including expenditures for research and development and plant and equipment, in order to meet its future cash requirements. See Cautionary Factors that May Have an Impact on Future Results herein for a description of matters that could affect Noven s short or long-term liquidity.

Outlook:

The principal factors that Noven now expects will influence its 2002 financial outlook include:

- The timing and magnitude of international product sales to Novartis AG;
- Novogyne s ability to increase Vivelle® family and CombiPatch® sales;
- Costs associated with new clinical studies for products in development; and
- Costs associated with the continued clinical trials of MethyPatch® and related launch preparation.

Other factors that could impact Noven s 2002 financial outlook are discussed under Cautionary Factors that May Have an Impact on Future Results herein.

International Product Sales

Sales of Noven s international products to Novartis AG in the second half of 2001 were substantially lower than in the first half of the year. Noven receives firm orders from Novartis AG on a partial year basis, which limits Noven s ability to accurately forecast full year sales to Novartis AG.

Based on discussions with Novartis AG, Noven believes that second half 2001 Estalis® sales were affected by high inventory levels and the lack of a second dosage strength in certain countries. Novartis AG has advised that it plans to seek approval of a second dosage strength in European countries where only one strength is presently approved. Noven expects Estalis® sales to decline in

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2002 compared to 2001, and does not expect significant renewed growth in Estalis® sales unless a second dosage is available in Europe and commercialized, which may take several years.

Noven received its first orders for Estradot® in the fourth quarter of 2001, and recorded its first Estradot® sales in the first quarter of 2002. These sales relate to initial Estradot® launches expected to begin in the second quarter of 2002 and to continue through 2003. Although Novartis AG has advised Noven that it expects to receive government approvals of Estradot® in time for planned launches, not all approvals have been received and there is no assurance that those approvals will be received on a timely basis or at all. Failure to receive those approvals on a timely basis could adversely affect Novartis AG s launch plans for Estradot® which would adversely impact Noven s Estradot® sales during 2002.

Vivelle® Family & CombiPatch®

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

MethyPatch® Launch Costs

Noven expects to complete its MethyPatch® Phase III clinical trial and evaluate the resulting data in the first half of 2002. If Phase III results support the filing of a MethyPatch® NDA, Noven would expect to incur sales, marketing and other expenses in 2002 in anticipation of a MethyPatch® approval and launch in the second half of 2003. These expenses could cause Noven s sales and marketing expenses to increase in 2002. Noven expects that these expenses will increase significantly as launch approaches.

New Clinical Studies

During 2002, Noven expects to initiate clinical trials for the development of as many as three new prescription transdermal therapies. These projects, together with continuing MethyPatch® research and development expenses, are expected to increase Noven s research and development expense in the mid 40% range in 2002 as compared to 2001. A significant portion of the expected ongoing MethyPatch® clinical expenses were incurred during the first quarter of 2002, when the majority of Phase III patients were under clinical study. The future level of research and development expenditures will depend on, among other things, the status of products under development and the outcome of clinical trials, strategic decisions by management, the consummation of new collaborative arrangements and Noven s liquidity. Noven s research and development expenses may vary significantly from quarter to quarter depending on product development cycles and the timing of clinical studies.

Liquidity and Capital Resources

In 2002, Noven expects to invest up to $2.0 million in plant and equipment to increase production capacity. Cash requirements for Federal and state income taxes, marketing expenditures related to the launch of MethyPatch® and clinical study expenses are also expected to increase

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compared to 2001. Noven expects that it will receive net cash distributions from Novogyne in 2002, although no assurances can be given that Novogyne s earnings will be sufficient to support distributions or that Novogyne s management committee will authorize them.

Full-Year 2002

Based on information and forecasts from Novartis AG, Estradot® sales in 2002 are not expected to fully offset the anticipated decline in Estalis® sales, resulting in an international sales decline in 2002. If Noven s 2002 sales targets for the Vivelle® family and CombiPatch® are achieved. Noven expects that growth in its United States revenues should offset this international decline. In such a case, Noven would expect 2002 revenues to increase modestly over 2001 and would expect diluted earnings per share to be $0.45 to $0.55. Noven expects gross margin for 2002 to be comparable to 2001 levels, subject to changes in product and country mix, higher than expected production costs, and unexpected changes in Novogyne s inventory. Novogyne s revenues are expected to increase 25% to 30% in 2002 compared to 2001, depending upon, among other things, the success of CombiPatch®. Noven expects its equity in earnings of Novogyne to increase in 2002 compared to the prior year, and expects its effective income tax rate for 2002 to be 34% to 37%.

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 Noven s and its 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 Noven s cu and beliefs concerning future events but are subject to risks and uncertainties, including but not limited to economic, competitive, governmental and technological factors affecting Noven s operations, results of operations, markets, products, prices and prospects, and other factors discussed elsewhere in this report and the other documents filed by Noven with the Securities and Exchange Commission (SEC). These factors may cause Noven s results to differ materially from the statements made in this report or otherwise made by or on behalf of Noven. The following is a brief summary of some of the risk factors, which are not listed in order of priority, that could adversely affect Noven s results. Most of these factors are described elsewhere in this report, but the risks described below are not the only risks Noven faces. Noven does not undertake to update any of these forward-looking statements or to announce the results of any revisions to these forward-looking statements except as required by law.

Noven faces competition from a number of companies in the development of transdermal and transmucosal drug delivery products, and competition is expected to intensify as more companies enter the field. Some of these companies are substantially larger than Noven and have greater financial and research and development resources than Noven, as well as greater experience in developing and commercializing pharmaceutical products. As a result, they may succeed in developing competing technologies or obtaining governmental approvals for products before us. Noven s products compete with other transdermal products as well as alternative

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dosage forms of the same or comparable chemical entities. There can be no assurance that Noven s products will successfully compete against competitive products or that developments by others will not render Noven s 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.

Noven s equity in earnings of Novogyne contributed 74% of Noven s income before taxes in 2001, and Novogyne s results will likely continue to be material to Noven in the future. Because, among other things, Noven and Novartis are vastly different in size, and because Novartis sells competing products outside of Novogyne, the interests of Noven and Novartis may not always be aligned. This may result in potential conflicts between Noven and Novartis 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. 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 than Noven, 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 Noven 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 Noven is the purchaser, there can be no assurance that Noven would not be adversely affected by the changes in capital and/or debt structure that would likely be required to finance the purchase transaction.

Noven expects to be dependent on sales to Novartis AG and Novogyne, as well as fees and royalties generated from such parties sales of its transdermal delivery systems, for a significant portion of its 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 any of these parties to market Noven s products successfully would cause the quantity of products purchased from Noven and the amount of fees and royalties ultimately paid to Noven to be reduced and would therefore have a material adverse effect on Noven s business and operations. In the short term, Noven s growth depends in part on Novartis AG s launch plans and marketing efforts with respect to Estalis® and Estradot®, and the scope and success of those efforts are outside the control of Noven. Noven receives firm orders from Novartis AG on a partial year basis which limits Noven s ability to accurately forecast full year sales to Novartis AG. Novartis and its affiliates sell competing products, both in the United States and abroad, and there can be no assurance that Novartis will promote Noven s products at the expense of its other products or that the present supply agreement for Vivelle® and Vivelle-Dot® will be extended. Due to Noven s 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.

Noven s pharmaceutical company partners market and sell many of the products Noven develops and manufactures. If one or more of those partners fails to pursue the marketing of Noven s products as planned, or if marketing of any of those products (including Estradot®or a second dosage strength of Estalis®) is otherwise delayed, Noven s revenues and gross profits may be

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adversely affected which may also adversely affect Noven s short-term liquidity. Noven cannot control the timing and other aspects of the development and launch of products incorporating its technologies and marketed by others because Noven s partners may have different priorities from Noven s. 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 of our products. Therefore, the commercialization and marketing of products Noven has under development may be delayed unexpectedly. Although Noven intends to establish an in-house sales force for certain of its products under development, including MethyPatch®, Noven s principal commercialized products are principally marketed and sold by Novogyne and Novartis, and Noven does not presently have a significant direct marketing channel to consumers for its 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 for Noven s products are not successful, our revenues and results of operations may be adversely affected, which may also adversely affect Noven s short-term liquidity.

Noven s 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 Noven will be able to identify 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 Noven will have the financial resources necessary to complete products under development, that those projects to which Noven dedicates sufficient resources will be successfully completed, that Noven 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 Noven 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 Noven s ability to recover its investment in the product. Some of Noven s 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 Noven s control. In some cases, Noven has begun and, in the future, may begin development of a product that it does 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 Noven 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, Noven s initial development investment in any such product may not be recovered.

Almost all of Noven s revenues are currently generated through sales of its hormone replacement therapy transdermal delivery systems. While these products have been found to be safe and effective by the FDA and the regulatory authorities of those countries where Noven s products are approved, published studies have concluded that there may be health risks associated with hormone replacement therapy, including potentially increased risk of endometrial or breast cancer. Evidence that hormone replacement therapy is or could be associated with such risks could adversely affect physician or patient preference for addressing the indications hormone replacement therapy is intended to address, which could adversely affect the ability of Noven to market its products.

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Noven depends upon collaborative agreements with pharmaceutical companies to obtain regulatory approval for, market and sell certain of its products. Additionally, Noven intends to seek developmental partners to develop, test and obtain regulatory approval for, and commercialize certain of its products presently under development. The number of Noven s products that are successfully developed and commercialized will affect Noven s revenues. If Noven does not enter into additional agreements in the future, or if our current or future agreements do not result in successful marketing of Noven s products, its revenue and results of operations may be adversely affected.

Noven s 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 regulations, product promotion, product manufacturing, including good manufacturing practices, and product changes or modifications. Noven s facilities handle controlled substances, resulting in additional extensive regulatory requirements and oversight. Noven devotes significant time, effort and expense addressing the extensive government regulations applicable to its 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.

Marketing claims are the basis for a product s labeling, advertising and promotion. After FDA approval of a product incorporating Noven s technologies, the Division of Drug Marketing, Advertising and Communication, must approve marketing claims asserted about that product. If approval of acceptable marketing claims is not obtained for any of Noven s products, revenues derived from that product may be limited. 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.

Noven s supply agreements with its licensees also impose strict obligations on Noven with respect to the manufacture and supply of Noven s products. Noven devotes significant time, effort and expense complying with these requirements. Failure to comply with the terms of these supply agreements may result in Noven being unable to supply product to its licensees, resulting in lost revenue by Noven and potential responsibility for damages and losses suffered by its 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, Noven cannot predict what impact any reform proposal ultimately adopted may have on the pharmaceutical industry or on the business or operating results of Noven.

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Substantially all of Noven s revenues are generated through sales of transdermal delivery systems. Noven s products are marketed primarily to physicians, some of whom are reluctant to prescribe a transdermal delivery system when an alternative delivery system is available. Noven and its 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 Noven s products is also based in part on patient preference, and difficulties in obtaining patient acceptance of Noven s transdermal or transmucosal delivery systems may similarly impact Noven s ability to market its products.

Noven s success will depend, in part, on its ability to obtain or license patents for its products, processes and technologies. If Noven does not do so, its competitors may exploit Noven s innovations and deprive Noven of the ability to realize revenues from those innovations. There is no assurance that Noven will receive patents for any of its patent applications or that any existing or future patents that it receives or licenses will provide competitive advantages for its products. Additionally, there can be no assurance that Noven s patents or any future patents will prevent other companies from developing similar or functionally equivalent products, or challenging, invalidating or avoiding Noven s patent applications or any existing or future patents that Noven receives or licenses. Furthermore, there is no assurance that any of Noven s future processes or products will be patentable, that any pending or additional patents will be issued in any or all appropriate jurisdictions or that Noven s processes or products will not infringe upon the patents of third parties.

Noven also relies on trade secrets, unpatented proprietary know-how and continuing technological innovation. Noven uses confidentiality agreements with licensees, suppliers, employees and consultants to protect its 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. Noven also cannot be certain that it will have adequate remedies for any breach. Disputes may arise concerning the ownership of intellectual property or the applicability of confidentiality agreements. Furthermore, Noven cannot be sure that its trade secrets and proprietary technology will not otherwise become known or that Noven s competitors will not independently develop Noven s trade secrets and proprietary technology. Noven also cannot be sure, if it does not receive patents for products arising from its research, that it will be able to maintain the confidentiality of information relating to its products.

Noven s success will also depend in part on its ability to operate without infringing the proprietary rights of others, and there can be no assurance that Noven s products and processes will not infringe upon the patents of others. If a third party asserts a claim of infringement, Noven may have to seek licenses, defend infringement actions or challenge the validity of those third-party patents in court. If Noven cannot obtain the required licenses, or is found liable for infringement or is not able to have these patents declared invalid, Noven 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 Noven has identified, or that in the future it will be able to identify, all U.S. and foreign patents that may pose a risk of potential infringement claims.

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Like all pharmaceutical companies, the testing, manufacturing and marketing of Noven s products may expose Noven to potential product liability and other claims resulting from their use. If any such claims against Noven are successful, Noven may be required to make significant compensation payments and suffer the associated adverse publicity. Noven maintains product liability insurance, but there can be no assurance that its insurance will cover all future claims or that Noven will be able to maintain existing coverage or obtain additional coverage at reasonable rates. If a claim is not covered or if Noven s coverage is insufficient, Noven may incur significant liability payments that would negatively affect our earnings and our business.

Certain raw materials and components used in the manufacture of Noven s products are available from limited sources, and, in some cases, a single source. 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, Noven s manufacturing operations may be interrupted until another supplier could be identified, its products approved and trading terms with it negotiated. Noven may not be able to identify an alternative supplier and any supplier that Noven does identify may not be able to obtain the requisite regulatory approvals in a timely manner, or at all. Furthermore, Noven may not be able to negotiate favorable terms with an alternative supplier. Any disruptions in Noven s manufacturing operations from the loss of an approved supplier may cause Noven to incur increased costs and lose revenues and may have an adverse effect on Noven s relationships with its partners and customers, any of which could have adverse effects on Noven s business and results of operations.

All of Noven s products are manufactured at a single facility located in Miami, Florida. An interruption of manufacturing operations resulting from regulatory issues, technical problems, casualty loss (including hurricane) or other factors could result in Noven s inability to meet production requirements, which may cause Noven to lose revenues and which could have an adverse effect on Noven s relationships with its partners and customers any of which could have a material adverse effect on Noven s business and financial results. Without Noven s existing production facility, Noven would have no other means of manufacturing its products until it was able to restore the manufacturing capability at our facility or develop an alternative manufacturing facility. Although Noven carries 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, Noven s business interruption insurance would not compensate it 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.

If Noven successfully completes clinical trials and files an NDA for its MethyPatch® product, Noven expects to establish a sales force to sell MethyPatch® in the United States rather than grant exclusive marketing rights to a third party. Establishing a sales force, and expanding Noven s

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sales, marketing and business infrastructure to support the sales force, would require the expenditure of substantial funds. There can be no assurance that, if MethyPatch® is approved for marketing by the FDA, Noven will generate sufficient sales of the product to cover the ongoing expense of Noven s sales and marketing organization and/or to realize adequate profits. In addition, some of these expenses may be incurred prior to receipt of marketing approval. In the event that MethyPatch® is not approved for marketing, these expenses will not be recovered. Additionally, any delays in organizing a sales force for MethyPatch® could have an adverse impact on Noven s ability to market the product and realize profits from sales of the product. Noven has no experience marketing or selling products to the physician group that would prescribe MethyPatch® and therefore has a disadvantage compared to certain of its competitors.

There is an ongoing public debate in the United States regarding the appropriateness of using methylphenidate and other medications to treat children with ADHD. Noven expects that this debate will continue for the foreseeable future. The outcome of this debate is uncertain, and Noven cannot predict what impact, if any, the increased public attention will have on the market for products indicated for ADHD generally, or on MethyPatch® specifically.

From time to time Noven may need to acquire licenses to patents and other intellectual property of third parties to develop, manufacture and commercialize its products. There can be no assurance that Noven will be able to acquire such licenses on commercially reasonable terms. The failure to obtain such a license would negatively affect the ability of Noven to develop, manufacture and commercialize certain products, and could therefore have an adverse effect on Noven s business and financial results.

Noven relies on insurance to protect it from many kinds of business risk, including product liability, business interruption, property and casualty loss, employment practices liability and directors and officers liability. As a result of the events of September 11, 2001, 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, and other factors, Noven has experienced, and expects to continue to experience, difficulty in obtaining insurance with adequate coverage at historical rates. In most cases, as insurance policies expire, Noven may be required to procure policies with narrower coverage, more exclusions, and higher premiums. There can be no assurance that the insurance that Noven maintains and intends to maintain will be adequate, or that the cost of insurance and limitations in coverage will not adversely affect Noven s business and financial results.

In 2001, Noven implemented a new enterprise resource planning system. Noven expects that, over time, the new system will result in improved business processes and increased operating efficiencies. As Noven s employees become familiar with the new system, Noven expects that some errors may occur, some of which could adversely impact Noven s 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, Noven could experience business interruptions, which could adversely impact Noven s business and financial results.

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In November and December 2001 and January 2002, individuals purporting to be shareholders of Noven 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. The plaintiffs each seek to act as representatives of a class consisting of all purchasers of Noven s common stock between March 27 and November 1, 2001. The plaintiffs each allege 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 seek 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 March 12, 2002, the Court entered an order consolidating all of the captioned actions into a single consolidated action and directing plaintiff s counsel to file a single amended and consolidated complaint. Noven believes that these lawsuits are without merit, and intends to defend these lawsuits vigorously, but their outcomes cannot be predicted. However, an adverse determination to Noven in any of such lawsuits could have a material adverse effect on Noven s financial position and results of operations.

Noven s corporate charter documents, Delaware law and Noven s 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 excess of prevailing market prices in an acquisition of Noven. Noven s 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 meetings of stockholders, call special meetings or nominate candidates to serve on Noven s Board of Directors.

Noven is 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.

Noven also has 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 Noven 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 Noven s common stock without the consent of Noven s Board of Directors.

The market price of Noven s common stock was extremely volatile in 2001 and may continue to be volatile going forward. In 2001, Noven s common stock traded as low as $13.12 per share and as

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high as $41.50 per share before closing at $17.75 on December 31, 2001, the last trading day of the year. Any number of factors, including many over which Noven has no control and many unrelated to Noven s business or financial results, may have a significant impact on the market price of Noven s common stock, including: announcements by Noven or its competitors of technological innovations or new commercial products, changes in governmental regulation, receipt by Noven or one of its competitors of regulatory approvals, developments relating to patents or proprietary rights of Noven or one of its competitors, publicity regarding actual or potential medical results or risks for products that Noven or one of its competitors market or has under development; and period-to-period changes in financial results and the economy generally. Noven, like any other company with a volatile stock price, may be subject to further securities litigation, which could have a material adverse effect on Noven s business and financial results.

Fluctuations in Noven s operating results may lead to fluctuations or declines in its stock price. Noven s operating results may fluctuate from quarter to quarter and from year to year depending on demand by its customers for Noven s products, new product introductions, pharmaceutical company ordering patterns, the number and timing of product development milestones that Noven achieves, and the level of Noven s spending on new drug delivery technology development and technology acquisition, and internal product development.

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

Noven had no variable rate debt outstanding during the year ended or at December 31, 2001. Therefore, changes in interest rates did not affect interest expense, earnings or cash flows in 2001. Market risks relating to Noven s operations may result from changes in LIBOR interest rates if Noven borrows under its Credit Facility. Noven cannot predict market fluctuations in interest rates and their impact on any variable rate debt that Noven may have outstanding from time to time, nor can there be any assurance that fixed rate long-term debt will be available at favorable rates, if at all.

Item 8. Financial Statements and Supplementary Data.

See Index to Financial Statements at page 52 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 Noven s Proxy Statement for its 2002 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 Noven s Proxy Statement for its 2002 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 Noven s Proxy Statement for its 2002 Annual Meeting of Shareholders.

Item 13. Certain Relationships and Related Transactions.

The information required by item 13 is incorporated by reference to Noven s Proxy Statement for its 2002 Annual Meeting of Shareholders.

PART IV

Item 14. Exhibits, Financial Statement Schedules and Reports on Form 8-K.

(a)(1) Financial Statements

See Index to Financial Statements at page 52 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.	Filed herewith.
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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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	Severance and Noncompetition Agreement between Noven and Steven Sablotsky dated as of September 21, 2000.*	Incorporated by reference to Exhibit 10.1 of Noven s Form 10-Q for the quarter ended September 30, 2000 (File No. 0-17254).
10.9	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).
10.10	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).

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10.11	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).
10.12	Operating Agreement of Vivelle Ventures LLC (a Delaware limited liability company) dated as of May 1, 1998.	Incorporated by reference to Exhibit 10.33 to Noven s Form 10-Q for the quarter ended March 31, 1998 (File No. 0-17254).
10.13	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).
10.14	Marketing and Promotional 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).
10.15	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).
10.16	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).
10.17	Amended and Restated Limited Assignment Agreement by and among Novartis Pharmaceuticals Corporation, Noven and Vivelle Ventures LLC dated as of April 1, 1999.	Incorporated by reference to Exhibit 10.17 of Noven s Form 10-K for the year ended December 31, 1999 (File No. 0-17254).
10.18	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).
10.19	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).

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10.20	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).
10.21	Amended and Restated Supply Agreement between Noven and Novartis Pharmaceuticals Corporation dated as of April 1, 1999 (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, 1999 (File No. 0-17254).
10.22	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).
10.23	Credit Agreement between Noven and SunTrust Bank Miami, N.A. dated as of December 5, 2000 (with certain provisions omitted pursuant to Rule 24b-2).**	Incorporated by reference to Exhibit 10.23 of Noven s Form 10-K for the year ended December 31, 2000 (File No. 0-17254).
10.24	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).
10.25	Sublicense Agreement among Rorer Pharmaceutical Products, Inc., Rhone-Poulenc Rorer Inc., Aventis Pharmaceuticals Products Inc., Rhone-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).
10.26	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).
10.27	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).

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10.28	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).
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.

* Compensation Plan or Agreement.

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

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

On November 6, 2001, Noven filed a Current Report on Form 8-K relating to the adoption of a shareholder rights plan.

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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, 2002

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 and CEO)	Principal Executive Officer and Chairman of the Board	March 21, 2002
By: /s/James B. Messiry James B. Messiry (Vice President and Chief Financial Officer)	Principal Financial Officer	March 21, 2002
By: /s/Diane M. Barrett Diane M. Barrett (Vice President, Finance and Treasurer)	Principal Accounting Officer	March 21, 2002
By: /s/Sidney Braginsky Sidney Braginsky	Director	March 21, 2002
By: /s/John G. Clarkson, M.D. John G. Clarkson, M.D.	Director	March 21, 2002

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By:	/s/Lawrence J. DuBow	Director	March 21, 2002
	Lawrence J. DuBow		
By:	/s/Regina E. Herzlinger	Director	March 21, 2002
	Regina E. Herzlinger		
By:	/s/Wayne P. Yetter	Director	March 21, 2002
	Wayne P. Yetter		

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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, 2001 and 2000, and the related statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2001. 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, 2001, 2000 and 1999. Noven s equity in Vivelle Ventures LLC of $32,043,000 and $15,431,000 at December 31, 2001 and 2000, respectively, and Noven s share of that joint venture s income of $14,013,000, $9,294,000 and $1,487,000 for the years ended December 31, 2001, 2000 and 1999, respectively, are included in the accompanying financial statements. Such financial statements 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 2001, 2000 and 1999, 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, 2001 and 2000, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States of America.

Deloitte & Touche LLP
Certified Public Accountants

Miami, Florida
February 15, 2002

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NOVEN PHARMACEUTICALS, INC.

Balance Sheets
At December 31, 2001 and 2000
(in thousands except share amounts)

	2001	2000
Assets		
Current Assets:		
Cash and cash equivalents	$ 49,389	$ 40,976
Accounts receivable (less allowance for doubtful accounts of $28 in 2001 and $121 in 2000)	1,308	5,677
Due from Novogyne	15,158	2,917
Inventories	4,324	6,098
Net deferred income tax asset	4,800	4,500
Prepaid and other current assets	304	495
	75,283	60,663
Property, plant and equipment, net	15,699	15,154
Other Assets:		
Investment in Novogyne	32,043	15,431
Net deferred income tax asset	10,150	10,700
Patent development costs, net	2,046	1,972
Deposits and other assets	1,007	111
	45,246	28,214
	$136,228	$104,031
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable	$ 5,620	$ 5,797
Notes payable, current portion	252	340
Due to Aventis Pharmaceuticals	10,000	
Accrued compensation and related liabilities	1,518	2,504
Other accrued liabilities	4,169	2,739
Deferred license revenue, current portion	7,936	2,586
	29,495	13,966
Long-Term Liabilities:		
Notes payable	13	265
Deferred license revenue	24,822	24,523
	54,330	38,754
Commitments and Contingencies (Note 15)		
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 22,481,977 in 2001 and 22,177,598 in 2000	2	2
Additional paid-in capital	77,394	72,864

Retained earnings (accumulated deficit)	4,502	(7,589)
	81,898	65,277
	$136,228	$104,031

See accompanying notes to financial statements.

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NOVEN PHARMACEUTICALS, INC.

Statements of Operations
Years Ended December 31, 2001, 2000 and 1999
(in thousands except per share amounts)

	2001	2000	1999
Revenues:			
Product sales	$43,096	$42,005	$31,334
License revenue	2,851	919	316
Total revenues	45,947	42,924	31,650
Expenses:			
Cost of products sold	20,376	19,219	12,721
Research and development	10,973	13,621	7,171
Marketing, general and administrative	11,554	8,737	7,860
Total expenses	42,903	41,577	27,752
Income from operations	3,044	1,347	3,898
Equity in earnings of Novogyne	14,013	9,294	1,487
Interest income, net	1,770	1,385	343
Income before income taxes	18,827	12,026	5,728
Income tax expense (benefit)	6,736	(7,608)	(4,732)
Net income	$12,091	$19,634	$10,460
Basic earnings per share	$ 0.54	$ 0.90	$ 0.49
Diluted earnings per share	$ 0.51	$ 0.84	$ 0.48
Weighted average number of common shares outstanding:			
Basic	22,367	21,914	21,508
Diluted	23,511	23,249	21,897

See accompanying notes to financial statements.

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NOVEN PHARMACEUTICALS, INC.

Statements of Stockholders Equity
Years Ended December 31, 2001, 2000 and 1999
(in thousands)

	Common Stock		Additional Paid-in Capital	Retained Earnings/ (Accumulated Deficit)	Treasury Stock	Total
	Shares	Amount				
Balance at December 31, 1998	21,482	2	66,669	(37,683)	(663)	28,325
Issuance of shares pursuant to stock option plan, net	96		247			247
Retirement of shares of treasury stock, at cost	(97)		(663)		663	
Issuance of shares for bonus compensation	65		361			361
Net income				10,460		10,460
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 shares of stock and options to charitable organizations			55			55
Net income				12,091		12,091
Balance at December 31, 2001	22,482	$ 2	$77,394	$ 4,502	$	$81,898

See accompanying notes to financial statements.

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NOVEN PHARMACEUTICALS, INC.

Statements of Cash Flows
Years Ended December 31, 2001, 2000 and 1999
(in thousands except share amounts)

	2001	2000	1999
Cash flows from operating activities:			
Net income	$ 12,091	$19,634	$10,460
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	2,488	1,325	1,363
Amortization of patent costs	233	237	208
Amortization of non-competition agreement	233		
Deferred income tax expense (benefit)	709	(9,401)	(5,000)
Recognition of deferred license revenue	(2,851)	(919)	(316)
Equity in earnings of Novogyne	(14,013)	(9,294)	(1,487)
Expense related to issuance of shares of stock and options to charitable organizations	55	111	
Decrease (increase) in accounts receivable	4,369	(2,662)	29
(Increase) decrease in due from Novogyne	(2,241)	767	(195)
Decrease (increase) in inventories	1,774	(2,520)	(845)
Decrease (increase) in prepaid and other current assets	191	(80)	6
(Increase) decrease in deposits and other assets	(1,129)	248	(245)
(Decrease) increase in accounts payable	(177)	712	131
(Decrease) increase in accrued compensation and related liabilities	(986)	1,049	1,683
Increase in other accrued liabilities	2,356	2,397	1,052
Increase in deferred license revenue	8,500	20,000	2,700
Cash flows provided by operating activities	11,602	21,604	9,544
Cash flows from investing activities:			
Purchase of property, plant and equipment, net	(3,033)	(1,150)	(1,173)
Investment in Novogyne	(15,680)		
Distribution from Novogyne	13,081	2,228	622
Payments for patent development costs	(307)	(404)	(248)
Cash flows provided by (used in) investing activities	(5,939)	674	(799)
Cash flows from financing activities:			
Issuance of common stock	3,090	3,707	247
Notes payable	(340)	(347)	773
Cash flows provided by financing activities	2,750	3,360	1,020
Net increase in cash and cash equivalents	8,413	25,638	9,765
Cash and cash equivalents, beginning of year	40,976	15,338	5,573
Cash and cash equivalents, end of year	$ 49,389	$40,976	$15,338

See accompanying notes to financial 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 products and 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 generally accepted accounting principles 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.

CASH AND CASH EQUIVALENTS:

Cash and cash equivalents includes cash and securities with an original maturity of three months or less.

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):

	2001	2000
Finished goods	$ 458	$ 319
Work in process	1,140	1,567
Raw materials	2,726	4,212
Total	$4,324	$6,098

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Inventories at December 31, 2001 and 2000 relate to Noven s transdermal and transmucosal delivery systems. To date, Noven has not experienced and does not anticipate any difficulty acquiring materials necessary to manufacture its transdermal and transmucosal delivery systems. No assurance can be given that Noven will not experience difficulty in the future.

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. 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, (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.

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

PATENT DEVELOPMENT COSTS:

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

INCOME TAXES:

Noven s share of Novogyne s earnings is included in income before 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).

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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. 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® 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 $4.2 million, $3.7 million and $2.9 million was included in product sales for 2001, 2000 and 1999, 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 has conformed its revenue recognition policy to 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.

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 (LOSS) 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.

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EMPLOYEE STOCK PLANS:

In accordance with the provisions of Statement of Financial Accounting Standards No. 123 (SFAS 123), Accounting for Stock-Based Compensation , 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 generally is not required to recognize compensation expense in connection with these plans. Companies that continue to use APB 25 are required to present, in the notes to the financial statements, the pro forma effects on reported net income and earnings per share as if compensation expense had been recognized based on the fair value of options granted (see Note 10).

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.

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 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 amounts related to contract revenues for prior years have been reclassified from license revenue to product revenue in the Statement of Operations and amounts related to deferred contract revenue have been reclassified from deferred license revenue and accounts payable to other liabilities in the Balance Sheets to conform to the current year s presentation. The reclassification does not have a material effect on the financial statements.

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RECENT ACCOUNTING PRONOUNCEMENTS:

In June 2001, the Financial Accounting Standards Board (FASB) issued SFAS No. 141, Business Combinations , and SFAS No. 142, Goodwill and Other Intangible Assets . These standards establish accounting and reporting for business combinations and intangible assets. SFAS No. 141 requires all business combinations entered into subsequent to June 30, 2001 to be accounted for using the purchase method of accounting. SFAS No. 142 provides that goodwill and other intangible assets with indefinite lives will not be amortized, but will be tested for impairment on an annual basis. SFAS No. 142 is effective for fiscal years beginning after December 15, 2001; however, early adoption is permitted. Noven does not expect the adoption of these statements to have a material effect on its financial statements or disclosures.

In June 2001, the FASB issued SFAS No. 143, Accounting for Asset Retirement Obligations , which addresses financial accounting and reporting for legal obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. SFAS No. 143 is effective for fiscal years beginning after June 15, 2002, with early adoption encouraged. Noven does not expect the adoption of SFAS No. 143 to have a material effect on its financial statements or disclosures.

In August 2001, the FASB issued SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, which addresses financial accounting and reporting for the impairment or disposal of long-lived assets. SFAS No. 144 is effective for fiscal years beginning after December 15, 2001, and interim periods within those fiscal years, with early adoption encouraged. The provisions of SFAS No. 144 generally are to be applied prospectively. Noven does not expect the adoption of SFAS No. 144 to have a material effect on its financial statements or disclosures.

3. CASH FLOW INFORMATION:

Cash payments for income taxes were $3.9 million, $0.6 million and $0.1 million in 2001, 2000 and 1999, respectively. Cash payments for interest were $35,000, $64,000 and $49,000 in 2001, 2000 and 1999, 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, to Aventis.

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.

In 2001 and 2000, respectively, Noven recorded a $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.

During 1999, Noven retired 97,000 shares of treasury stock valued at $0.7 million.

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4. PROPERTY, PLANT AND EQUIPMENT, NET:

Property, plant and equipment consists of the following at December 31, 2001 and 2000 (in thousands):

	2001	2000
Land	$ 2,540	$ 2,540
Building and improvements	2,393	2,393
Leased property and leasehold improvements	8,929	8,826
Manufacturing and testing equipment	8,242	7,710
Furniture	1,044	998
Software and software development costs	1,448	
	24,596	22,467
Less accumulated depreciation and amortization	8,897	7,313
	$15,699	$15,154

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 Vivelle-Dot® 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 connection with the sublicense transaction, and pursuant to Noven s license agreement with Aventis, Noven received $2.7 million in cash from Aventis as Noven s share of the sublicense fees paid by Novartis to Aventis. This amount was recorded as deferred license revenue and is being recognized as license revenue over seven and one half years beginning in the fourth quarter of 1999.

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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 its territory, to any product improvements and future generations of estrogen patches developed by Noven. Noven received an up-front license payment of $20.0 million upon execution of the agreement. The up-front payment was deferred and is being recognized as license revenue over 10 years beginning in the fourth quarter of 2000. In March 2001, Estradot® was approved for marketing in the Netherlands. In November 2001, Novartis AG successfully completed the European Mutual Recognition Procedure. This product has since been approved for marketing in certain other European countries and the regulatory authorities of other countries are reviewing Novartis registration application. The agreement provides that receipt of regulatory approval in one of several specified countries triggers a $5.0 million milestone payment to Noven. Noven received the $5.0 million payment in the fourth quarter of 2001 even though the applicable regulatory approvals had not been obtained. The milestone payment has been deferred and will be recognized as license revenue over the same period as the up-front payment, beginning in the quarter when the applicable approval is obtained.

On March 30, 2001, Novogyne acquired the exclusive United States marketing rights to CombiPatch® (estradiol/norethindrone acetate transdermal system) 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, is $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. 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 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 entered into a development agreement relating to future generations of combination estrogen/progestin patch products.

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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 2001, 2000 and 1999, Novogyne produced $37.9 million, $29.1 million and $10.7 million, respectively, of net income, and Noven recorded $14.0 million, $9.3 million and $1.5 million, respectively, as equity in earnings of Novogyne. In 2001, 2000 and 1999, Noven received cash distributions of $13.1 million, $2.2 million and $0.6 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.

During the years ended December 31, 2001, 2000 and 1999, Noven had the following transactions with Novogyne (in thousands):

	2001	2000	1999
Revenue:			
Trade product	$13,634	$13,220	$ 5,661
Sample product and other	3,055	2,269	2,805
Royalty	4,037	3,429	2,555
	$20,726	$18,918	$11,021
Expenses:			
Services	$16,187	$10,180	$ 8,367
Product specific marketing Expenses	5,849	4,133	2,695
	$22,036	$14,313	$11,062

As of December 31, 2001 and 2000, the due from Novogyne is as follows (in thousands):

	2001	2000
Sales of product	$ 3,071	$ 1,266
Services provided by Noven	2,637	2,272
Royalty	952	935
CombiPatch® license installment	10,000	
Deferred profit on Novogyne inventory	(1,502)	(1,556)
	$15,158	$ 2,917

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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 and other administrative services are provided by Novartis.

The condensed Statements of Operations of Novogyne for the years ended December 31, 2001, 2000 and 1999 are as follows (in thousands):

	2001	2000	1999
Revenues	$89,958	$58,544	$34,274
Cost of sales	16,796	9,698	6,530
Selling, general and administrative expenses	31,384	21,315	17,720
Amortization of intangible assets	4,635		
Income from operations	37,143	27,531	10,024
Interest income	734	1,562	661
Net income	$37,877	$29,093	$10,685

The condensed Balance Sheets of Novogyne at December 31, 2001 and 2000 are as follows (in thousands):

	2001	2000
Current assets	$23,695	$41,885
Long-term assets	57,160	
Total assets	80,855	41,885
Total liabilities (all of which are current)	23,452	10,459
Members capital	$57,403	$31,426

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.

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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 up to the lesser of (a) $10.0 million or (b) the then eligible accounts receivable. The Credit Facility will terminate in April 2003. Amounts outstanding under the credit facility bear interest at LIBOR plus 1.50% (1.876% at December 31, 2001). 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, 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.

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):

	2001	2000
Borrowings under Master Lease, 8%, maturing in 2003	$245	$402
Capitalized equipment lease, 11%, maturing in 2004	20	26
Insurance installment note, 6%, maturing in 2001		177
	265	605
Less: installments due within one year	252	340
	$ 13	$265

Principal payments on existing long-term debt for the years succeeding December 31, 2001 are $252,000 in 2002, $8,000 in 2003 and $5,000 in 2004.

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9. INCOME TAXES:

The provision (benefit) for income taxes in 2001, 2000 and 1999 consists of (amounts in thousands):

	2001	2000	1999
Current income taxes			
Federal	$5,400	$ 1,251	$ 193
State	627	542	75
	6,027	1,793	268
Deferred income tax expense (benefit)			
Federal	448	(8,789)	(4,655)
State	261	(612)	(345)
	709	(9,401)	(5,000)
Income tax expense (benefit)	$6,736	$(7,608)	$(4,732)

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:

	2001	2000
Deferred income tax assets:		
Deferred license revenue	$10,270	$ 8,062
General business credit	3,131	6,052
Joint venture interest	891	575
Alternative minimum tax credit	483	586
Other	478	417
Total deferred income tax assets	15,253	15,692
Deferred income tax liabilities:		
Basis difference in fixed assets	(303)	(492)
Total deferred income tax liabilities	(303)	(492)
Net deferred income tax asset	$14,950	$15,200

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 $15.0 million and $15.2 million at December 31, 2001 and 2000, 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, 2001 and 2000.

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At December 31, 2001 and 2000, Noven had research and development credit carryforwards of $3.1 million and $6.1 million, respectively, which will expire in 2013 through 2016.

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

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):

	2001		2000		1999	
	Amount	%	Amount	%	Amount	%
Income taxes at statutory rate	$6,589	35.0	$ 4,089	34.0	$ 1,947	34.0
Increase (decrease) in taxes:						
State income tax, net of federal benefits	577	3.1	470	3.9	(178)	(3.1)
Research and development expenditures	(458)	(2.4)	(700)	(5.8)	225	3.9
Other	28	0.1	63	0.5	19	0.3
Reduction of valuation allowance on deferred income tax assets			(11,530)	(95.9)	(6,745)	(117.7)
Income tax expense (benefit)	$6,736	35.8	$ (7,608)	(63.3)	$(4,732)	(82.6)

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, 2001, there were approximately 1,759,196 stock options outstanding under the 1999 Plan. Generally, the options vest over a period of five years, beginning one year after date of grant.

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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, 2001, there were approximately 966,485 stock options outstanding under the 1997 Plan. The 1997 Plan is also administered by the Compensation and Stock Option Committee, and the terms and conditions of the 1997 Plan are similar to those of the 1999 Plan.

Noven also has an earlier stock option plan, which had provisions similar to those of the 1997 and 1999 Plans. This plan terminated on December 31, 1996, and no additional options may be granted under this plan. At December 31, 2001, there were approximately 118,762 stock options outstanding under this plan.

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

	2001		2000		1999	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding at beginning of year	2,501	$14.57	2,554	$ 8.32	2,026	$7.61
Granted	792	$17.59	626	$33.37	755	$9.54
Exercised	(308)	$10.45	(634)	$ 8.41	(105)	$2.91
Canceled and expired	(140)	$20.32	(45)	$ 8.06	(122)	$8.63
Outstanding at end of year	2,845	$15.57	2,501	$14.57	2,554	$8.32
Options exercisable at end of year	960	$11.89	745	$ 8.87	851	$8.28
Shares of common stock reserved	4,895		4,909		5,834	

The following table summarizes information concerning outstanding and exercisable options at December 31, 2001 (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	851	3.4	$ 5.70	519	$ 5.88
$ 6.31 - 9.13	176	3.4	$ 8.38	73	$ 8.30
$10.00 - 14.38	467	4.1	$11.44	204	$12.15
$15.13 - 21.47	707	6.9	$15.51	24	$19.92
$26.64 - 36.44	635	6.0	$33.55	137	$34.25
$40.69 - 41.81	9	4.5	$41.20	3	$40.98
	2,845			960	

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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 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. FAIR VALUES OF STOCK OPTIONS:

Noven has elected to follow Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB 25) and related Interpretations in accounting for its employee stock options as allowed pursuant to FASB Statement No. 123. Accordingly, no compensation expense has been recognized in the years ended December 31, 2001, 2000 and 1999. FASB Statement 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.

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Had compensation cost for Noven s stock option plans been determined on the fair value at the grant date for awards under those plans, consistent with FASB Statement No.123, Noven s 2001, 2000 and 1999 net income and earnings per share would have been reduced to the pro forma amounts indicated below (in thousands except per share amounts):

	2001	2000	1999
Net income:			
As reported	$12,091	$19,634	$10,460
Pro forma	$ 6,061	$16,527	$ 8,412
Basic earnings per share:			
As reported	$ 0.54	$ 0.90	$ 0.49
Pro forma	$ 0.27	$ 0.75	$ 0.39
Diluted earnings per share:			
As reported	$ 0.51	$ 0.84	$ 0.48
Pro forma	$ 0.26	$ 0.71	$ 0.38

The effect of applying the fair value method of accounting for stock options on reported net income and earnings per share for 2001, 2000 and 1999 may not be representative of the effects for future years because outstanding options vest over a period of several years and additional awards are generally made each year.

The fair value of each option granted during 2001, 2000 and 1999 is estimated as $12.80, $23.44 and $5.40, respectively, on the date of the grant using the Black Scholes option-pricing model with the assumptions listed below.

	2001	2000	1999
Volatility	92.0%	84.6%	61.3%
Risk free interest rate	4.11%	5.75%	5.72%
Expected life (years)	6	6	7

12. 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 the 401(k) Plan now provides for employer matching of 50% of employee contributions up to the first 3% of the participants contributions. Noven contributed $126,000 for the year ended December 31, 2001. 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 years ended December 31, 2000 and 1999, Noven made no matching contributions.

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13. SEGMENT, GEOGRAPHIC AND CUSTOMER DATA:

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, 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):

	2001	2000	1999
United States	$25,018	$25,386	$22,623
Other countries	20,929	17,538	9,027
Total Revenues	$45,947	$42,924	$31,650

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

	2001	2000	1999
Novogyne	$20,726	$18,918	$11,021
Novartis AG/Novartis	19,809	15,614	1,749
Aventis	4,736	7,620	18,059
Other	676	772	821
Total Revenues	$45,947	$42,924	$31,650

14. UNAUDITED QUARTERLY CONDENSED FINANCIAL DATA

(in thousands, except per share amounts):

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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2000	First	Second	Third	Fourth	Full Year
Revenues	$9,603	$10,481	$11,163	$11,677	$42,924
Total operating expenses	8,418	10,374	10,215	12,570	41,577
Income (loss) from operations	1,185	107	948	(893)	1,347
Equity in earnings of Novogyne	477	3,253	2,653	2,911	9,294
Interest income, net	200	267	306	612	1,385
Income tax provision (benefit)	35	153	282	(8,078)	(7,608)
Net income	$1,827	$ 3,474	$ 3,625	$10,708	$19,634
Basic earnings per share	$ 0.08	$ 0.16	$ 0.16	$ 0.48	$ 0.90
Diluted earnings per share	$ 0.08	$ 0.15	$ 0.15	$ 0.45	$ 0.84

15. COMMITMENTS AND CONTINGENCIES:

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 2002.

Noven has a formula bonus plan that includes company and individual performance goals, and Noven incurred $0.7 million, $2.2 million and $2.1 million of bonus expenses in 2001, 2000 and 1999, 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 2000 and 1999, Noven met or exceeded each of the company performance goals, and in accordance with the plan formula the bonus awards to most employees were greater than their initial target awards.

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

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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. 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 allege 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 Pharma AG. The plaintiffs seek unspecified damages, for themselves and the purported class, based on the allegedly artificially inflated prices paid for their shares of Noven s common stock. Noven believes that these lawsuits are without merit, and intends to defend these lawsuits vigorously, but their outcomes cannot be predicted. However, an adverse determination to Noven in any of such lawsuits could have a material adverse effect on Noven s financial position and results of operations. Noven s ultimate liability with respect to any of the foregoing proceedings is presently not determinable.

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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 statement of operations, members capital and cash flows present fairly, in all material respects, the financial position of Vivelle Ventures LLC at December 31, 2001 and December 31, 2000, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001 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 24, 2002
Florham Park, New Jersey

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Vivelle Ventures LLC
d/b/a Novogyne Pharmaceuticals

Balance Sheet
As of December 31, 2001 and 2000

	2001	2000
Assets		
Current assets		
Due from affiliate Novartis Pharmaceuticals Corporation	$16,493,027	$35,979,478
Due from Novartis Pharmaceuticals Canada, Inc.	876,263	244,688
Finished goods inventory (net of reserves of $250,000 and $200,000 as of December 31, 2001 and 2000)	5,976,405	5,660,562
Other current assets	349,407	
Total current assets	23,695,102	41,884,728
Long-term assets (see Note 3)	57,160,047	
Total assets	$80,855,149	$41,884,728
Liabilities and Members Capital		
Current liabilities		
Due to affiliate Noven Pharmaceuticals, Inc.	$16,660,758	$ 4,472,350
Accrued liabilities	118,116	113,120
Allowance for returns	6,673,109	5,873,352
Total current liabilities	23,451,983	10,458,822
Commitments and contingencies (see Note 6)		
Members capital		
Capital contributions	33,832,707	2,332,707
Accumulated earnings	23,570,459	29,093,199
Total members capital	57,403,166	31,425,906
Total liabilities and members capital	$80,855,149	$41,884,728

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, 2001, 2000 and 1999

	2001	2000	1999
Net sales			
Third parties	$88,808,362	$57,221,383	$33,285,381
Novartis Pharmaceuticals Canada, Inc.	1,149,817	1,322,772	988,962
	89,958,179	58,544,155	34,274,343
Cost of sales			
Third parties	16,272,541	9,165,457	6,060,087
Novartis Pharmaceuticals Canada, Inc.	523,358	532,187	470,004
	16,795,899	9,697,644	6,530,091
Gross profit	73,162,280	48,846,511	27,744,252
Operating expenses			
Administrative expenses	1,926,320	1,391,446	1,387,405
Sales and marketing expenses	29,457,702	19,923,978	16,332,452
Amortization expense	4,634,598		
Income from operations	37,143,660	27,531,087	10,024,395
Other income			
Interest income	733,600	1,562,112	660,864
Net income	$37,877,260	$29,093,199	$10,685,259

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, 2001, 2000 and 1999

	Total
Members capital at December 31, 1998	$ 10,878,871
Net income	10,685,259
Distributions to members	(6,166,519)
Members capital at December 31, 1999	15,397,611
Net income	29,093,199
Distributions to members	(13,064,904)
Members capital at December 31, 2000	31,425,906
Net income	37,877,260
Distributions to members	(43,900,000)
Capital contributions by members	32,000,000
Members capital at December 31, 2001	$ 57,403,166

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, 2001, 2000 and 1999

	2001	2000	1999
Operating activities			
Net income	$ 37,877,260	$ 29,093,199	$ 10,685,259
Adjustments to reconcile net income to net cash provided in operations			
Amortization of marketing rights	4,634,598		
Obsolescence reserve	50,000		
Changes in assets and liabilities, net of assets acquired			
Due from affiliate Novartis Pharmaceuticals Corporation	19,486,451	(13,853,727)	(8,412,876)
Due from Novartis Pharmaceuticals Canada, Inc.	(631,575)	(104,292)	(140,396)
Other current assets	(349,407)	104,040	(19,065)
Inventories	3,111,424	(3,597,441)	1,264,424
Due to affiliate Noven Pharmaceuticals, Inc.	2,188,408	426,583	557,041
Other liabilities	804,753	996,542	2,232,132
Net cash provided by operating activities	67,171,912	13,064,904	6,166,519
Investing activities			
Cash paid to purchase the CombiPatch® marketing rights and inventory (see Note 3)	(55,271,912)		
Net cash used in investing activities	(55,271,912)		
Financing activities			
Contribution by members (see Note 4)	32,000,000		
Distributions to members	(43,900,000)	(13,064,904)	(6,166,519)
Net cash used in financing activities	(11,900,000)	(13,064,904)	(6,166,519)
Net increase in cash from above activities			
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
For the Years Ended December 31, 2001, 2000 and 1999

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 a 17B-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® and Noven had previously supplied Vivelle® to Novartis under a supply agreement (the Supply Agreement). 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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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.

Revenue Recognition

Revenues are recognized when the products are shipped and title passes 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, 2001, 2000 and 1999 are net of $8,785,599, $5,989,323 and $5,345,003, 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 represents management s best estimate of these charges that apply to sales of the Company.

Revenues for the years ended December 31, 2001, 2000 and 1999 are net of sales returns of $5,401,758, $4,221,545 and $4,545,525, respectively. Returns are estimated based on historical experience and may vary in future periods.

Advertising Costs

Advertising costs are expensed as incurred. Advertising costs incurred during the years ended December 31, 2001, 2000 and 1999 were $8,628,409, $6,255,770 and $4,947,824, respectively.

Income Taxes

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

Reclassifications

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

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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 Noven in June, September and December 2001, respectively. The Company has assigned $3,477,267 to the value of the inventory and the remainder to the license and marketing rights which are being amortized over a period of 10 years. To fund the purchase price of $65,000,000 the members contributed $32,000,000 of cash and the remaining amount will be funded by the Company and reduce the Novartis due from affiliate account.

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.

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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.

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. 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 of which $500,000 represented a return of capital. 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. In 1999, distributions of $5,544,920 were made to Novartis and $621,599 to Noven related to the period of May 1, 1998 through December 31, 1998. Distributions during the years ended December 31, 2001, 2000 and 1999 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 where 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.

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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.

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

During the years ended December 31, 2001, 2000 and 1999, Novartis charged the Company $1,976,952, $1,148,953 and $905,920, 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 of this account of $16,493,027 as of December 31, 2001, $35,979,478 as of December 31, 2000 and $22,125,751 as of December 31, 1999 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, 2001, 2000 and 1999 at an average annual rate of 5%, 7% and 5%, respectively. During these periods interest of $733,600, $1,562,112 and $660,864, respectively, was earned and is reflected in the amount due from Novartis.

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

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

	For the Years Ended December 31,		
	2001	2000	1999
Balance at the beginning of the period	$ 35,979,478	$ 22,125,751	$ 13,712,875
Capital contributions by members	32,000,000		
Net sales (excluding returns)	94,210,120	62,765,692	38,819,868
Sales returns processed	(4,602,001)	(3,250,631)	(2,132,308)
Interest income on cash balances	733,600	1,562,112	660,864
Distributions to members	(43,900,000)	(13,064,904)	(6,166,519)
Payment to Noven for inventory purchases royalties and other items	(40,284,456)	(33,363,053)	(21,421,674)
Disbursements made on behalf of the Company	(1,001,799)	(280,459)	(1,347,731)
Novartis service charges	(1,976,952)	(1,148,953)	(905,920)
Receivable from Novartis Canada transferred to the Company	518,241	(244,687)	(140,396)
Payments for CombiPatch® license	(55,000,000)		
Other	(183,204)	878,610	1,046,692
Total	$ 16,493,027	$ 35,979,478	$ 22,125,751

Noven is responsible for providing the following services:

Manufacture and packaging of the 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.

Procurement of advertising services in connection with the marketing and promotion of the products.

During the years ended December 31, 2001, December 31, 2000 and December 31, 1999, Noven charged the Company $16,187,211, $10,179,559 and $8,367,130, respectively, for these services.

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Royalties

Royalties, which are included in sales and marketing expense, 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, 2001, 2000 and 1999, total royalties of $4,036,972, $3,429,288 and $2,554,544, respectively, were incurred, of which $952,312, $935,110 and $1,053,482 remained payable to Noven as of December 31, 2001, 2000 and 1999, respectively.

Product Transactions

Vivelle®, Vivelle-Dot and CombiPatch® are manufactured by Noven and sold to the Company at an agreed upon price. During the years ended December 31, 2001, 2000 and 1999 the Company purchased products from Noven in the amounts of $13,634,475, $13,220,064 and $5,661,182, 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.

The following represents the amounts payable to Noven related to:

	As of December 31,	
	2001	2000
Purchases of inventory	$ 3,071,180	$1,265,547
Services provided by Noven	2,637,266	2,271,693
Royalties	952,312	935,110
CombiPatch® license installment	10,000,000	
Total	$16,660,758	$4,472,350

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 will supply to the Company finished goods only. The Company is obligated to purchase a nominal amount of inventory in the subsequent fiscal year. The supply agreement expires in January 2003.